UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA

RAJESH M. SHAH, MATT BRIERLEY, ERIC LEVY, UFCW LOCAL 1500, and STEVEN CASTILLO, Individually and On Behalf of All Others Similarly Situated,

Plaintiffs,

v.

ZIMMER BIOMET HOLDINGS, INC., CHRISTOPHER B. BEGLEY, BETSY J. BERNARD, PAUL M. BISARO, GAIL K. BOUDREAUX, TONY W. COLLINS, DAVID C. DVORAK, MICHAEL J. FARRELL, DANIEL P. FLORIN, LARRY GLASSCOCK, ROBERT A. HAGEMANN, ARTHUR J. HIGGINS, ROBERT J. MARSHALL JR., MICHAEL W. MICHELSON, CECIL B. PICKETT, JEFFREY K. RHODES, KKR BIOMET LLC, TPG PARTNERS IV, L.P., TPG PARTNERS V, L.P., TPG FOF V-A, L.P., TPG FOF V-B, L.P., TPG LVB CO-INVEST LLC, TPG LVB CO-INVEST II LLC, GS CAPITAL PARTNERS VI FUND, L.P., GS CAPITAL PARTNERS VI PARALLEL, L.P., GS CAPITAL PARTNERS VI OFFSHORE FUND, L.P., GS CAPITAL PARTNERS VI GMBH & CO. KG, GOLDMAN SACHS BMET INVESTORS, L.P., GOLDMAN SACHS BMET INVESTORS OFFSHORE HOLDINGS, L.P., PEP BASS HOLDINGS, LLC, PRIVATE EQUITY PARTNERS 2004 DIRECT INVESTMENT FUND L.P., PRIVATE EQUITY PARTNERS 2005 DIRECT L.P., PRIVATE EQUITY PARTNERS IX DIRECT L.P., and GS LVB CO-INVEST, L.P.,

Defendants.

Case No.: 3:16-cv-00815-PPS-MGG

SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

TABLE OF CONTENTS

I. PRELIMINARY STATEMENT 1

II. INTRODUCTION 3

A. ZBH's Organic Growth Story 5

B. ZBH's QS Deficiencies And Problems With The FDA 6

C. ZBH Actively Conceals Adverse Facts And Risks While Continuing To Express High Confidence In Increasing Organic Revenue Growth 9

D. The Risks Concealed During The Class Period Materialize, Causing ZBH's Stock Price To Plummet And Wiping Out Billions Of Market Capitalization 16

III. JURISDICTION AND VENUE 20

IV. PARTIES 20

A. Plaintiffs 20

B. Corporate Defendant 21

C. Officer Defendants 22

D. Director Defendants 24

E. Private Equity Defendants 27

V. RELEVANT NON-PARTIES 32

VI. BACKGROUND AND RELEVANT EVENTS PRIOR TO THE CLASS PERIOD 33

A. ZBH's Products And Facilities Are Strictly Regulated By The FDA 33

B. Important Information Regarding The Types And Frequency Of FDA QS Inspections 34

C. The 2015 Merger: A Marriage Of Two Crosstown Rivals 38

D. ZBH's Organic Revenue Growth Rate Was The Most Important Metric To ZBH's Stock Price 40

1. ZBH's Organic Revenue Growth Rate Underperforms The Market/Industry Level In 2015 41

2. Prior To The Class Period, ZBH's Organic Revenue Growth Rate Starts To Reaccelerate In Q1'16 43

E. The FDA Was Carefully Scrutinizing ZBH's Facilities Following Problematic QS Inspections Of Legacy Zimmer's Flagship West Campus And Facilities In Puerto Rico And Canada 43

VII. SUMMARY OF THE ACTION 49

A. During The Class Period, ZBH And The Officer Defendants Declare That ZBH Reached An "Inflection Point" And That Organic Revenue Growth Will Return To And Exceed Market Level In The Second Half Of 2016 49

B. The Truth Begins To Emerge When ZBH's Q3'16 Results Blindside Investors 53

1. The October 31, 2016, Materializations Of Concealed Risks 54

2. The November 8, 2016, Partial Corrective Disclosure 55

C. A Disastrous FDA Inspection Of The North Campus In The Fall of 2016 Identifies Grave "Systemic" QS Issues Requiring Substantial Remediation And Causing Severe Supply Shortages in Q3'16 And Q4'16 58

D. By The Start Of The Class Period In June 2016, ZBH And The Officer Defendants Knew That An FDA Inspection Of The North Campus Was Imminent, Knew About The Precise "Systemic" QS Issues Cited By The FDA Inspectors In The November 2016 North Campus FDA 483, And Knew That ZBH Was Not Taking Prompt And Meaningful Steps To Fully Remediate The QS Issues 64

1. ZBH Knew At The Start Of The Class Period That An Inspection Of The North Campus Was Imminent Because The North Campus Was Due For Its Mandated Biennial Inspection 64

2. ZBH "Corporate Management" Had Already Known About The Precise "Systemic" QS Issues At The North Campus Because Of Corporate Audit Reports Issued On March 31, April 13, And June 7, 2016 65

3. Contrary To ZBH's Assertions, ZBH Did Not Take Prompt Remedial Actions To Address The "Systemic Issues" That ZBH Corporate Management Had Learned Of In The Spring Of 2016 69

4. Former ZBH Employees Confirm That ZBH Waited Until The September 2016 North Campus Inspection To Take Serious Remedial Actions, Which Devastated The Output At The North Campus 70

E. Defendants Dvorak And Florin Instruct Barney To Concoct A Story To Mislead Investors About The Root Cause Of The Q3'16 Supply Shortages And To Terminate Employees For Cause Under A False Pretext 75

F. Securities Analysts' Reactions Confirm That The Issues Cited By The FDA In The November 2016 North Campus FDA 483 Were Serious And Highly Concerning 86

G. ZBH's Post-Class Period Disclosures Reveal That The North Campus Remediation Will Cost $300 Million And Cause Continued Supply Shortages Throughout 2017 Of Key Products "Strategically Relevant" To Accelerating Revenue 90

VIII. DEFENDANTS' VIOLATIONS OF THE EXCHANGE ACT 96

A. ZBH And The Officer Defendants' Material Misstatements And Omissions In Violation Of The Exchange Act 98

1. The June 7, 2016 Statement 98

2. The June 2016 SPO Materials 99

3. The July 28, 2016 Statements 108

4. The August 8, 2016 Quarterly Report On Form 10-Q 113

5. The August 2016 SPO Materials 115

6. The September 7, 2016, Wells Fargo Securities Healthcare Conference Statement 117

7. The September 12, 2016 Morgan Stanley Global Healthcare Conference Statements 118

8. The October 31, 2016 Conference Call Statements 123

B. Additional Allegations Regarding The Officer Defendants' Scienter 125

C. The Private Equity Defendants Sold ZBH Common Stock While In Possession Of Material Nonpublic Information In Violation Of The Exchange Act 133

1. The Private Equity Defendants Designated ZBH Board Members And Received Material Nonpublic Information From Their Designees 135

2. The Private Equity Funds Sold ZBH Common Stock While In Possession Of Material Nonpublic Information 138

D. Additional Allegations Regarding Loss Causation 144

E. Presumption Of Reliance 145

IX. VIOLATIONS OF THE SECURITIES ACT 147

X. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND THE BESPEAKS CAUTION DOCTRINE 150

XI. CLASS ACTION ALLEGATIONS 150

XII. CLAIMS FOR RELIEF 152

XIII. PRAYER FOR RELIEF 171

XIV. JURY TRIAL DEMANDED 171

TABLE OF KEY TERMS

Term	Definition/Description
2015 10-K	ZBH's Annual Report on Form 10-K for the year ended December 31, 2015 filed on February 29, 2016
2016 10-K	ZBH's Annual Report on Form 10-K for the year ended December 31, 2016 filed on March 1, 2017
August 2016 Offering	The August 9, 2016, public offering of 7,440,675 shares of ZBH common stock by Defendant KKR Biomet and the TPG Defendants
August 2016 SPO Materials	The August Final Prospectus together with the Registration Statement and the August Preliminary Prospectus
Barney	Robin T. Barney, who was ZBH's SVP of Global Operations and Logistics during the Class Period and one of only 12 members of ZBH's "Executive Management Team," who reported directly to ZBH's CEO Defendant Dvorak
Barney Complaint	Employment litigation initiated by Barney captioned *Barney v. Zimmer Biomet Holdings, Inc.*, 3:17-cv-00616-JD-MGG
Blackstone	The Blackstone Group L.P.
CAPA	Corrective and preventive action
cGMP	Current Good Manufacturing Processes as set out in the FDCA
Class	All persons and entities that purchased or acquired ZBH's securities, including common stock or options, during the Class Period, and who were damaged thereby, and also including persons or entities that: (i) purchased ZBH common stock pursuant and/or traceable to the June 2016 Offering; and/or (ii) purchased ZBH common stock pursuant and/or traceable to the August 2016 Offering. 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

Class Period	June 7, 2016, to November 7, 2016
Company	Zimmer Biomet Holdings, Inc.
December 21, 2016 Letter	ZBH's December 21, 2016, response to the November 2016 North Campus FDA 483
Director Defendants	Defendants Glasscock, Begley, Bernard, Bisaro, Boudreaux, Farrell, Hagemann, Higgins, Michelson, Pickett, and Rhodes
Exchange Act	The Securities and Exchange Act of 1934
FDA	The United States Food and Drug Administration
FDA Inspection Guide	The FDA's Guide to Inspections of Quality Systems
FDA Manual	The FDA's Compliance Program Guidance Manual (Inspection of Medical Device Manufacturers)
FDCA	The Federal Food, Drug, and Cosmetic Act
FOIA	The Freedom of Information Act
GS Capital Partners	Goldman Sachs Capital Partners
GSCP Entities or GSCP Defendants	Defendants GSCP VI Fund, GSCP VI Parallel, GSCP VI Offshore, GSCP VI GMBH, GS BMET Investors, Goldman Sachs BMET Investors Offshore, PEP Bass, Private Equity Partners 2004, Private Equity Partners 2005, Private Equity Partners IX, and GS LVB Co-Invest, all of which are affiliated with GS Capital Partners
ISC	Integration Steering Committee
July 28th Call	The July 28, 2016 conference call ZBH held with investors, analysts, and the public, to discuss the Company's Q2 2016 financial results
July 31, 2017 Letter	ZBH's July 31, 2017, third update to the FDA regarding the November 2016 North Campus FDA 483

June 2014 North Campus FDA 483	The FDA 483 issued to Legacy Biomet as a result of inspections at the Legacy Biomet North Campus from June 16, 2014, to June 30, 2014
June 2014 North Campus Inspection	The FDA inspection of Warsaw North between June 16, 2014, and June 30, 2014
June 2016 Offering	The June 13, 2016, public offering of 11,116,533 shares of ZBH common stock by the Private Equity Defendants
June 2016 SPO Materials	The June Prospectus together with the Registration Statement and the June Preliminary Prospectus
KKR	Kohlberg Kravis Roberts & Co. L.P.
KKR Biomet	Defendant KKR Biomet LLC, an entity affiliated with KKR
LDR	LDR Holding Corporation
Lead Plaintiffs	Rajesh M. Shah, Matt Brierley, and Eric Levy
Legacy Biomet	Biomet, Inc.
Legacy Zimmer	Zimmer Holdings, Inc.
LVB	LVB Acquisition, Inc.
Martin	Terry Martin who was Vice President of Manufacture Engineering at the North Campus from 2007 until 2015 and became the "Senior Director of Facilities and Maintenance" and was relocated to the West Campus in connection with the 2015 Merger between Legacy Zimmer and Legacy Biomet
Martin Complaint	Employment litigation initiated by Martin captioned *Martin v. Zimmer Biomet Inc., et al.*, 3:17-cv-00615-JD-MGG (N.D. Ind.)
Merger	The merger between competitors Zimmer Holdings, Inc. and Biomet, Inc. that closed in June 2015
North Campus	The primary Legacy Biomet facility, located at 56 E. Bell Dr., Warsaw, Indiana

November 2015 West Campus FDA 483	The FDA 483 issued November 20, 2015, to ZBH as a result of inspections at the Legacy Zimmer West Campus from October 20, 2015, until November 20, 2015
November 2015 West Campus Inspection	The inspection of the Legacy Zimmer West Campus between October 20, 2015, and November 20, 2015
November 2016 North Campus FDA 483	The FDA 483 issued November 22, 2016 to ZBH as a result of inspections at Warsaw North from September 12, 2016, to November 22, 2016
November NCR Report	The November 8, 2016, Northcoast Research analyst report entitled “Downgrading to Neutral”
NYSE	The New York Stock Exchange
Officer Defendants	Defendants Dvorak, Florin, Marshall, and Collins
P&PC	Production and Process Controls
PMA	Premarket approvals
Plaintiffs	Lead Plaintiffs together with UFCW 1500
Private Equity Defendants	Defendants KKR Biomet, the TPG Defendants, and the GSCP Defendants
Private Equity Funds	Private Equity Defendants, consisting of the 18 private equity fund affiliated with GS Capital Partners, TPG, and KKR
Q1’16 10-Q	The ZBH Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed May 10, 2016
Q2’16 10-Q	The ZBH Quarterly Report on Form 10-Q for quarter ended June 30, 2016, filed August 8, 2016
QMS	Quality Management System
QS	Quality System
QSIT	Quality System Inspection Technique

Registration Statement	The Form S-3 ZBH filed with the SEC on February 4, 2016
SEC	The United States Securities and Exchange Commission
Securities Act	The Securities Act of 1933
September 2016 North Campus Inspection	An inspection of the North Campus on September 12, 2016
Stockholders Agreement	The April 24, 2014 Agreement and Plan of Merger by and among Zimmer Holdings, Inc., Owl Merger Sub., Inc. and LVB Acqusition, Inc
TPG	TPG Global, LLC
TPG Entities or TPG Defendants	Defendants TPG Partners IV, L.P., TPG Partners V, L.P., TPG FOF V-A, L.P., TPG FOF V-B, L.P., TPG LVB Co-Invest LLC, and TPG LVB Co-Invest II LLC, all of which were affiliates of TPG
UFCW 1500	Plaintiff UFCW Local 1500
Underwriters	Goldman Sachs & Co. LLC and J.P. Morgan Securities LLC
Warsaw	Warsaw, Indiana
Warsaw North	Also, "North Campus," or the primary Legacy Biomet facility located at 56 E. Bell Dr., Warsaw, Indiana
West Campus	The primary Legacy Zimmer facility located at 1800 W. Center St, Warsaw, Indiana
ZBH	The merged company, Zimmer Biomet Holdings, Inc.

TABLE OF EXHIBITS

EXHIBIT	DESCRIPTION
A	December 21, 2016 Response to FDA 483 Observations Issued on November 22, 2016 to Zimmer Biomet, Warsaw North
B	July 31, 2017 Fourth Update to FDA 483 Observations Issued on November 22, 2016 to Zimmer Biomet, Warsaw North
C	Complaint and Demand for Jury Trial, *Barney v. Zimmer Biomet Holdings, Inc.*, No. 3:17-cv-616 (N.D. Ind. August 11, 2017)
D	November 22, 2016 FDA Form 483 Issued to Zimmer Biomet, Warsaw North
E	November 20, 2015 FDA Form 483 Issued to Zimmer Biomet, West Campus
F	February 12, 2016 Update to Response to FDA 483 Observations Issued on November 20, 2015 to Zimmer Biomet, West Campus
G	Complaint and Demand for Jury Trial, *Martin v. Zimmer Biomet Holdings, Inc. and Zimmer Biomet Holdings, Inc. Restated Severance Plan*, No. 3:17-cv-615 (N.D. Ind. August 11, 2017)

I. PRELIMINARY STATEMENT

1. Lead Plaintiffs Rajesh M. Shah, Matt Brierley and Eric Levy ("Lead Plaintiffs"), along with Plaintiffs UFCW Local 1500 ("UFCW 1500"), and Steven Castillo (collectively, "Plaintiffs"), by and through their attorneys, 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, *inter alia*, their counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Zimmer Biomet Holdings, Inc., ("ZBH," "Zimmer Biomet," or the "Company"), with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by ZBH; (c) interviews of former ZBH employees; (d) review of materials from the U.S. Food and Drug Administration ("FDA"); (e) review of reports issued by industry and securities analysts; and (f) review of other publicly available information concerning ZBH.

2. This is a securities class action on behalf of all persons or entities that purchased or acquired ZBH's securities (including common stock and options) between June 7, 2016, and November 7, 2016, inclusive (the "Class Period"), including persons or entities that purchased or otherwise acquired ZBH common stock pursuant or traceable to the Company's secondary public offerings on or around June 13, 2016 (the "June 2016 Offering"), and on or around August 9, 2016 (the "August 2016 Offering"), and were damaged thereby.

3. ZBH designs, develops, manufactures, and markets medical equipment. The Company offers orthopedic and dental reconstructive implants, spinal implants, trauma products, and related surgical products.

4. ZBH was the product of a $13.4 billion mega-merger between competitors

Zimmer Holdings, Inc. ("Legacy Zimmer") and Biomet, Inc. ("Legacy Biomet") that closed in June of 2015 (the "Merger"). Both companies were major medical device manufacturers headquartered in Warsaw, Indiana ("Warsaw"). To effectuate the Merger, Legacy Zimmer (a publicly traded company) acquired LVB Acquisition, Inc. ("LVB") (a private company), which owned Legacy Biomet. The combined entities and their subsidiaries became ZBH, headquartered in Warsaw, and publicly traded on the New York Stock Exchange (the "NYSE"). ZBH operates in more than 100 countries and now has approximately 18,500 employees.

5. LVB, prior to the Merger, had been owned by approximately twenty-five private equity funds affiliated with four of the largest private equity firms in the world: (i) Kohlberg Kravis Roberts & Co. L.P. ("KKR"); (ii) The Blackstone Group L.P. ("Blackstone"); (iii) TPG Global, LLC ("TPG"); and (iv) Goldman Sachs Capital Partners ("GS Capital Partners"). In the Merger, those funds received approximately 15% of the combined company and, pursuant to a stockholders agreement (the "Stockholders Agreement"), received certain registration rights and the right to designate two members of ZBH's board of directors ("Board of Directors") who were contractually permitted to share confidential information (related to ZBH's management, operations and finances) with those funds.

6. During the Class Period, the eighteen private equity fund affiliates of GS Capital Partners, TPG and KKR (collectively, the "Private Equity Funds") sold their remaining holdings of ZBH common stock in two underwritten public offerings, which represented approximately 9.43% of ZBH's common stock outstanding.[1] In the June 2016 Offering, the Private Equity Funds unloaded approximately $1.3 billion of their stock to the public and almost another $1

[1] Seven funds affiliated with Blackstone sold their remaining shares of ZBH common stock in a $1 billion public offering just prior to the Class Period in February 2016. The funds affiliated with GS Capital Partners also participated in the February 2016 offering and had sold approximately half of their ZBH holdings.

billion shortly thereafter in the August 2016 Offering. ZBH assisted the Private Equity Funds to sell their stock by registering the shares for sale and assisting with the preparation, filing and dissemination of the relevant offering documents, including registration statements and prospectuses.

7. In this Complaint, Plaintiffs assert three different sets of claims on behalf of purchasers of ZBH's securities during the Class Period. Counts I and II assert securities fraud claims under Section 10(b) and Section 20(a) of the Securities and Exchange Act of 1934 ("Exchange Act") and SEC Rule 10b-5, against ZBH and certain senior executives (identified below at ¶¶52-55). Counts III and IV assert insider trading claims under Section 20(A) of the Exchange Act against the Private Equity Defendants (identified below at ¶¶69-75, 77-87). Counts V through X assert strict liability and/or negligence claims under the Securities Act of 1933 ("Securities Act") against those defendants who are statutorily responsible under Sections 11, 12(a)(2) and 15 of the Securities Act for materially untrue statements and misleading omissions made in connection with the documents for the June 2016 Offering and the August 2016 Offering.

II. INTRODUCTION[2]

8. This is a straightforward case of securities fraud. ZBH, a global leader in the medical device industry, purported to develop and market products of the highest quality that were both safe and effective. By early 2016, ZBH recognized that the growth story it was touting to investors would be waylaid by "systemic" quality control issues identified by internal audits that directly affected Legacy Biomet's primary manufacturing facility responsible for supplying its most important products. The Company also knew an FDA inspection of that

[2] Throughout the Complaint, all emphasis is added unless otherwise noted.

facility was imminent and ongoing FDA scrutiny of ZBH's other facilities further heightened the Company's internal concerns. The quality issues warranted major remediation of the Legacy Biomet facility, which would effectively require shutting down the facility to meaningfully fix the issues. Instead of promptly and meaningfully addressing the quality deficiencies, during the Class Period, ZBH chose to address the issues through piecemeal efforts and did not disclose these issues to investors. The Private Equity Funds, who saw the writing on the wall, abused their access to this nonpublic information and dumped their ZBH holdings for $2.25 billion during the three months before the FDA commenced an inspection of the facility. The FDA inspection of the Legacy Biomet facility was a complete disaster and the Company was forced to immediately undertake (or as ZBH called it, "accelerate") the meaningful remediation activities, which ZBH had already known were needed to address the "systemic" issues. Ultimately, the risks concealed by Defendants concerning the quality issues materialized as the extensive remediation resulted in substantial disruptions to operations and caused severe supply shortages, all of which stalled growth. At the end of the Class Period, when ZBH disclosed supply shortages and lowered growth, and the market learned about the quality issues at the Legacy Biomet facility, it caused ZBH's artificially inflated share price to plummet and wiped out billions of dollars in shareholder value.

9. As alleged herein, ZBH's stock price was inflated during the Class Period as a result of ZBH's material misstatements and omissions regarding, among others: (i) ZBH's discovery after the Merger of wide-ranging "systemic issues" with the quality system ("QS") at the primary Legacy Biomet manufacturing facility in Warsaw (known as the "North Campus")[3];

[3] Also relevant to the allegations is the primary Legacy Zimmer facility in Warsaw (known as the "West Campus"), which also had severe "systemic issues" with its QS during the relevant period. Herein, the West Campus refers to the Legacy Zimmer facility and the North Campus refers to

(ii) ZBH's failure to take prompt and necessary actions to fully remediate these issues; and (iii) ZBH's inability to simultaneously satisfy the demand for its products while remediating these issues.

A. ZBH's Organic Growth Story

10. At all relevant times, ZBH's organic revenue growth rate was the most important metric to the Company's stock price and was closely followed by investors and securities analysts. When the plans for the Merger were announced in 2014, increased organic revenue growth was a key selling point for combining the second and fourth largest providers of orthopedic products. The thesis was simple: complimentary sales channels would generate cross-selling opportunities that would accelerate organic revenue growth well above market level (which was generally deemed to be 3%).

11. However, when the Merger closed in mid-2015, this thesis appeared to be in jeopardy. ZBH's growth rate had decelerated dramatically below market level, causing much concern among investors in the fall of 2015. Investors became impatient and as organic revenue growth languished, so did the Company's stock price.

12. In early 2016, ZBH and its executives sought to convince investors that in the second half of 2016 organic revenue growth would return to and then exceed market level. Investors were told that ZBH had successfully integrated the commercial operations of Legacy Zimmer and Legacy Biomet in the fourth quarter of 2015 (or "Q4'15").[4] This was billed as a crucial post-Merger step that would purportedly provide ZBH with the ability to generate and

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the Legacy Biomet facility. To assist the reader and avoid confusion, emphasis has been added to certain references to "West" or "North" to clarify or distinguish which facility is being discussed.

[4] ZBH's fiscal quarters are based on a calendar year. Herein, the Company's various fiscal quarters are denoted as "Q_'__" by quarter and year. For example, the Company's 2015 fiscal fourth quarter ending December 31, 2015, is referenced as "Q4'15."

capture the benefits from the cross-selling opportunities needed to return ZBH to above market level growth in the second half of 2016.

13. In early 2016 and during the Class Period (*i.e.*, June 7, 2016 to November 7, 2016), ZBH and its executives aggressively insisted that the thesis underlying the Merger was being validated. In press releases, conference calls with investors, and discussions with analysts, ZBH claimed that the cross selling opportunities were taking hold, that organic revenue growth was reaccelerating, and that the organic revenue growth rate would once return to market level growth and exceed market level in the second half of 2016 and 2017. While touting accelerating revenue and the substantial synergies being captured from the Merger, ZBH and its executives omitted disastrous information that they had discovered in the first half of 2016 about the existing regulatory environment at the primary Legacy Biomet North Campus. Investors were not informed that ZBH was unable to return to or sustain above market level growth because ZBH had to first extensively remediate the QS at the North Campus. Nor were they informed that remediation would limit supply of key Legacy Biomet products needed to accelerate revenue growth.

B. ZBH's QS Deficiencies And Problems With The FDA

14. Unbeknownst to investors, in the first half of 2016, ZBH and its facilities were under intense FDA scrutiny. The Company's hands were full trying to remediate serious QS deficiencies that the FDA had identified in the fall of 2015 during an inspection of the primary Legacy Zimmer ***West*** Campus (the "West Campus"). The inspection had resulted in the issuance of a serious FDA Form 483 ("FDA 483")[5] identifying a large number of repeat observations

[5] An overview of FDA QS inspections and FDA 483s is contained below in Section VI.B.

from prior FDA inspections that had not been adequately remediated.[6] In private correspondence to the FDA in December 2015 and February 2016, ZBH acknowledged the severity of the "systemic issues" with the West Campus' QS and outlined extensive remediation work that would purportedly occur during 2016 and as far out as June 2017. In the first half of 2016, substantial remediation and corrective actions were also needed or underway to address highly critical FDA inspections of Legacy Zimmer facilities in Puerto Rico (in November 2015) and Montreal (in January 2016), the latter of which resulted in a warning letter from the FDA in May 2016.

15. In part because of their ongoing problem with the ***West*** Campus, after the Merger closed, ZBH corporate management requested that corporate audits of the ***North*** Campus' QS be conducted in early 2016. Unbeknownst to investors, audit reports issued on March 31, April 13, and June 7, 2016, "alerted" ZBH's "corporate management" to even far worse "systemic issues" with respect to the QS at the North Campus.[7] The findings contained in the audit reports were neither minor nor technical. Rather, ZBH admitted that the findings "self-identified major compliance-related issues in areas such as design controls, sterile packaging, complaint handling, nonconforming material, and [corrective and preventive actions ("CAPAs")]."[8] As set forth in greater detail herein, the foregoing "major-compliance-related issues" covered a wide-range of the primary components to a quality management system.

16. Making matters worse, at the start of the Class Period on June 7, 2016, ZBH knew

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[6] As detailed below, the inspection occurred between October 20, 2015, and November 20, 2015, and followed a highly critical inspection between April 21, 2014, and May 28, 2014.

[7] This information was not publicly disclosed and, as set forth in greater detail herein, ZBH admitted these facts in a post-Class Period letter to the FDA dated December 21, 2016 (the "December 21, 2016 Letter") (a partially redacted copy received from the FDA is attached hereto as Exhibit ("Ex.") A).

[8] Ex. A (December 21, 2016 Letter).

that an FDA quality inspection of Legacy Biomet's flagship North Campus was imminent. ZBH knew this because, as a manufacturer of class III devices, the Company's manufacturing facilities are subject to mandatory biennial inspections by law and the last FDA inspection of that facility had concluded on June 30, 2014. Moreover, that prior inspection had resulted in the FDA issuing observations on an FDA Form 483, which ZBH had not remediated.

17. Because of the magnitude of the "systemic issues" identified in the corporate audit reports, it was impossible that ZBH would be able to remediate the issues prior to the expected FDA inspection of the North Campus. Not only was ZBH already saddled with "systemic issues" with the West Campus' QS (as well as the Puerto Rico and Montreal facilities), but the issues identified with the North Campus' QS were far more severe. The North Campus QS would ultimately need over a year of extensive remediation work costing over $300 million.

18. As a medical device company, compliance with FDA regulations, including quality manufacturing regulations, was one of the most important aspects of ZBH's operations. For this reason, the Company's proxy materials explained, "The full Board considers specific risk topics, including risk-related issues pertaining to laws and regulations enforced by the [FDA]." The proxy materials also indicated that the directors received "detailed regular reports … that include discussions of the risks and exposures," and that directors were "routinely informed of developments that could affect our risk profile."

19. ZBH, its executives, and its Board of Directors were nearly all seasoned veterans of the medical device industry and well versed in FDA quality regulations, compliance, and the risks associated with not complying with FDA regulations. As a result, ZBH and its senior officers and directors understood the significance and magnitude of the issues uncovered by the

corporate audit reports.

20. ZBH faced a serious conundrum. The products produced and distributed at the North Campus included Legacy Biomet's most important products. As one of the Company's officers would later admit, the products provided ZBH with its most competitive opportunities and were "strategically relevant" to ZBH's ability to accelerate organic revenue growth. ZBH could not meet existing demand for its products while promptly and meaningfully remediating these issues. In other words, the Company could not simultaneously fix the issues and generate the supply necessary to support the cross selling that ZBH was telling investors would drive organic revenue growth.

21. ZBH did not take prompt or meaningful remedial action. Instead it continued manufacturing and distributing products from the North Campus, and generally ignored the "systemic issues" with the QS at the North Campus.[9] A former employee at the North Campus indicated that ZBH was waiting until November 2016 to convert the North Campus to Legacy Zimmer policies and procedures over a six to eight month process.

C. ZBH Actively Conceals Adverse Facts And Risks While Continuing To Express High Confidence In Increasing Organic Revenue Growth

22. At the start of the Class Period on June 7, 2016, ZBH announced the acquisition of a company named LDR Holding Corporation ("LDR") for $1 billion. During a conference call with investors that day, ZBH and its officers reaffirmed that ZBH would return to and

[9] An FDA document memorializing discussion points raised by FDA inspectors during a meeting with senior ZBH management at the conclusion of an inspection of the North Campus on November 22, 2016, noted that the FDA had chastised ZBH for not timely initiating corrective actions. Specifically, the FDA document stated, "Zimmer Biomet should be timely in concluding internal audits and ***initiating corrective actions***." In response, ZBH indicated that on October 20, 2016 (in the midst of an ongoing FDA inspection), the Company (ironically) initiated a CAPA "to investigate the lack of timely issuance of CAPAs resulting from the audit report from a March, 2016 Design Control Audit …."

exceed market level growth in the second half of 2016. When asked about the potential risk to organic revenue growth – from adding the integration of LDR to the complexities of integrating Legacy Zimmer and Legacy Biomet – ZBH's Chief Executive Officer ("CEO") David Dvorak ("Dvorak") told investors: "***We are highly confident and we are reiterating guidance for the year*** … I think you ought to interpret this announcement as being confidence in the state of the integration, the progress that we've made on the [Legacy] Biomet side." Defendant Dvorak added, "So, ***highly confident in the tracking of synergies and realization of all the benefits that we've described previously*** from the [Legacy] Biomet combination." ZBH's CEO did not disclose any of the recently discovered information about the serious problems with the Legacy Biomet North Campus nor that ZBH was unable to return to market level organic revenue growth in 2016 while remediating the issues with the North Campus. This information was omitted once again days later when the Private Equity Funds sold $1.3 billion worth of ZBH common stock in the June 2016 Offering.

23. When ZBH announced its Q2'16 financial results on July 28, 2016, ZBH represented to investors that accelerating organic revenue growth in Q2'16 marked an "inflection point" and the Company ***increased the bottom end of its organic revenue growth projection for the second half of 2016***. Again, investors were neither told about the problems uncovered with the North Campus' QS nor told that ZBH lacked the ability to meet existing demand while remediating "systemic issues" with the QS. Moreover, ZBH did not disclose that the organic growth guidance was effectively premised on the hope and prayer that the FDA would not timely conduct an inspection of the North Campus. This adverse information about the North Campus was again omitted two weeks later when the remaining Private Equity Funds sold the last of their ZBH common stock to investors for $1 billion in the August 2016 Offering (on or around August

9, 2016).

24. As expected, FDA inspectors arrived shortly thereafter on September 12, 2016, to conduct an inspection of the North Campus. Upon their arrival, they issued a standard Notice of Inspection on FDA Form 482 at approximately 9:27 a.m. to Ms. Robin T. Barney ("Barney"), who was ZBH's Senior Vice President ("SVP") of Global Operations and Logistics. Ms. Barney was one of ZBH's highest ranking executives and, as one of only 12 members of ZBH's "Executive Management Team," she reported directly to ZBH's CEO (Defendant Dvorak).

25. The FDA inspection of the North Campus was a disaster from the start.[10] As detailed herein, the inspection resulted in immediate disruptions to production and distribution at the facility, which negatively impacted the Company's supply of products. For example, subsequent correspondence from the Company to the FDA reflected[11] substantial disruptions to operations at the North Campus immediately following the start of the inspection, including numerous quality holds, products that were quarantined, halting cleaning operations, and other containment actions:

Date	**Description**
September 12, 2016	Contained non-conforming sterile load #08296-C.
September 14, 2016	Confirmed all products from [REDACTED] remained in quarantine status.
September 20, 2016	Quality Hold 16-050 was implemented for all in-house finished [REDACTED] Sports Medicine products that were sterilized by

[10] In the post-Class Period December 21, 2016 Letter, ZBH conceded that it was aware early in the inspection that the severity of the issues being cited by the FDA meant that the Company was going to receive an FDA Form 483: "Rather than wait for the issuance of the FDA 483 to plan and take action, we immediately took steps to correct and improve various aspects of the North Campus quality management system."

[11] This below information was derived from a letter dated July 31, 2017, from ZBH updating the FDA on the progress of the Company's ongoing remediation efforts at the North Campus (the "July 31, 2017 Letter) (a partially redacted copy of the letter received from the FDA is attached hereto as "Ex. B").

	the [REDACTED] after a biological indicator displayed microbial growth following [REDACTED] sterilization.
September 20, 2016	Quality Hold 16-052 was initiated on finished products [REDACTED].
September 21, 2016	Halted cleaning operations at work centers associated with the inadequate cleaning validation [REDACTED].
September 22, 2016	Quality Hold 16-055-01 was implemented for [REDACTED] Cleaning and placed all in-process [REDACTED] material in quarantine [REDACTED].
September 27, 2016	Quality Hold 16-059-01 was implemented.
September 28, 2016	Quality Hold 16-061 was initiated and Item [REDACTED] was placed into containment as a result of a non-conformance observation.

26. However, to investors, Q3'16 and the second half of 2016 looked incredibly promising for ZBH. In September 2016, ZBH and its officers continued to express confidence throughout the last month of Q3'16 as they participated in multiple conferences and roadshows where they met with investors and analysts. For example, at a conference on September 12, 2016, ZBH's Chief Financial Officer ("CFO") Defendant Daniel P. Florin ("Florin") stated, "[W]e are confident we're going to get back to at or above market growth rate as we exit this year." An analyst report issued on September 29, 2016 (*i.e.*, the second to last day of Q3'16) characterized meetings with ZBH management ***a day earlier*** (*i.e.*, September 28, 2016), "as quite positive and [the analyst was] comfortable that ZBH is on the path to meeting its stated goal of 4% plus top-line growth going forward."

27. By September 29, 2016, the FDA inspection was such a catastrophe that ZBH was forced to implement a "Product ship hold … to stop shipments of ***all final product cleaned, sterile packed, and sterilized at the Warsaw North Campus***."[12] Subsequent correspondence

[12] Ex. A (December 21, 2016 Letter).

from the Company to the FDA provided details[13] about additional disruptions to North Campus operations on September 29, 2016:

Date	Description
September 29, 2016	Quality Hold QH 16-064 was initiated for finished products in inventory at distribution centers and processed through Warsaw North cleanrooms to contain all work orders that did not have process monitoring and testing completed.
September 29, 2016	Temporarily stopped all sealers used for manufacturing operations in productions.
September 29, 2016	All cleaning operations at the North Campus were halted until the implementation of Interim Control IC-004 on October 20, 2016.
September 29, 2016	Quality Hold 16-068 was implemented to contain [work-in-process inventory ("WIP")] passing through gowning areas or work environments at the North Campus.

28. Needless to say, the Company's Q3'16 results were devastated by the supply shortages being caused by the various quality holds and other actions being taken since the inspection started, but especially by the complete product ship hold on September 29, 2016, which was the second to last day of Q3'16.

29. The FDA inspection continued into Q4'16 and throughout the month of October.[14] Severe supply disruptions also continued throughout October 2016 and were having a negative impact on the Company's performance in Q4'16. For example, subsequent correspondence between the Company and the FDA revealed[15] that ZBH was taking a large number of disruptive actions at the North Campus in October 2016 while the FDA inspection was continuing, including quality holds for sports medicine and microfixation devices, knee femoral implant products, and devices made of ultra-high molecular-weight polyethylene

[13] This information was derived from the July 31, 2017 Letter. *See* Ex. B.

[14] As noted below, the inspection continued until November 22, 2016.

[15] This information was derived from the July 31, 2017 Letter. *See* Ex. B.

(UHMWPE), quarantines, halting cleaning operations, subjecting products to retrospective testing, halting operations while interim controls were put into place, and requalifying cleanrooms:

Date	Description
October 2, 2016	Suspended production of [REDACTED] product and quarantined and held all [REDACTED] product in WIP inventory with appropriate NCR documentation, and subjected [REDACTED] product in finished goods inventory at the Warsaw North Campus to Quality Hold 16-067.
October 7, 2016	Sports medicine and microfixation devices made with [REDACTED] placed on quality hold 16-068 were subjected to retrospective testing.
October 11, 2016	Cleaning operations were halted at the work centers associated with the inadequate cleaning validation.
October 12, 2016	Quality Hold QH 16-068 was implemented for all WIP processed through Warsaw North cleanrooms. It was implemented to contain the knee femoral implant products impacted by the cleaning validation issues identified during inspections.
October 12, 2016	Subjected [REDACTED] devices placed on quality hold to retrospective testing.
October 12, 2016	Suspended all [REDACTED] production.
October 13, 2016	Halted preparation of [REDACTED] bar manufacturing at Zimmer Biomet, and hence preparation [REDACTED].
October 13, 2016	Cleaning operations were halted at [REDACTED] or [REDACTED] for final cleanings.
October 14, 2016	Halted preparation of [REDACTED] while an interim control could be implemented.
October 16, 2016	Knee femoral implant products impacted by the quality hold were subjected to retrospective testing and found to be conforming and were released.
October 16, 2016	QH 16-068 was implemented to contain WIP that had been packaged using one of the cleanroom sealers.
October 19, 2016	UHMWPE devices placed on Quality Hold 16-068-01 were subjected to retrospective testing.
October 19, 2016	Requalified the [REDACTED] cleanroom.
October 20, 2016	Quality Hold QH 16-071 was implemented for WIP originally listed on Sterilization Hold 16-068 to prevent shipment of product while investigation for end of line processing was completed.
October 20, 2016	Production of manual cleaning process for UHMWPE devices was restarted.
October 21, 2016	Quality Hold 16-074 was implemented for lots processed on

	sealers [REDACTED] between August 18, 2016 and October 5, 2016.
October 24, 2016	Subjected [REDACTED] devices placed on quality hold to retrospective testing and, based on the testing, released them from the hold.
October 24, 2016 - December 2, 2016	Metal hip, extremities, knee, and trauma devices placed on Quality Hold 16-068-01 were subjected to retrospective testing.
October 29, 2016	Knee femoral implant products placed on quality hold were subjected to retrospective testing under [redacted] and found to be conforming and were released.
October 30, 2016	Requalified the [REDACTED] cleanroom.

30. In October 2016, Defendants Florin and Dvorak pressured Barney to assist them with a scheme to mislead investors about what had caused the deceleration of organic revenue growth in Q3'16 and to terminate employees under false pretext. According to Barney [16]:

> … Around October of 2016, ***[ZBH's] Chief Financial Officer [Defendant Florin] demanded that Ms. Barney concoct a 'story' to mislead [ZBH] investors about the root cause of the 2016 Q3 shortfalls in sales on an upcoming investor call*** that would take place on November 1, 2016."
>
> … Ms. Barney refused to make material misrepresentations to the investors.

31. Despite Barney's refusal to participate in their scheme to mislead investors about the real cause of the supply shortages in Q3'16, Defendants Dvorak and Florin went ahead with their plan to misrepresent what had occurred in Q3'16 and cover up the ongoing FDA inspection of the North Campus, as well as the future impact of remediating the "systemic issues" with the QS at the North Campus.

[16] This information is from a complaint Barney filed on August 11, 2017, against ZBH captioned *Barney v. Zimmer Biomet Holdings, Inc.*, 3:17-cv-00616-JD-MGG (N.D. Ind.) (the "Barney Complaint") (attached hereto as "Ex. C"). According to the Barney Complaint, "[O]n October 29, 2016, Ms. Barney submitted her two-week's notice of resignation via email, which would be effective November 11, 2016."

D. The Risks Concealed During The Class Period Materialize, Causing ZBH's Stock Price To Plummet And Wiping Out Billions Of Market Capitalization

32. When ZBH reported its Q3'16 financial results on October 31, 2016, the Company shocked investors and analysts by reporting decelerating revenue growth in Q3'16 and lowering its organic revenue growth guidance for Q4'16. During a conference call that day, Defendants Dvorak and Florin blamed "variable sales performances" in Q3'16 on "unanticipated supply constraints, related to our transitioning supply chain infrastructure:"

> ***Variable commercial performances by our sales teams were in part caused by unanticipated supply constraints, related to our transitioning supply chain infrastructure.*** This resulted in shortfalls of needed implants and additional instrument sets, to fully exploit sales opportunities in key product categories.
>
> In response to this challenge, we've accelerated work to enhance certain aspects of our supply chain infrastructure as we harmonize and optimize our sourcing, manufacturing and quality management systems.

33. On the conference call, Defendants Dvorak and Florin told investors that the cause of the supply shortages in Q3'16 was that the Legacy Zimmer and Legacy Biomet supply chains, demand forecasting, and production planning had not yet been integrated. For example, Defendant Florin stated:

> . . . [C]ustomer demand was strong in the quarter but ***certain aspects of our supply chain integration impacted our ability to effectively respond to shifting product mix***, most notably within our Knee and Hip portfolios.
>
> As a consequence, ***we underestimated demand for certain key cross-sell brands within our existing customer base, leading to a depletion of our safety stock*** and also affecting our ability to capitalize on new customer opportunities. ***We are working diligently to enhance our supply chain processes and execution, particularly in the areas of demand forecasting, global inventory tracking, and asset deployment systems*** while we replenish our safety stock levels. However, these issues had some carryover effect into the fourth quarter, which I will address shortly in the context of our updated Q4 guidance. [17]

[17] During the conference call, Defendant Florin similarly stated: "And our current supply chain not being fully integrated did hamper our ability to respond effectively to this shifting product mix. And while not anticipated, we understand the root causes. We understand the fixes that are

34. During the conference call on October 31, 2016, Defendants Dvorak and Florin were repeatedly peppered with questions from incredulous analysts who were surprised that management had not seen the supply issues coming (and how management had been so positive in the waning days of Q3'16). Despite repeated questions about the supply shortages, Defendants Dvorak and Florin omitted any mention about the ongoing FDA inspection of the North Campus, the various product and quality holds, and the substantial/costly remediation needed to address the "systemic issues" with the QS at that facility, which would cause continued supply disruptions of key products well into 2017.

35. Defendants' disclosures on October 31, 2016, about ZBH's decelerated Q3'16 revenue growth rate, the lowered organic revenue growth rate guidance for Q4'16, and the existence of supply shortages, were materializations of the risks concealed during the Class Period about, *inter alia*, ZBH's inability to accelerate revenue growth in the second half of 2016, the "systemic issues" with the QS at the North Campus, and ZBH's inability to meet demand for its products (while remediating the North Campus QS deficiencies).[18]

36. On this news, shares of ZBH plummeted by ***$17.15 per share***, or ***nearly 14%,*** to close on October 31, 2016, at $105.40 per share, on usually heavy trading volume. The disclosure ***wiped out more than $3.4 billion*** of market capitalization in a single day.

37. Defendant Dvorak and Florin's premeditated scheme to mislead investors about

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necessary and we're highly confident in our ability to implement those changes. It will take several months to make those corrections."

[18] The October 31, 2016, disclosures did not fully disclose the truth about the prior misrepresentations and omissions and, additionally, the disclosures were themselves materially misleading because the disclosures omitted, *inter alia*: (i) that the true cause of the supply shortages in Q3'16 was the disruption being caused by the disastrous ongoing FDA inspection of the North Campus; (ii) there were "systemic issues" with the QS at the North Campus; and (iii) that ZBH lacked the ability to meet demand for its products while remediating the issues at the North Campus.

the true cause of the supply shortages and hide the existence of the disastrous FDA inspection was short lived. Days later on November 8, 2016, an analyst issued a report (the "November NCR Report") that further partially revealed the truth about the prior misrepresentations and omissions during the Class Period:

> . . . Based on our recent conversations with industry contacts, we believe at least part of the reason for the unanticipated product supply issues discussed during ZBH's 3Q16 earnings call is ***related to manufacturing problems at Biomet's Warsaw, Indiana, operations***.
>
> ***
>
> ***. . . According to our industry contacts, the FDA inspected Biomet's Warsaw manufacturing operations over a roughly six-week period recently as part of a routine review. Following the FDA inspection, we have heard some Biomet product lines manufactured in Warsaw have been shut down from operations and cannot be shipped to the field. We believe this could be at least part of the explanation for ZBH's unanticipated product supply issues for certain Biomet hip implants.***
>
> ***
>
> **Conclusion**
>
> ***We were initially willing to give ZBH the benefit of the doubt regarding its explanation behind unanticipated product supply issues on its 3Q16 earnings call. However, following our conversations with industry contacts, we are concerned there is more to the story.*** Moreover, we worry future acknowledgement of manufacturing issues at Biomet's Warsaw operations (either by the company or in FDA Form 483 observations) could lead to additional investor concern and limit upside potential for the stock. Given these concerns, we are downgrading ZBH to Neutral.

38. On November 8, 2016, ZBH was forced to admit that the supply shortages and lowered organic revenue growth guidance for Q4'16 had been caused by issues with the Legacy Biomet North Campus. That day, ZBH issued a statement in response to the analyst report and admitted that issues with North Campus had actually been factored into the lowered guidance ZBH announced on October 31, 2016 (even though ZBH had omitted this fact when announcing the guidance):

> … [A]s discussed on the third quarter earnings conference call, the Company has also accelerated work to enhance certain aspects of its supply chain infrastructure as it harmonizes and optimizes its sourcing, manufacturing and quality management systems. ***While these ongoing efforts have in instances led to certain product shipment delays, including product manufactured at the legacy Biomet operation in Warsaw, Indiana,*** the Company is making excellent progress in addressing the issues and many of the shipment delays are already resolved and the impacted product has been released for commercial distribution. The Company expects to return to full shipping capacity with the impacted products over the next few weeks.

39. On this news, shares of ZBH fell another $2.62 per share, to close on November 8, 2016 at $101.83 per share, on usually heavy trading volume. The disclosure wiped out roughly $500 million worth of market capitalization in a single day.

40. On November 22, 2016, the FDA inspection finally concluded, at which time the Company received an extensive 57 page FDA 483 (the "November 2016 North Campus FDA 483") (a partially redacted copy from the FDA is attached hereto as Ex. D). In mid-December 2016, various securities analysts obtained a partially redacted copy via FOIA requests and issued reports after having their own regulatory consultants analyze the document. The reports expressed disbelief at the scope and seriousness of the issues raised by the FDA and indicated that the Form 483 was one of the worst the analysts and their consultants had ever seen.[19]

41. In the weeks and months that followed, ZBH disclosed further supply shortages and that the ongoing remediation work, which had continued into Q1'17, would continue to cause supply shortages at least through Q2'17. Moreover, ZBH revealed that the remediation costs through 2018 would be upwards of $300 million.

42. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have

[19] For example, a Wells Fargo analyst report noted,"The bottom line is, ***this is one of the longest and most serious 483s [the] consultant has ever seen***" and "[the consultant] believes it will take ZBH ***at least a year*** to address all the issues in the 483."

suffered significant losses and damages.

III. JURISDICTION AND VENUE

43. The claims asserted herein arise under Sections 10(b), 20(a), and 20(A) of the Exchange Act (15 U.S.C. §§ 78j(b), 78t(a), and 78(t-1)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5), as well as Sections 11, 12(a)(2), and 15 of the Securities Act (15 U.S.C. §§ 77k, 77l, and 77o).

44. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 27 of the Exchange Act (15 U.S.C. § 78aa), and Section 22 of the Securities Act (15 U.S.C. § 77v).

45. 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 and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located in this Judicial District.

46. 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.

IV. PARTIES

A. Plaintiffs

47. Lead Plaintiff Rajesh M. Shah, as set forth in the certification previously filed with the Court (ECF No. 30), incorporated by reference herein, purchased ZBH common stock

during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

48. Lead Plaintiff Matt Brierley, as set forth in the certification previously filed with the Court, incorporated by reference herein (ECF No. 30), purchased ZBH common stock during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

49. Lead Plaintiff Eric Levy, as set forth in the certification previously filed with the Court (ECF No. 16-2), incorporated by reference herein, purchased ZBH options during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

50. Plaintiff UFCW 1500, as set forth in the certification previously filed with the Court (ECF No. 30), incorporated by reference herein, purchased ZBH common stock during the Class Period (including ZBH common stock purchased from one of the underwriters in connection with the June 2016 Offering and the August 2016 Offering, as well as ZBH stock purchased contemporaneously with the Private Equity Defendants sales in those offerings), and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

50.1 Plaintiff Steven Castillo, as set forth in the certification previously filed with the Court (ECF No. 188-1), incorporated by reference herein, purchased ZBH common stock during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

B. Corporate Defendant

51. Defendant ZBH is a Delaware Corporation headquartered in Warsaw. ZBH's

common stock trades on the NYSE under the symbol "ZBH."

C. Officer Defendants

52. Defendant Dvorak was, at all relevant times, CEO, President, and a director of ZBH. Dvorak also signed or authorized the signing of the Company's registration statements in connection with the June 2016 Offering and the August 2016 Offering. Dvorak was a member of the Integration Steering Committee ("ISC") in connection with the Merger. Dvorak previously served in various capacities as Legacy Zimmer's Group President, Global Businesses, Chief Legal Officer, Executive Vice President, Corporate Services, Chief Counsel and Secretary, Chief Compliance Officer, and SVP, Corporate Affairs and General Counsel. Before, Dvorak served as Senior Vice President, General Counsel and Corporate Secretary of STERIS Corporation. Dvorak formerly practiced corporate law, focusing on mergers and acquisitions and on securities law.

53. Defendant Florin was, at all relevant times, SVP and CFO of ZBH. Florin was also a member of the ISC in connection with the Merger. Florin signed or authorized the signing of the Company's registration statements for the June 2016 Offering and the August 2016 Offering, as well as ZBH's Quarterly Report on Form 10-Q for Q2'16. Florin served as SVP and CFO of Legacy Biomet from June 2007 to June 2015. Prior to joining Legacy Biomet, Florin served as Vice President and Corporate Controller of Boston Scientific Corporation from 2001 through May 2007, after serving in financial leadership positions within Boston Scientific Corporation. Florin worked for C.R. Bard from October 1990 to June 1995.

54. Defendant Robert J. Marshall Jr. ("Marshall") was, at all relevant times, ZBH's Vice President of Investor Relations and Treasurer. At times relevant hereto, Marshall frequently represented the Company at analyst conferences, often with Defendants Dvorak and

Florin. Defendant Marshall also frequently participated, along with Defendants Dvorak and Florin, in non-deal roadshows with securities analysts (from major brokerage firms) and investors, including on at least two occasions in September 2016.

55. Defendant Tony W. Collins ("Collins") was, at all relevant times, Vice President, Corporate Controller and Chief Accounting Officer (Principal Accounting Officer) of ZBH. Collins also signed or authorized the signing of the registration statements and ZBH's Quarterly Report on Form 10-Q for Q2'16. Collins previously served as Vice President, Finance for the Global Reconstructive Division and Global Operations organization. Collins joined Legacy Zimmer in 2010 as Vice President, Finance for the Global Reconstructive Division and U.S. Commercial organization. From 1997 to 2007, he was employed at Guidant Corporation and Boston Scientific Corporation, where he held a number of positions, including Finance Director and CFO of the Guidant Japan organization, Global Director of Operations Finance and Director of Strategic Planning.

56. Defendants Dvorak, Florin, Marshall, and Collins (collectively the "Officer Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of Zimmer's reports to the SEC, press releases, and presentations to securities analysts, investment managers, and institutional investors, *i.e.*, the market. The Officer Defendants were provided with copies of ZBH's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, the Officer Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The

Officer Defendants are liable for the false statements pleaded herein.

D. Director Defendants

57. Defendant Larry Glasscock ("Glasscock") was, at all relevant times, Chairman of ZBH's Board of Directors and a member of the Audit Committee. Defendant Glasscock signed or authorized the signing of ZBH's registration statements filed with the SEC. Glasscock was Chairman of WellPoint, Inc. from 2005 until 2010 and President and CEO of WellPoint, Inc. from 2004 to 2007. Glasscock served as President and CEO of Anthem, Inc. from 2001 to 2004, and Chairman from 2003 to 2004.

58. Defendant Christopher B. Begley ("Begley") was, at all relevant times, a director of ZBH, a member of the Audit Committee, and signed or authorized the signing of ZBH's registration statement. Begley was Executive Chairman of the Board of Hospira, Inc. from May 2007 until January 2012, and CEO from 2004 to March 2011. Begley served in various positions with Abbott Laboratories between 1986 and 2004, most recently as SVP of Abbott's Hospital Products division.

59. Defendant Betsy J. Bernard ("Bernard") was, at all relevant times, a director of ZBH, and signed or authorized the signing of ZBH's registration statements. Bernard was President of AT&T Corp. from October 2002 until December 2003. From April 2001 to October 2002, Bernard was CEO of AT&T Consumer. Prior to joining AT&T, Bernard held senior executive positions with Qwest Communications International, Inc., US WEST, Inc., AVIRNEX Communications Group and Pacific Bell.

60. Defendant Paul M. Bisaro ("Bisaro") was, at all relevant times, a director of ZBH, and signed or authorized the signing of ZBH's registration statements. Bisaro has been Executive Chairman of Allergan plc (formerly Actavis plc) since July 2014. Bisaro served in

various roles as Chairman, President, CEO, and director of Actavis between 2007 and 2014. Bisaro served as President, Chief Operating Officer and a member of the board of directors of Barr Pharmaceuticals, Inc. from 1999 to 2007, and General Counsel from 1992 to 1999.

61. Defendant Gail K. Boudreaux ("Boudreaux") was, at all relevant times, a director of ZBH, member of the Audit Committee, and signed or authorized the signing of ZBH's registration statements. Boudreaux has been CEO and Founder at GKB Global Health, LLC since 2015. Boudreaux served as CFO of UnitedHealthcare from 2011 to 2014 and Executive Vice President of UnitedHealth Group from 2008 to 2015. From 2005 to 2008, Boudreaux served as Executive Vice President, External Operations for Health Care Services Corporation, and prior to that served as President of Blue Cross and Blue Shield of Illinois. Before joining HCSC, Boudreaux held various positions at Aetna.

62. Defendant Michael J. Farrell ("Farrell") was, at all relevant times, a director of ZBH, and signed or authorized the signing of ZBH's registration statements. Farrell has been CEO of ResMed Inc. since 2013, and was President since 2011. Farrell was SVP of the global business unit for sleep apnea therapeutic and diagnostic devices from 2007 to 2011, and before that held various senior roles in marketing and business development. Before joining ResMed in September 2000, Farrell worked in management consulting, biotechnology, chemicals and metals manufacturing at Arthur D. Little, Genzyme Corporation, The Dow Chemical Company and BHP Billiton.

63. Defendant Robert A. Hagemann ("Hagemann") was, at all relevant times, a director of ZBH, a member of the Audit Committee, and signed or authorized the signing of ZBH's registration statements. Hagemann held various positions at Quest Diagnostics Incorporated and a subsidiary of its former parent company, Corning Incorporated, including

Senior Vice President and CFO from 1992 until 2013.

64. Defendant Arthur J. Higgins ("Higgins") was, at all relevant times, a director of ZBH, and signed or authorized the signing of ZBH's registration statements. Higgins was a Consultant with the Blackstone Group since 2010 and had served as Chairman of the Board of Management of Bayer HealthCare AG from 2006 to 2010 and Chairman of the Bayer HealthCare Executive Committee from 2004 to 2010. Prior to joining Bayer HealthCare, Higgins served as Chairman, President and CEO of Enzon Pharmaceuticals, Inc, after spending fourteen years with Abbott Laboratories, most recently as President of the Pharmaceutical Products Division from 1998 to 2001.

65. Defendant Michael W. Michelson ("Michelson") was, at all relevant times, a director of ZBH, and signed or authorized the signing of ZBH's registration statements. Michelson has been a Member of KKR Management LLC, a private equity investment manager and the general partner of KKR, since October 2009, and has worked for various KKR entities since 1981. Michelson worked at Latham & Watkins where he was involved in a broad corporate practice while specializing in management buyouts. Michelson was a director of Legacy Biomet prior to the Merger. Michelson was designated for nomination to ZBH's Board by the Private Equity Funds.

66. Defendant Cecil B. Pickett ("Pickett") was, at all relevant times, a director of ZBH, and signed or authorized the signing of ZBH's registration statements. Pickett was President of Research and Development and a member of the board of directors of Biogen Idec Inc. from 2006 until 2009. Prior to joining Biogen Idec, Pickett held several senior R&D positions, including Corporate SVP of Schering-Plough Corp. and President of Schering-Plough Research Institute, as well as, several senior R&D positions at Merck & Co.

67. Defendant Jeffrey K. Rhodes ("Rhodes"), was at all relevant times, a director of ZBH, and signed or authorized the signing of the ZBH's registration statements filed with the SEC. Rhodes is a partner at TPG and a leader of the firm's investment activities in the healthcare services, pharmaceutical and medical device sectors. Prior to joining TPG Capital, L.P. in 2005, Rhodes was with McKinsey & Company and Article27 LTD, a start-up software company. Rhodes was a director of Legacy Biomet prior to the Merger. Rhodes was nominated to ZBH's Board by the Private Equity Defendants.

68. Defendants Glasscock, Begley, Bernard, Bisaro, Boudreaux, Farrell, Hagemann, Higgins, Michelson, Pickett, and Rhodes, are herein referred to as the "Director Defendants."

E. Private Equity Defendants

69. Defendant KKR Biomet LLC ("KKR Biomet") was, during the Class Period, a major shareholder of ZBH that owned approximately 7,529,640 shares of ZBH common stock as a result of the Merger. Defendant KKR Biomet sold approximately 3,764,820 shares of stock in the June 2016 Offering for net proceeds of approximately $434 million and sold approximately 3,764,820 shares of stock in the August 2016 Offering for net proceeds of approximately $485 million. Combined, Defendant KKR Biomet received net proceeds of approximately $919 million from the June 2016 Offering and August 2016 Offering. Defendant KKR Biomet was identified in the registration statements and prospectuses for the June 2016 Offering and the August 2016 Offering as one of the "Selling stockholders" offering ZBH common stock in the offerings. Defendant KKR Biomet is an affiliate of KKR.

70. Defendant TPG Partners IV, L.P. ("TPG Partners IV") was, during the Class Period, a major shareholder of ZBH and owned approximately 280,938 shares of ZBH common stock as a result of the Merger. Defendant TPG Partners IV sold approximately 140,469 shares

of stock in the June 2016 Offering for net proceeds of approximately $16.2 million and approximately 140,469 shares of stock in the August 2016 Offering for net proceeds of approximately $18 million. In total, Defendant TPG Partners IV received net proceeds of $34.2 million from both offerings.

71. Defendant TPG Partners V, L.P. ("TPG Partners V") was, during the Class Period, a major shareholder of ZBH and owned approximately 5,703,170 shares of ZBH common stock as a result of the Merger. Defendant TPG Partners V sold approximately 2,851,585 shares of stock in the June 2016 Offering for net proceeds of approximately $328.8 million and approximately 2,851,585 shares of stock in the August 2016 Offering for net proceeds of approximately $367.8 million. In total, Defendant TPG Partners V received net proceeds of $696.6 million in both offerings.

72. Defendant TPG FOF V-A, L.P. ("TPG FOF V-A") was, during the Class Period, a major shareholder of ZBH and owned approximately 14,921 shares of ZBH common stock as a result of the Merger. Defendant TPG FOF V-A sold approximately 7,461 shares of stock in the June 2016 Offering for net proceeds of approximately $860,000 and approximately 7,460 shares of stock in the August 2016 Offering for net proceeds of approximately $1 million. In total, Defendant TPG FOF V-A received net proceeds of $1.8 million in both offerings.

73. Defendant TPG FOF V-B, L.P. ("TPG FOF V-B") was, during the Class Period, a major shareholder of ZBH and owned approximately 12,033 shares of ZBH common stock as a result of the Merger. Defendant TPG FOF V-B sold approximately 6,016 shares of stock in the June 2016 Offering for net proceeds of approximately $693,700 and approximately 6,017 shares of stock in the August 2016 Offering for net proceeds of approximately $776,100. In total, Defendant TPG FOF V-A received net proceeds of $1.47 million in both offerings.

74. Defendant TPG LVB Co-Invest LLC ("TPG LVB Co-Invest I") was, during the Class Period, a major shareholder of ZBH and owned approximately 1,325,152 shares of ZBH common stock as a result of the Merger. Defendant TPG LVB Co-Invest I sold approximately 662,576 shares of stock in the June 2016 Offering for net proceeds of approximately $76.4 million and approximately 662,576 shares of stock in the August 2016 Offering for net proceeds of approximately $85.5 million. In total, Defendant TPG LVB Co-Invest I received net proceeds of $161.9 million in both offerings.

75. Defendant TPG LVB Co-Invest II LLC (TPG LVB Co-Invest II) was, during the Class Period, a major shareholder of ZBH and owned approximately 15,496 shares of ZBH common stock as a result of the Merger. Defendant TPG LVB Co-Invest II sold approximately 7,748 shares of stock in the June 2016 Offering for net proceeds of approximately $900,000 and approximately 7,748 shares of stock in the August 2016 Offering for net proceeds of approximately $1 million. Combined, Defendant TPG LVB Co-Invest II received net proceeds of $1.9 million in both offerings.

76. Defendants TPG Partners IV, TPG Partners V, TPG FOF V-A, TPG FOF V-B, TPG LVB Co-Invest I, and TPG LVB Co-Invest II, are herein collectively referred to as the "TPG Entities" or "TPG Defendants." The TPG Defendants were all affiliates of TPG. The TPG Defendants were all identified in the registration statements and prospectuses for the June 2016 Offering and the August 2016 Offering as "Selling stockholders" offering shares of ZBH common stock being sold in the offerings.

77. Defendant GS Capital Partners VI Fund, L.P. ("GSCP VI Fund") was, during the Class Period, a major shareholder of ZBH and owned approximately 1,218,373 shares of ZBH stock as a result of the Merger. Defendant GSCP VI Fund sold approximately 1,218,373 shares

of ZBH stock in the June 2016 Offering for net proceeds of approximately $157.1 million.

78. Defendant GS Capital Partners VI Parallel, L.P. ("GSCP Partners VI Parallel") was, during the Class Period, a major shareholder of ZBH and owned approximately 335,030 shares of ZBH stock as a result of the Merger. Defendant GSCP VI Parallel sold approximately 335,030 shares of ZBH stock in the June 2016 Offering for net proceeds of around $38.6 million.

79. Defendant GS Capital Partners VI Offshore Fund, L.P. ("GSCP VI Offshore") was, during the Class Period, a major shareholder of ZBH and owned approximately 1,013,399 shares of ZBH common stock as a result of the Merger. Defendant GSCP VI Offshore sold approximately 1,013,399 shares of ZBH stock in the June 2016 Offering for net proceeds of around $116.9 million.

80. Defendant GS Capital Partners VI GmbH & Co. KG ("GSCP VI GMBH") was, during the Class Period, a major shareholder of ZBH and owned approximately 43,302 shares of ZBH stock as a result of the Merger. Defendant GSCP VI GMBH sold approximately 43,302 shares of ZBH stock in the June 2016 Offering for net proceeds of approximately $5 million.

81. Defendant Goldman Sachs BMET Investors, L.P. ("GS BMET Investors") was, during the Class Period, a major shareholder of ZBH and owned approximately 177,379 shares of ZBH stock as a result of the Merger. Defendant GS BMET Investors sold approximately 177,379 shares of ZBH stock in the June 2016 Offering for net proceeds of around $20.5 million.

82. Defendant Goldman Sachs BMET Investors Offshore Holdings, L.P. ("Goldman Sachs BMET Investors Offshore") was, during the Class Period, a major shareholder of ZBH and owned approximately 519,134 shares of ZBH stock as a result of the Merger. Defendant Goldman Sachs BMET Investors Offshore sold approximately 519,134 shares of ZBH stock in the June 2016 Offering for net proceeds of around $60 million.

83. Defendant PEP Bass Holdings, LLC ("PEP Bass") was, during the Class Period, a major shareholder of ZBH and owned approximately 124,916 shares of ZBH stock as a result of the Merger. Defendant PEP Bass sold approximately 124,916 shares of ZBH stock in the June 2016 Offering for net proceeds of around $14.4 million.

84. Defendant Private Equity Partners 2004 Direct Investment Fund L.P. ("Private Equity Partners 2004") was, during the Class Period, a major shareholder of ZBH and owned approximately 17,727 shares of ZBH stock as a result of the Merger. Defendant Private Equity Partners 2004 sold approximately 17,727 shares of ZBH stock in the June 2016 Offering for net proceeds of approximately $2 million.

85. Defendant Private Equity Partners 2005 Direct L.P. ("Private Equity Partners 2005") was, during the Class Period, a major shareholder of ZBH and owned approximately 25,322 shares of ZBH common stock as a result of the Merger. Defendant Private Equity Partners 2005 sold approximately 25,322 shares of common stock in the June 2016 Offering for net proceeds of approximately $3 million.

86. Defendant Private Equity Partners IX Direct L.P. ("Private Equity Partners IX") was, during the Class Period, a major shareholder of ZBH and owned approximately 27,442 shares of ZBH stock as a result of the Merger. Defendant Private Equity Partners IX sold approximately 27,442 shares of ZBH stock in the June 2016 Offering for net proceeds of approximately $3.2 million.

87. Defendant GS LVB Co-Invest, L.P. ("GS LVB Co-Invest") was, during the Class Period, a major shareholder of ZBH and owned approximately 173,834 shares of ZBH stock as a result of the Merger. Defendant GS LVB Co-Invest sold approximately 173,834 shares of ZBH stock in the June 2016 Offering for net proceeds of around $20 million.

88. Defendants GSCP VI Fund, GSCP VI Parallel, GSCP VI Offshore, GSCP VI GMBH, GS BMET Investors, Goldman Sachs BMET Investors Offshore, PEP Bass, Private Equity Partners 2004, Private Equity Partners 2005, Private Equity Partners IX, and GS LVB Co-Invest, are herein collectively referred to as the "GSCP Entities" or "GSCP Defendants." The GSCP Defendants were identified in the registration statement and prospectus for the June 2016 Offering as "Selling stockholders" offering shares of ZBH common stock being sold in the offering. The GSCP Defendants are affiliates of GSCP. Affiliates of The Goldman Sachs Group, Inc. and Goldman, Sachs & Co. are the general partner, managing limited partner, managing partner or manager of the GSCP Entities. Goldman, Sachs & Co. is the investment manager for certain of the GSCP Entities and Goldman, Sachs & Co. is a direct and indirect wholly-owned subsidiary of The Goldman Sachs Group, Inc.

89. Defendant KKR Biomet, the TPG Defendants, and the GSCP Defendants are herein collectively referred to as the "Private Equity Defendants" or the "Private Equity Funds."

V. RELEVANT NON-PARTIES

90. Confidential Witness ("CW") 1 ("CW1") was a Production Supervisor at the North Campus since before the Merger and served in that position in the poly bearing department for the last five years of his employment at the Company. CW1 left his position at the Company after the Class Period. CW1 reported to a Production Manager that oversaw CW1's department and all of the other Production Supervisors, who according to CW1, reported to Director Robert Gunner. As a Production Supervisor in the poly bearing department, CW1 was responsible for managing the employees on his shift, which included monitoring employee attendance, reviews, and counseling employees on performance. CW1's production area included a manufacturing area, as well as a "clean room" where products were sterilized and packaged.

91. CW2 was a former Senior Manufacturing Engineer II at the Legacy Zimmer West Campus throughout the Class Period. CW2 originally started with Legacy Zimmer soon after the Merger was announced. CW2 held the position of Senior Manufacturing Engineer II in the Advanced Manufacturing department where he was part of a team looking at improvement opportunities in numerous areas such as headcount, efficiency and quality; CW2 said the managers directed the group on where to focus to find improvement opportunities. CW2 was later part of the Continuous Improvement team and reported to Anthony Carra (who reported to the Plant Manager for the West Campus) and later Sean Ferguson (after Anthony Carra was moved to a different position at the North Campus). CW2 indicated that the Plant Manager reported to Barney, who reported to Defendant Dvorak.

VI. BACKGROUND AND RELEVANT EVENTS PRIOR TO THE CLASS PERIOD

92. ZBH designs, manufactures and markets orthopaedic reconstructive products; sports medicine, biologics, extremities and trauma products; spine, bone healing, craniomaxillofacial and thoracic products; dental implants; and related surgical products. ZBH's products and solutions treat bones, joints or supporting soft tissues.

A. ZBH's Products And Facilities Are Strictly Regulated By The FDA

93. ZBH's products are subject to extensive regulation[20] by the FDA because they are "medical devices" under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 321(h). The FDCA provides that a medical device must be manufactured, packed, stored, and installed in conformity with Current Good Manufacturing Processes ("cGMP") to ensure its safety and effectiveness. 21 U.S.C. § 360j(f). The statutory good manufacturing practice

[20] ZBH's products include Class I, Class II, and Class III devices. Class III devices are generally considered the highest risk category of devices and are subject to the highest level of regulatory control.

requirement is set out in the QS regulation for devices, 21 C.F.R. Part 820. A device that has been manufactured, packed, stored, or installed in violation of this requirement is deemed to be adulterated. 21 U.S.C. § 351(h). The introduction or delivery for introduction into interstate commerce of an adulterated article of device is a violation of the FDCA. 21 U.S.C. § 331(a).

94. FDA regulations explicitly make senior company management responsible for ensuring adherence to cGMP. When evaluating quality controls, FDA inspectors are required to evaluate, among other things, "whether management with executive responsibility ensures that an adequate and effective quality system has been established and maintained." FDA Guide To Inspections Of Quality Systems, at 18. The FDA treats management responsibility for adherence to cGMP as a very serious matter; when the FDA concludes that management is not providing sufficient oversight of the procedures used in a manufacturing facility, it may impose a requirement that top officers personally sign off on every procedure used in the facility. If the procedures and quality control systems are not adequate, are ineffective, and/or are not being maintained, then executive management is not upholding its responsibilities under the FDCA.

B. Important Information Regarding The Types And Frequency Of FDA QS Inspections

95. All manufacturers of medical devices are subject to periodic inspections by the FDA to ensure compliance with the FDCA and other applicable laws and regulations,[21] including regular QS inspections. Pursuant to 21 U.S.C. § 360(h)(2), ***manufacturers of Class II and Class III devices (such as ZBH) should expect their facilities to be inspected every two years***:

> (2) BIENNIAL INSPECTIONS FOR DEVICES
>
> ***Every establishment*** described in paragraph (1), in any State, ***that is engaged in***

[21] The FDA's authority to inspect device manufacturers is provided for by 21 U.S.C. § 360(h)(1) ("Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 374 of this title.").

> ***the manufacture, propagation, compounding, or processing of a device or devices classified in class II or III shall be so inspected*** by one or more officers or employees duly designated by the Secretary, or by persons accredited to conduct inspections under section 374(g) of this title, at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section ***and at least once in every successive 2-year period thereafter.***

96. The FDA's Guide to Inspections of Quality Systems (the "FDA Inspection Guide") provides for inspections to follow a "top-down" approach that relies on performing "subsystem" inspections. As explained in the FDA Inspection Guide:

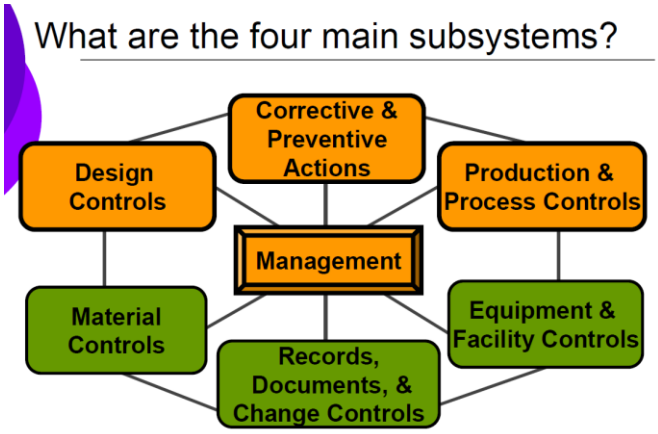
> . . . [W]ith the "top-down" approach, ***we are looking at the firm's "systems" for addressing quality before we actually look at specific quality problems.*** In the "top-down" approach, we "touch bottom" in each of the subsystems by sampling records, rather than working our way from records review backwards towards procedures.
>
> ***The "top-down" approach begins each subsystem review with an evaluation of whether the firm has addressed the basic requirements in that subsystem by defining and docu-menting appropriate procedures.*** This is followed by an analysis of whether the firm has implemented the require-ments of that subsystem.

97. As per the FDA's Compliance Program Guidance Manual (Inspection of Medical Device Manufacturers) (the "FDA Manual"), the QS regulation can be grouped into seven subsystems; however, the following ***four subsystems are considered major subsystems*** and the basic foundation of a firm's QS: (i) ***Management Controls***; (ii) ***Design Controls***; (iii) CAPAs[22]; and (iv) ***Production and Process Controls*** ("P&PC"). The FDA Manual notes that the three remaining subsystems (Facilities and Equipment Controls; Materials Controls; and Records, Documents and Change Controls) cut across a firm's quality management system and are evaluated while covering the four major subsystems.

98. The below chart reflects the four major subsystems (and three other subsystems)

[22]The FDA Manual notes that MDR, Corrections and Removals, and Tracking requirements (where applicable) should be covered when covering the CAPA subsystem.

that comprise the quality management system:



99. There are four general types of QS inspections conducted by the FDA: (a) pre-approval inspections; (b) routine inspections; (c) compliance follow-up inspections; and (d) for-cause inspections.

100. Routine inspections are mandated by law every 2 years for class II and class III device manufacturers. *See* 21 U.S.C. § 360(h)(2). These inspections follow a prescribed method known as Quality System Inspection Technique ("QSIT") and generally fall into two categories: (a) Level 1 or "Abbreviated" QSIT inspections; and (b) Level 2 or "Baseline" QSIT (comprehensive) inspections.

101. Level 2 QSIT inspections entail a comprehensive review of the firm's QS. Specifically, the inspection covers all of the four major subsystems (Management Controls, Design Controls, CAPA, and P&PC). Level 2 inspections are conducted when a firm has never had a Level 2 inspection and are supposed to occur every six years thereafter.

102. Level 1 (Abbreviated) QSIT inspections cover only two of the major subsystems and occur after a firm has passed a Level 2 inspection. The inspections always cover a review of the CAPA subsystem and either the (a) PP&C subsystem or (b) Design Control subsystem.

103. The FDA Manual also dictates the following be included for Level 1 inspections:

"The adequacy of the correction(s), corrective action(s) or preventive action(s) related to any FDA 483 item(s) from the previous inspection should be covered, even if the entire subsystem will not be reviewed during the current Level 1 inspection."

104. The FDA's customary practice is to provide five calendar days advanced notice prior to conducting pre-approval and routine inspections.

105. According to FDA procedures, if an FDA inspector discovers "significant" deviations from cGMP during an inspection, the inspector issues an FDA 483 to senior management at the conclusion of the inspection. "The Form FDA 483 Inspectional Observations …is intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the [FDCA] and related Acts …which were observed during the inspection." FDA Investigations Operations Manual 2017 § 5.2.3.

106. According to FDA Field Management Directive No. 120, "Inspectional Observations (FDA 483) are of critical importance to both the Agency and regulated industry." Inspectors are instructed that "[o]bservations which are listed should be significant and correlate to regulated products or processes being inspected," and that "[o]bservations of questionable significance should not be listed on the FDA 483." The Directive also requires that copies of each FDA 483 be sent to "the top management official of the firm inspected." Moreover, FDA investigators conduct exit or close out interviews at inspection sites with company personnel to ensure that senior management at the company has notice of the nature and seriousness of the findings, ensure that the company understands the issues identified in the observations and confirm that the facts underlying the observations are correct and that relevant documentation has been collected (if the inspection is of a serious nature). Thus, senior management of

companies whose facilities are inspected by the FDA, such as ZBH, are immediately made aware of any problems at the conclusion of the on-site inspection process.

107. A "repeat" or "recurring" observation listed on an FDA 483 occurs when, on two or more successive investigations, FDA investigators observe continuing problems with the same quality system(s). Repeat observations often form the basis for a Warning Letter or other enforcement action by the FDA.

108. A company will typically respond to the FDA 483 within fifteen days by providing the FDA with a detailed plan to remedy the deficiencies. If the significant deviations from cGMP noted in an FDA 483 are not remedied, the FDA may then issue a "Warning Letter," which generally states that the company has made products that are adulterated or misbranded, violating the FDCA, and that the company has a very limited amount of time to address the problem(s) before the FDA takes further regulatory action against the firm, the adulterated product, and responsible individuals.

C. The 2015 Merger: A Marriage Of Two Crosstown Rivals

109. On April 24, 2014, Legacy Zimmer announced that it was acquiring competitor Legacy Biomet[23] for 13.35 billion, including $10.35 billion in cash and an aggregate amount of Legacy Zimmer shares valued at approximately $3 billion, with the Legacy Biomet shareholders owning approximately 16% of the combined company upon closing. The transaction was expected to close in the first quarter of 2015.

110. At the time, Legacy Zimmer was the second largest provider of orthopedic products and Legacy Biomet was the fourth. It was perceived that the merged entity would be a

[23] As noted above, Legacy Zimmer actually acquired LVB, which owned Legacy Biomet. At the time, LVB was approximately 97% owned by a private equity consortium that included the Private Equity Defendants. The private equity consortium had taken Legacy Biomet private for $11.3 billion in 2007.

leader in the $45 billion musculoskeletal healthcare market with combined revenues of approximately $7.8 billion in 2013.

111. Shareholders were told to anticipate $135 million of synergies in the first year and approximately $270 million in revenue and operating synergies by the third year post-closing. These synergies would purportedly be achieved through disciplined expense management, advanced manufacturing and streamlined logistics. It was also emphasized that the combination would leverage the companies' complementary sales channels and that the generation of cross-selling opportunities would be an important source of synergies from the proposed combination.

112. Investors were promised that once the commercial/sales channels were integrated, investors would see the benefits from cross-selling in the form of above market-level revenue growth. For example, during a conference call with investors on April 24, 2014, Legacy Zimmer's then CFO explained that initially revenue growth would be in line with the market/industry level,[24] but then "***when the integration is complete, we would expect all categories to be growing ahead of their respective markets*** given the breadth of scale and the global reach of the combined sales channel."

113. After the Merger finally closed on June 24, 2015, both companies' facilities remained opened, including both companies' primary facilities located in Warsaw, and responsible for manufacturing their respective products. ZBH's 2016 10-K (filed March 1, 2017) states that it has approximately 2,600 employees at its Warsaw production facilities, which includes the West and North Campuses.

[24] As noted below (*see* fn.26), market/industry level growth was deemed to be 3%.

D. ZBH's Organic Revenue Growth Rate Was The Most Important Metric To ZBH's Stock Price[25]

114. Leading up to the close of the Merger in June 2015, shareholders had been conditioned to live with stagnant/flat organic revenue growth until the ***post***-Merger commercial integration of the legacy companies was completed. Once completed, the benefits of cross-selling opportunities would purportedly drive increased organic revenue growth.

115. However, in 2015 there was a notable ***deceleration*** of organic revenue growth leading up to the close of the Merger. When the Merger closed on June 24, 2015, ZBH lowered full year 2015 top-line revenue guidance to 1.5 to 2.0%, versus its prior guidance of 1.5 to 2.5%. Further deceleration caused a dramatic amount of concern about growth rates in the fall of 2015.

116. Before and during the Class Period, ZBH's ability to return to market level growth (*i.e.*, 3%) and then exceed market level was the primary focus of investors and research analysts. [26] During the public investor conference calls and analyst conferences, Defendants Dvorak, Florin and Marshall were constantly asked about this topic and would routinely acknowledge that increasing organic revenue growth was one of ZBH's primary focuses.

117. To increase ZBH's stock price, the Company had to increase ZBH's organic growth rate. For example, at a conference on March 16, 2016, a securities analyst moderating a

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[25]This section summarizes ZBH's pre-Class Period decelerating organic revenue growth, which provides crucial context to ZBH's representations during the Class Period about the Company's ability to return to and exceed market/industry level organic revenue growth (which was generally deemed to be approximately 3%). *See infra* §VII.A (summary of ZBH and the Officer Defendants' Class Period statements).

[26] ZBH, investors, and analysts understood that market/industry level growth was approximately 3%. For example, when asked (on January 28, 2016) asked, "And then just to clarify your view of market growth and getting to market growth in the back half of the [2016] year, is that 2.5%, 3%?," Defendant Dvorak confirmed, "I think about that market growth rate in round numbers of 3%."

discussion with Defendant Florin polled the audience and the clear consensus was that organic revenue growth was the primary concern/focus among investors:

> I want to ask the audience another question here. This is kind of an open-ended question about Zimmer performance, and it is just, ***what area is important for the Company to improve on to drive better stock price performance?*** Is it organic revenue growth, gross margins, operating margins, earnings growth or cash flow growth? And then we can dovetail into some of these other topics.
>
> ***So it looks like, by far, organic revenue growth is the winner*** …[27]

1. ZBH's Organic Revenue Growth Rate Underperforms The Market/Industry Level In 2015

118. When ZBH held its first post-Merger earnings conference call on July 30, 2015, Defendant Dvorak reiterated that investors should still expect accelerated organic revenue growth into 2016. Defendant Dvorak explained that ZBH expected to complete the integration of its commercial operations by the end of 2015, which would allow the Company to benefit from cross-selling opportunities:

> . . . ***Zimmer Biomet is in an excellent position to accelerate top-line growth over the course of our global integration, principally through a host of cross-selling opportunities between our two legacy portfolios***.
>
> Our integration teams have already achieved key milestones in support of these commercial opportunities, including the implementation of critical sales infrastructure, and the completion of initial-product trainings, which have supported our ability to begin deploying specialized commercial teams in key product categories and geographies.
>
> We expect to substantially complete our commercial integration by the end of this year ….
>
> ***We expect to begin realizing the benefits of our integrated sales channel, as well as these commercial opportunities, in the form of sequentially-accelerating revenue growth as we exit 2015 and progress through 2016.***

[27] In response, Defendant Florin stated, "***The management team is very focused on driving organic growth and to the point that our incentives are weighted towards driving organic revenue growth. So we understand the import of that.*** We are focused on it and feel really bullish about our opportunity to drive that acceleration."

119. In late 2015, doubts about ZBH's ability to reaccelerate its top line growth were dragging down ZBH's stock price. For example, an October 2, 2015, J.P. Morgan report noted:

> ***ZBH trades at a notable discount to the group … as the Street wrestles with a top-line [revenue] that decelerated into the Biomet [Merger] and the prospect of revenue dis-synergies and low-single-digit (1-2%) top-line growth in the back half of the year.*** Our view is that the post-close sales disruption is likely to play out longer than just 1-2 quarters and that ***it's likely Zimmer we'll see 2-3 years of below end market growth, suggesting 1-2% may in fact be the new norm***…

120. Things got worse before they got better. When ZBH reported its Q3'15 results, ZBH lowered its revenue guidance for 2015 indicating organic growth was only expected to be 1 to 1.5% compared to its previous guidance of 1.5 to 2.0%. Nevertheless, on the Q3'15 earnings conference call on October 29, 2015, Defendant Florin reiterated, "We will be working towards achievement of market growth rates, as we progress through 2016." Defendant Dvorak stated, "we expect to substantially complete all commercial integration efforts by the end of this year," and expect "[s]equential improvement throughout 2016."

121. In early 2016, the Company claimed to have nearly completed the crucial step of integrating its commercial operations. For example, at the January 12, 2016, J.P. Morgan Healthcare Conference, Defendant Dvorak discussed the integration, claiming "that process is ***substantially complete*** … And we are in a great position as a consequence of that to start running the offense that the combined company possesses in 2016." Defendant Dvorak also stated: "As some of those revenue dyssynergies ***are countered by the sales cross-sell opportunities, then you are going to normalize back to something that resembles a market growth rate***."

122. On January 28, 2016, ZBH reported its financial results for Q4'15 and the 2015

fiscal year, which reflected further ***deceleration***.[28] During a conference call that day, Defendant Dvorak stated: "During [Q4'15], we substantially completed the integration of our global commercial organizations. …Based upon our significant progress, we're confident in our ability to drive sequential revenue improvement as we progress through 2016."

2. Prior To The Class Period, ZBH's Organic Revenue Growth Rate Starts To Reaccelerate In Q1'16

123. On April 28, 2016, ZBH released better than expected financial results for Q1'16, notably reporting that revenue growth had accelerated to 1.2%. ZBH also raised its prior 2016 guidance for growth of 2.0-3.0% (up from 1.5-2.5%). Defendant Dvorak expressed continued confidence in returning to market/industry growth rates, citing the Company's detailed integration plans and ZBH's ability to benefit from cross selling opportunities.

124. The reaction to ZBH's accelerating organic revenue growth rate was positive. An April 29, 2016 J.P. Morgan analyst report noted that the Company "appears to be turning the corner and has started to recover from some of the early integration challenges in 2015." A William Blair analyst report issued a day earlier noted that the price of the Company's "shares are up about 20% in the last two months."

125. As the first half of 2016 progressed, ZBH continued to tout its increasing organic revenue growth rate and cited its ability to drive further growth from cross-selling opportunities made possible after successfully integrating its commercial operations in Q4'15.

E. The FDA Was Carefully Scrutinizing ZBH's Facilities Following Problematic QS Inspections Of Legacy Zimmer's Flagship West Campus And Facilities In Puerto Rico And Canada

126. In early 2016, ZBH was under intense FDA scrutiny following a highly critical

[28] A J.P. Morgan report issued that day noted that the results "were below the Street [expectations] as ***organic growth of just 0.5% was disappointing*** given the easing of y/y comps."

inspection of the Legacy Zimmer ***West*** Campus between October 20 and November 20, 2015 (the "November 2015 West Campus Inspection"), that had resulted in the issuance of an FDA 483 on November 20, 2015 (the "November 2015 West Campus FDA 483"),[29] as well as highly critical inspections of Legacy Zimmer facilities in Puerto Rico in November 2015 and Montreal in January 2016 that had also resulted in FDA 483s. In early to mid-2016, ZBH was busy attempting to remediate and correct the extensive issues that the FDA had cited at the West Campus, as well as the issues at ZBH's other facilities in Puerto Rico and Canada.

127. The November 2015 West Campus FDA Inspection posed a very serious problem for ZBH. Not only had the FDA identified numerous QS deficiencies, but a large number of the deficiencies cited by the FDA were uncorrected observations from prior inspections.

128. The November 2015 West Campus Inspection had been a follow up to a prior FDA inspection of the West Campus between April 21 and May 28, 2014. At the conclusion of that inspection, the FDA had issued an extensive FDA 483 on May 28, 2014, containing the following 12 adverse observations:

> (1) Device packaging and/or shipping containers are not designed and constructed to protect the device from alteration or damage during processing, storage, handling, and distribution.
>
> (2) Procedures for corrective and preventive action have not been established. (3) Sampling plans are not based on valid statistical rationale.
>
> (4) Quality system procedures and instructions have not been established.
>
> (5) A correction or removal, conducted to reduce a health risk posed by a device, was not reported in writing to FDA.
>
> (6) An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

[29] A partially redacted copy (obtained from the FDA) of the November 2015 West Campus FDA 483 hereto as "Ex. E."

(7) Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

(8) Records of complaint investigations do not include required information.

(9) Procedures to ensure equipment is routinely calibrated have not been established.

(10) Procedures have not been established to control product that does not conform to specified requirements.

(11) The design history file does not demonstrate that the design was developed following the requirement of 21 CFR 820.

(12) Procedures for design validation have not been established.[30]

129. On June 18, 2014, Legacy Zimmer responded to the FDA, noting various actions that the Company had implemented and planned to implement to remediate the observations. On August 29, 2014, Legacy Zimmer sent an update to the FDA detailing ZBH's remediation progress.[31] The FDA's observations and Legacy Zimmer's responses reflected that the issues with the West Campus would require substantial remediation.

130. The FDA returned to inspect the West Campus in the fall of 2015 and found that ZBH had failed to implement adequate corrective actions to address the observations identified in the prior Form 483 issued on May 28, 2014. Of the ten observations in the November 2015 West Campus FDA 483, nine were repeat observations from prior inspections, including seven repeat observations from the May 28, 2014, Form 483. Six of the observations were repeat observations from two or more prior inspections. The ten observations in the November 2015 West Campus FDA 483 included:

1) Sampling plans are not based on valid statistical rationale.

[30] The Form 483 indicated that Observations 1, 2, 5, 9, and 12 were repeat Observations from prior inspections.

[31] Defendant Dvorak and other senior executives received copies of this update.

> 2) Procedures for corrective and preventive action have not been adequately established.
>
> 3) Procedures have not been adequately established to control product that does not conform to specified requirements.
>
> 4) A process whose results cannot be fully verified by subsequent inspection and test has not been validated according to established procedures.
>
> 5) When test/measurement equipment was found to not meet accuracy and precision limits, inadequate action was taken to evaluate whether there was any adverse effect on the device's quality.
>
> 6) Device packaging and/or shipping containers are not designed and constructed to protect the device from alteration or damage during processing, storage, handling, and distribution.
>
> 7) Procedures for design validation have not been adequately established.
>
> 8) Design output was not documented before release.
>
> 9) Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established.
>
> 10) The written MDR procedure does not include an internal system which provides for a standardized review process/procedure for determining when an event meets the criteria for reporting.

131. The issues identified in the November 2015 West Campus FDA 483 were very serious. On December 21, 2015, the Company sent the FDA a 99 page response (including attachments), in which ZBH recognized the gravity of the repeat observations:

> ***We recognize and take seriously the significance of the observations in the FDA-483*** and are committed to taking all actions necessary to ensure that our systems are in compliance with FDA requirement, and that our products are safe and effective. As is described in our detailed response below, in addition to correcting the specific items listed in the FDA-483, ***we have taken and are continuing take actions to address systemic issues***.[32]

132. In the same letter, ZBH acknowledged that it understood the gravity of the fact

[32] Defendant Dvorak and Barney, along with other ZBH senior executives, were copied on the response.

that these issues came on the heels of another critical FDA inspection of the Legacy Zimmer facility in Puerto Rico. Specifically, the letter indicated, "As you may be aware, our Mercedita, Puerto Rico facility (Zimmer Manufacturing B.V. (ZMBV)) was inspected by FDA on October 28, 2015 to November 17, 2015, and we are working closely with ZMBV to coordinate our remediation efforts and to ensure that applicable corrective actions are consistently and systematically implemented across both facilities."[33]

133. Shortly thereafter, on February 12, 2016, ZBH sent the FDA a 70 page letter (the "February 12, 2016 Letter")[34] (including attachments) further updating the agency on ZBH's progress remediating the observations in the November 2015 West Campus FDA 483.[35] Both ZBH's initial 99 page response dated December 21, 2015, and the 70 page February 12, 2016 Letter reflected that remediating the "systemic issues" at the West Campus required substantial time and money. Included in each was a detailed "Planned Action Summary" providing a list "by target completion date, of all planned actions for all FDA 483 observations." The responses indicated that remediation efforts would require, among others, quality holds being placed on various products, as well as field actions to remove inventory from the field and to prevent the reoccurrence of complaints. ZBH also indicated that it (purportedly) had or would implement interim controls while it was investigating issues raised by the November 2015 West Campus

[33] This was not ZBH's only problem with facilities in Puerto Rico. During the Class Period, ZBH indicated that in September 2012, ZBH had received a warning letter from the FDA citing concerns relating to certain processes pertaining to products manufactured at its Ponce, Puerto Rico manufacturing facility, that ZBH had provided detailed information to the FDA "about corrective actions and will continue to work expeditiously to address the issues" cited by the FDA, and that the warning letters remained open with the FDA.

[34] A partially redacted copy of the February 12, 2016 Letter obtained from the FDA is attached hereto as "Ex. F."

[35] Defendant Dvorak and Barney, along with other ZBH senior executives, were copied on the response.

FDA 483, revise procedures, and work instructions which were found to be deficient, implement new procedures and train pertinent personnel. ZBH also indicated that it would be taking significant steps to remediate these issues throughout the first half of 2016 and beyond. According to the schedule, a number of actions were not targeted for completion until June and July 2016, with at least one action being targeted for completion in June 2017 and the target completion date for several other actions being reported as unknown at the time the February 2016 update was sent to the FDA.

134. Remediating the issues at the West Campus, which was Legacy Zimmer's primary facility, would obviously be a huge task and distraction for the Company in 2016 and difficult to accomplish without disrupting manufacturing and supply of key products produced at the facility.

135. In early 2016, ZBH was also dealing with the fallout from a problematic FDA inspection of a Legacy Zimmer facility in Montreal in January 2016. In connection therewith, on June 6, 2016, ZBH disclosed:

> ***On May 31, 2016, [ZBH] received a warning letter dated May 27, 2016 from the U.S. Food and Drug Administration (the "FDA") related to observed non-conformities with current good manufacturing practice requirements of the Quality System regulation at the Company's facility in Montreal, Quebec, Canada.***
>
> ***The FDA inspected the Company's Montreal facility in January 2016. The Montreal facility is the principal location of the Company's wholly-owned subsidiary, ORTHOsoft, Inc. (d/b/a Zimmer CAS). At the conclusion of the inspection, the FDA issued a Form 483, List of Inspectional Observations. The warning letter relates to the observations reflected in the Form 483.***
>
> ***
>
> Since the conclusion of the inspection, the Company has provided detailed responses to the FDA as to its corrective actions and will continue to work expeditiously to address the issues identified by the FDA. The Company takes these matters seriously and intends to respond fully and in a timely manner to the

> FDA's warning letter. The Company believes that the FDA's concerns set forth in the warning letter can be resolved without a material impact to the Company's financial results. The Company cannot, however, give any assurances that the FDA will be satisfied with its response to the warning letter or as to the expected date of the resolution of the matters included in the warning letter. Until the violations are corrected, the Company may be subject to additional regulatory action by the FDA.

136. By the start of the Class Period (*i.e.*, the next day on June 7, 2016), ZBH had its hands full trying to remediate QS deficiencies cited by the FDA at various facilities in a very short period of time. Because of this, ZBH knew that the Company was under the FDA's microscope.

137. In part because of the QS problems with the Legacy Zimmer ***West*** Campus, ZBH corporate management requested corporate audits of the Legacy Biomet ***North*** Campus in early 2016 "to evaluate the applicability of the lessons learned from the [Legacy] Zimmer Warsaw West Campus design control 483 observations."[36]

VII. SUMMARY OF THE ACTION

A. During The Class Period, ZBH And The Officer Defendants Declare That ZBH Reached An "Inflection Point" And That Organic Revenue Growth Will Return To And Exceed Market Level In The Second Half Of 2016

138. At the start of the Class Period, when announcing plans to buy LDR on June 7, 2016, ZBH confidently reaffirmed its revenue growth guidance for 2016. Given the difficulty of integrating another large company, analysts understandably asked whether there would be any risk to ZBH's ability to accelerate its organic revenue growth in the second half of 2016. Defendant Dvorak proclaimed that ZBH remained "highly confident and we are reiterating guidance for the year." Defendant Dvorak added, "I think you ought to interpret this announcement as being confident in the state of the integration, the progress that we've made on

[36] Ex. A (post-Class Period December 21, 2016 Letter).

the [Legacy] Biomet side."

139. The purported reacceleration of ZBH's organic revenue growth rate and the Officer Defendants' confidence pushed ZBH's stock price back to the record levels reached in early 2015. On June 13, 2016, the Private Equity Defendants took advantage and unloaded nearly $1.3 billion of their stock in the June 2016 Offering. In the offering the GSCP Entities sold all of their remaining ZBH common stock, and the TPG Entities and Defendant KKR Biomet sold half of their remaining holdings of ZBH common stock.

140. When ZBH reported its financial results for Q2'16 on July 28, 2016, the Company again delivered better than expected results and notably reported that organic revenue had grown by 2.7%. The 2.7% was incredibly strong in comparison to the 1.2% ZBH reported for Q1'16 and the approximately 1.6% consensus expectation among analysts for Q2'16.

141. On July 28, 2016, the Company also reiterated its organic revenue growth rate guidance for the second half of 2016 and even increased the bottom end of the range. A J.P. Morgan analyst report issued that day noted: "Management tightened the bottom end for organic sales and EPS guidance. Full year organic growth pro forma for Biomet, ***the metric most investors are focused on for ZBH***, is now expected to increase 2.5-3.0%, up from previous guidance for +2.0-3.0%."

142. During a July 28, 2016, conference call to discuss the Company's Q2'16 financial results, Defendant Dvorak declared that ZBH had reached "an important inflection point:"

> Our Company has reached ***an important inflection point, having successfully reestablished top-line momentum by beginning to capture the promise of the attractive cross-selling opportunities inherent in our merger***, in addition to successfully delivering on our synergy commitments.
>
> ***
>
> Consistent with this progress, ***Zimmer Biomet generated solid revenue***

> ***acceleration in the second quarter, again above the top end of our expectations, further validating our strategies to achieve above-market revenue growth by the close of 2016.*** Our steady advance towards this goal demonstrates the increasing productivity and focused execution of our commercial organization and for the balance of the year, will continue to exploit the opportunities presented by our differentiated musculoskeletal portfolio.

143. With the Company's stock at all-time highs, on August 9, 2016, the TPG Defendants and Defendant KKR Biomet sold their remaining holdings of ZBH stock in the August 2016 Offering for proceeds of nearly $1 billion.

144. In September 2016, the final month of Q3'16, ZBH and Defendants Dvorak, Florin and Marshall exuded confidence in ZBH's ability to continue accelerating revenue growth in the second half of 2016 and into 2017. For example, at an analyst conference on September 12, 2016, Defendant Florin stated, "[W]e are confident we're going to get back to at or above market growth rate as we exit this year."

145. On September 14, 2016 (approximately two and a half weeks prior to the end of Q3'16), RBC Capital Markets issued an analyst report entitled, "Management Remains Confident in Sales Acceleration and Synergy Targets." As noted in the report, RBC had "hosted a non-deal roadshow with ZBH's senior management team, including [Defendant] Dvorak, [Defendant] Florin, and [Defendant] Marshall" and the takeaway from the meeting was that "Management remains confident that revenues will accelerate in 2H16 and into 2017 while Biomet cost savings will drive double-digit EPS growth." Specifically, the report noted:

> . . . Management had an opportunity to address several "Hot Topics" impacting the company and the industry. Below are our takeaways from the road show. ***Overall, we came away confident in the company's outlook and we reiterate our Outperform rating. ZBH remains our favorite idea for value investors.***
>
> ***Hot Topic No. 1: 2016 guidance***
>
> ***Organic top-line growth should continue accelerating in 2H16, and management is confident that it will exit 2016 at or above market growth rates***

> ***Recall that on the company's 2Q16 earnings call, management raised 2016 revenue guidance by $135M at the midpoint to $7.68B to $7.715B. This now represents a 3.0–3.5% growth rate on an adjusted proforma constant currency basis, with stronger growth expected in 2017.*** ZBH management's current 2016 revenue guidance assumes constant currency day-rate growth of 2.5–3.5% y/y in 3Q16 and 3.5–4.5% in 4Q16, pointing to expectations for a continued acceleration in top-line organic growth in 2H16. Recall that ZBH grew its top line organically on a same-day selling basis by 2.5% in 2Q16, 1.2% in 1Q16, and 0.5% in 4Q15 . . . ***and we expect ZBH's top-line momentum to continue into 2H16 as the company returns to more market rates of growth (defined as growth in the ~3–4% range). Additionally, management emphasized that its forecast for sales acceleration in 2016 will be led by cross-selling,*** while 2017 growth will be led by 2016 pipeline launches . . . ***We sense that management remains very comfortable with sales and EPS guidance***.

146. Similarly, on September 29, 2016 (the second to last day of Q3'16), Piper Jaffray issued an analyst report entitled, "Travel with Mgmt; Pathway to 4%+ Top-Line & 10% EPS Growth Seems Reasonable." Therein the analyst report noted:

> Yesterday, we hosted investor meetings with the company's CEO, CFO, and VP of Treasury and IR. ***We would characterize the meetings as quite positive and are comfortable that ZBH is on the path to meeting its stated goal of 4% plus top-line growth going forward, driven by steady performance in a number of businesses (large joints)*** and share gains in trauma and spine …
>
> ***
>
> Yesterday, we hosted investor meetings with Zimmer-Biomet's CEO [Defendant] Dvorak, CFO [Defendant] Florin, and VP of Treasury and IR [Defendant] Marshall. ***Given how late it is in the quarter, the meetings were entirely focused on the future of the company and its ability to reach its stated goals of 4% plus top-line growth in the coming years, which would be slightly ahead of overall market growth rates in the categories where it participates.***

147. When ZBH's fiscal third quarter (*i.e.*, Q3'16) closed on September 30, 2016, there was little for investors and analysts to be concerned about given the confidence ZBH management had displayed in September 2016, which echoed the positive statements ZBH had made between June and August 2016.

B. The Truth Begins To Emerge When ZBH's Q3'16 Results Blindside Investors

148. Beginning on October 31, 2016, and again on November 8, 2016, the true facts concerning the prior misrepresentations and omissions during the Class Period were partially revealed and/or concealed risks materialized.

149. The true facts that were partially revealed through the combined disclosures, included, *inter alia*: (i) that ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016; (ii) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming, and costly remediation and corrective activities; (iii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iv) that an FDA inspection of the Legacy Biomet North Campus was imminent; and (v) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus.

150. The revelations also included the following materializations of the risks, among others, that had been concealed from investors – a sharp deceleration of organic revenue growth in Q3'16 and lowered Q4'16 organic revenue growth guidance as a result of supply shortages caused by disruptions due to an FDA inspection of the North Campus and remediation work being undertaken to address "systemic issues" with the QS at the North Campus. It was foreseeable that by continuing to manufacture, package, and distribute products from the North Campus – while aware that "systemic issues" with the QS had not been meaningfully remediated and that an FDA inspection of the facility was imminent – ZBH would be unable to meet the demand for its products and ultimately experience a disruption to the production and supply of key products as a result of the need to undertake significant remediation and corrective actions.

1. The October 31, 2016, Materializations Of Concealed Risks

151. On October 31, 2016, ZBH announced its financial results for Q3'16 (which ended on September 30, 2016). As described by a Suntrust analyst, the Company "blindsided investors" by reporting that organic sales growth declined to 1.6% and lowering its organic revenue guidance for the fourth quarter and full year 2016 to reflect no improvement in 2016. ZBH lowered its full-year adjusted pro forma growth outlook from 2.5-3.0% to 1.65-1.90%.

152. Defendants' disclosures on October 31, 2016, about ZBH's decelerated Q3'16 revenue growth rate, its lowered organic revenue growth rate guidance for Q4'16, and the existence of supply shortages, were partial materializations of the risks concealed during the Class Period about, *inter alia*, ZBH's inability to accelerate revenue growth in the second half of 2016, the "systemic issues" with the QS at the North Campus, and ZBH's inability to meet demand for its products (while remediating the QS with the QS at the North Campus).

153. During an October 31, 2016, conference call to discuss the Q3'16 financial results, Defendant Dvorak claimed that the issue with the Company's Q3'16 performance and lowered guidance for Q4'16 related, in part, to "unanticipated supply constraints, related to our transitioning supply chain infrastructure" and also partially related to efforts to "harmonize and optimize [ZBH's] sourcing, manufacturing and quality management systems:"

> ***Variable commercial performances by our sales teams were in part caused by unanticipated supply constraints, related to our transitioning supply chain infrastructure. This resulted in shortfalls of needed implants and additional instrument sets, to fully exploit sales opportunities in key product categories.***
>
> In response to this challenge, we've accelerated work to enhance certain aspects of our supply chain infrastructure as we harmonize and optimize our sourcing, manufacturing and quality management systems. Through these efforts, we expect to improve our demand fulfillment in the coming months.
>
> ***As a consequence of these supply constraints, we project fourth quarter sales results to be similar to those of the third quarter*** …

154. On this news, shares of ZBH fell $17.15 per share, or nearly 14%, to close on October 31, 2016, at $105.40 per share. The disclosure wiped out approximately $3.4 billion of market capitalization in a single day.

155. The October 31, 2016, disclosures did not fully disclose the truth about the prior misrepresentations and omissions during the Class Period. Additionally, the October 31, 2016, disclosures were themselves materially misleading because the disclosures omitted, *inter alia*: (i) that the true cause of the supply shortages in Q3'16 and lowered Q4'16 organic revenue guidance was the disruption being caused by a disastrous ongoing FDA inspection of the North Campus; (ii) that there were "systemic issues" with the QS at the North Campus; and (iii) that ZBH lacked the ability to meet demand for its products while remediating the issues at the North Campus.

2. The November 8, 2016, Partial Corrective Disclosure

156. On November 8, 2016, a securities analyst at Northcoast Research issued the November NCR Report, entitled, "Downgrading to Neutral." The November NCR Report further partially revealed the QS issues with the North Campus, the true cause of the supply shortages, and the true reasons behind the Q3'16 results and lowered Q4'16 guidance. The report, in relevant part, stated:

> • ***We are downgrading ZBH from Buy to Neutral. Based on our recent conversations with industry contacts, we believe at least part of the reason for the unanticipated product supply issues discussed during ZBH's 3Q16 earnings call is related to manufacturing problems at Biomet's Warsaw, Indiana, operations. While we do not know the extent of the problem, we are now concerned ZBH's unanticipated product supply issues involve more than just long lead times from Persona knee instrument suppliers and the need to integrate supply systems for Zimmer and Biomet.***
>
> • ***According to our industry contacts, the FDA inspected Biomet's Warsaw manufacturing operations over a roughly six-week period recently as part of a***

routine review. Following the FDA inspection, we have heard some Biomet product lines manufactured in Warsaw have been shut down from operations and cannot be shipped to the field. We believe this could be at least part of the explanation for ZBH's unanticipated product supply issues for certain Biomet hip implants. By contrast, we note ZBH claims its product supply issue in knee implants primarily reflects lead times for Persona knee instrumentation. ***When we contacted ZBH, the company would not comment directly about the recent FDA inspection of Biomet's Warsaw manufacturing operations and whether it resulted in the inability to ship certain product lines to the field.*** All the company would say is that its unanticipated product supply issues have more to do with lead times for Persona knee instruments.

• ***According to our contacts, Robin Barney (ZBH's Senior Vice President, Global Operations and Logistics) resigned from the company on November 1. We have also heard several other senior-level employees in ZBH's quality and regulatory department were let go by the company recently. We believe the recent FDA inspection at Biomet's Warsaw manufacturing operations could be at least partially responsible for this turnover.***

• We worry potential remediation activities at Biomet's Warsaw manufacturing operations could delay the timing of new product launches in the company's hip and knee implant business. While we are encouraged by improving momentum in ZBH's S.E.T. business as well as in what further new product innovation and the expansion of specialty sales forces could mean for this division, we worry it could be overshadowed by increased concerns about how long it will take to return hips and knees to market growth levels.

Conclusion

We were initially willing to give ZBH the benefit of the doubt regarding its explanation behind unanticipated product supply issues on its 3Q16 earnings call. However, following our conversations with industry contacts, we are concerned there is more to the story. Moreover, we worry future acknowledgement of manufacturing issues at Biomet's Warsaw operations (either by the company or in FDA Form 483 observations) could lead to additional investor concern and limit upside potential for the stock. Given these concerns, we are downgrading ZBH to Neutral.

157. Also on November 8, 2016, the Company filed its Quarterly Report on Form 10-Q with the SEC for Q3'16. Therein, the Company admitted that the deceleration of revenue growth in Q3'16 had been, at least in part, caused by "operational process enhancements that have resulted in various shipment delays," *i.e.*, the issues with the North Campus:

> In 2016, we have continued to make progress in our commercial and operational integration of Biomet and other acquisitions across all geographies and functions. ***Despite this progress, revenues in the three month period ended September 30, 2016 were below our expectations due in part to some temporary disruption in product supply in certain Knee, Hip, Upper Extremities and Sports Medicine product lines related to several factors, including implementation of operational process enhancements that have resulted in various shipment delays***, and manufacturing forecasting constraints related to continued integration of our supply chain. . . .

158. In response to the November NCR Report, that same day the Company issued a statement entitled, "Zimmer Biomet Responsive Statement on Product Supply Matters." Therein the Company stated:

> As was discussed in detail on the Company's third quarter earnings conference call on October 31, 2016, in the third quarter and continuing into the fourth quarter, Zimmer Biomet has seen increased demand for certain products, particularly related to cross-selling various offerings across the combined Zimmer Biomet portfolio. The increased demand has impacted the Company's ability to effectively respond to this shifting product mix. The Company is in the process of deploying new demand planning and production planning tools. Upon full implementation, these integrated tools will better ensure the Company's ability to forecast and satisfy product demand in the future.
>
> ***In addition, as discussed on the third quarter earnings conference call, the Company has also accelerated work to enhance certain aspects of its supply chain infrastructure as it harmonizes and optimizes its sourcing, manufacturing and quality management systems. While these ongoing efforts have in instances led to certain product shipment delays, including product manufactured at the legacy Biomet operation in Warsaw, Indiana, the Company is making excellent progress in addressing the issues and many of the shipment delays are already resolved and the impacted product has been released for commercial distribution. The Company expects to return to full shipping capacity with the impacted products over the next few weeks.***
>
> Importantly, the above-described voluntary actions have not been prompted by any identified concern over patient safety or risk associated with any Zimmer Biomet product. The Company has not issued a recall of any of the products impacted by these voluntary operational enhancement actions.
>
> ***On October 31, 2016, the Company issued updated sales and earnings guidance for full-year 2016, including specific guidance for the fourth quarter. It is important to note that the anticipated full impact of the various supply chain issues and the related harmonization and optimization of sourcing,***

manufacturing and quality management systems mentioned above is already included in the Company's sales and earnings guidance update from October 31, 2016.

159. The November NCR Report and ZBH's disclosures on November 8, 2016, partially revealed, *inter alia*: (i) that the true cause of the supply shortages in Q3'16 was the disruption being caused by a disastrous FDA inspection of the North Campus; (ii) that there were regulatory deficiencies with the QS at the North Campus; and (iii) that ZBH lacked the ability to meet demand for its products while remediating the regulatory deficiencies at the North Campus.

160. On this news, shares of ZBH fell another $2.62 per share, or 2.51%, to close on November 8, 2016 at $101.83 per share. The disclosures wiped out approximately $500 million of market capitalization in a single day.

C. A Disastrous FDA Inspection Of The North Campus In The Fall of 2016 Identifies Grave "Systemic" QS Issues Requiring Substantial Remediation And Causing Severe Supply Shortages in Q3'16 And Q4'16

161. Three FDA investigators arrived and commenced an inspection of the North Campus on September 12, 2016 (the "September 2016 North Campus Inspection"). That morning, at approximately 9:27 a.m., the investigators issued an FDA Form 482 to Barney at the start of the inspection.[37]

162. The FDA inspection of the North Campus was a disaster from the start.[38] As detailed herein, the inspection resulted in immediate disruptions to production and distribution at the facility, which negatively impacted the Company's supply of products. For example,

[37] Plaintiffs are informed and believe that, based on the FDA's customary practice, an FDA inspector informed Barney or another senior ZBH executive at least five days beforehand that an inspection of the North Campus would commence on September 12, 2016.

[38] In the December 21, 2016 Letter (Ex. A), ZBH conceded that it was aware early in the inspection that the severity of the issues being cited by the FDA meant that the Company was going to receive an Form 483: "Rather than wait for the issuance of the FDA 483 to plan and take action, we immediately took steps to correct and improve various aspects of the North Campus quality management system."

subsequent correspondence between the Company and the FDA reflected[39] substantial disruptions to operations at the North Campus immediately following the start of the inspection:

Date	Description
September 12, 2016	Contained non-conforming sterile load #08296-C.
September 14, 2016	Confirmed all products from [REDACTED] remained in quarantine status.
September 20, 2016	Quality Hold 16-050 was implemented for all in-house finished [REDACTED] Sports Medicine products that were sterilized by the [REDACTED] after a biological indicator displayed microbial growth following [REDACTED] sterilization.
September 20, 2016	Quality Hold 16-052 was initiated on finished products [REDACTED].
September 21, 2016	Halted cleaning operations at work centers associated with the inadequate cleaning validation [REDACTED]
September 22, 2016	Quality Hold 16-055-01 was implemented for [REDACTED] Cleaning and placed all in-process [REDACTED] material in quarantine [REDACTED].
September 27, 2016	Quality Hold 16-059-01 was implemented.
September 28, 2016	Quality Hold 16-061 was initiated and Item [REDACTED] was placed into containment as a result of a non-conformance observation.

163. By September 29, 2016, the FDA inspection was going so poorly that ZBH was forced to implement a "Product ship hold … to stop shipments of ***all final product cleaned, sterile packed, and sterilized at the Warsaw North Campus***."[40] For example, subsequent correspondence between the Company and the FDA provided details[41] about additional disruptions to North Campus operations on September 29, 2016:

[39] This information in the below chart is derived from the July 31, 2017 Letter (Ex. B). The redacted text reflects redactions in the copy of the document Plaintiffs obtained from the FDA.

[40] Ex. A (post-Class Period December 21, 2016 Letter).

[41] This information in the below chart is derived from the July 31, 2017 Letter (Ex. B). The redacted text reflects redactions in the copy of the document Plaintiffs obtained from the FDA.

Date	Description
September 29, 2016	Quality Hold QH 16-064 was initiated for finished products in inventory at distribution centers and processed through Warsaw North cleanrooms to contain all work orders that did not have process monitoring and testing completed.
September 29, 2016	Temporarily stopped all sealers used for manufacturing operations in productions.
September 29, 2016	All cleaning operations at the North Campus were halted until the implementation of Interim Control IC-004 on October 20, 2016.
September 29, 2016	Quality Hold 16-068 was implemented to contain WIP passing through gowning areas or work environments at the North Campus.

164. The Company's Q3'16 results were devastated by the supply shortages being caused by the various quality holds and other actions being taken since the inspection started.

165. The FDA inspection continued into Q4'16 and throughout the month of October. Severe supply disruptions also continued throughout October 2016, and had a negative impact on the Company's performance in Q4'16. For example, subsequent correspondence[42] between the Company and the FDA revealed that ZBH was taking a large number of disruptive actions at the North Campus in October 2016 while the FDA inspection was continuing:

Date	Description
October 2, 2016	Suspended production of [REDACTED] product and quarantined and held all [REDACTED] product in WIP inventory with appropriate NCR documentation, and subjected [REDACTED] product in finished goods inventory at the Warsaw North Campus to Quality Hold 16-067.
October 7, 2016	Sports medicine and microfixation devices made with [REDACTED] placed on quality hold 16-068 were subjected to retrospective testing.
October 11, 2016	Cleaning operations were halted at the work centers associated with the inadequate cleaning validation.
October 12, 2016	Quality Hold QH 16-068 was implemented for all WIP processed through Warsaw North cleanrooms. It was implemented to contain the knee femoral implant products

[42] The information in the below chart was derived from the July 31, 2017 Letter (Ex. B). The redacted text reflects redactions in the copy of the document Plaintiffs received from the FDA.

	impacted by the cleaning validation issues identified during inspections.
October 12, 2016	Subjected [REDACTED] devices placed on quality hold to retrospective testing.
October 12, 2016	Suspended all [REDACTED] production.
October 13, 2016	Halted preparation of [REDACTED] bar manufacturing at Zimmer Biomet, and hence preparation [REDACTED].
October 13, 2016	Cleaning operations were halted at [REDACTED] or [REDACTED] for final cleanings.
October 14, 2016	Halted preparation of [REDACTED] while an interim control could be implemented.
October 16, 2016	Knee femoral implant products impacted by the quality hold were subjected to retrospective testing and found to be conforming and were released.
October 16, 2016	QH 16-068 was implemented to contain WIP that had been packaged using one of the cleanroom sealers.
October 19, 2016	UHMWPE devices placed on Quality Hold 16-068-01 were subjected to retrospective testing.
October 19, 2016	Requalified the [REDACTED] cleanroom.
October 20, 2016	Quality Hold QH 16-071 was implemented for WIP originally listed on Sterilization Hold 16-068 to prevent shipment of product while investigation for end of line processing was completed.
October 20, 2016	Production of manual cleaning process for UHMWPE devices was restarted.
October 21, 2016	Quality Hold 16-074 was implemented for lots processed on sealers [REDACTED] between August 18, 2016 and October 5, 2016.
October 24, 2016	Subjected [REDACTED] devices placed on quality hold to retrospective testing and, based on the testing, released them from the hold.
October 24, 2016 - December 2, 2016	Metal hip, extremities, knee, and trauma devices placed on Quality Hold 16-068-01 were subjected to retrospective testing.
October 29, 2016	Knee femoral implant products placed on quality hold were subjected to retrospective testing under [redacted] and found to be conforming and were released.
October 30, 2016	Requalified the [REDACTED] cleanroom.

166. At the conclusion of the inspection on November 22, 2016, FDA investigators issued the November 2016 North Campus FDA 483 to David J. Kunz, ZBH's SVP, Global Quality Assurance and Clinical Affairs. The 57 page FDA 483 included an extensive and

detailed list of 14 observations, at least two of which were repeat observations from a prior inspection of that facility that had occurred between June 16 and 30, 2014. During a closing meeting on November 22, 2016, the investigators also raised an extensive list of at least 15 discussion points relating to the inspection of the North Campus.

167. The 57 page November 2016 North Campus FDA 483 contained the following 14 observations:

> (1) A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures;
>
> (2) Procedures to control environmental conditions have not been adequately established;
>
> (3) Procedures have not been adequately established to control product that does not conform to specified requirements;
>
> (4) Procedures for design control have not been established;
>
> (5) Procedures for corrective and preventative action have not been adequately established;
>
> (6) Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been adequately established;
>
> (7) Procedures for monitoring and control of process parameters for a validated process have not been adequately established;
>
> (8) Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established;
>
> (9) Procedures for acceptance activities have not been adequately established;
>
> (10) Buildings are not of suitable design to perform necessary operations;
>
> (11) Sampling plans are not based on valid statistical rationale;
>
> (12) Procedures for rework of nonconforming product have not been adequately established;

> (13) Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established; and
>
> (14) Document control procedures have not been adequately established.

168. The size and scope of the November 2016 North Campus FDA 483 demonstrated the severity of the FDA's concerns. For example, Observation 1, which was a repeat observation from a prior June 30, 2014 inspection, ***contained 9 categories of process violations and was 21 pages long***. Many of the observations in the November 2016 North Campus FDA 483 related to safety, addressing sterilization issues and noted that various processes were not properly validated by those responsible for overseeing the processes. Also, the November 2016 North Campus FDA 483 evidenced that the September 2016 North Campus Inspection had impacted several of the Company's most important devices and products.[43]

169. The November 2016 North Campus FDA 483 was so severe that ZBH had to request a special extension to file its response "[b]ased on the extent of the FDA-483 observations." ZBH later responded to the FDA in the December 21, 2016 Letter (Ex. A). Also, ZBH provided detailed responses to each observation in the November 2016 North Campus FDA 483 and to each of the 15 discussion points raised by the FDA investigators at the conclusion of the inspection.

170. The December 21, 2016 Letter admitted, in detail, that the quality issues at the

[43] The devices that were impacted, included, metal hip, extremities, knee, trauma, microfixation, and sports medicine devices. The products impacted by the observations included, among others, Vanguard knees, Oxford knees, Taperloc hips, Arcos hips, Echo Hips, Comprehensive Primary Mini Shoulder Stem, and devices made of ultra-high molecular-weight polyethylene (UHMWPE). For example: Observation 4 noted design issues with Vanguard, one of the Company's key product lines; Observation 7, a repeat observation from the June 16, 2014 to June 30, 2014 inspections, noted that the Company had a six month backlog of samples requiring testing, impacting the Oxford knee, one of the Company's key products; Observation 8 also impacted the Oxford knee; and Observation 9 impacted both hip and comprehensive shoulder products.

North Campus, (i) had existed prior to and throughout the Class Period and (ii) were "systemic issues." For example, ZBH indicated that "in addition to correcting the specific items listed in the FDA-483, we have taken and are continuing to take actions to address systemic issues" and that remediation programs had been established to address the "systemic issues."

171. ZBH continued to provide the FDA with "updates" regarding the Company's progress with substantial and sweeping remedial and corrective actions. This included update letters dated February 17, 2017, April 25, 2017, and the July 31, 2017 Letter (Ex. B).

D. By The Start Of The Class Period In June 2016, ZBH And The Officer Defendants Knew That An FDA Inspection Of The North Campus Was Imminent, Knew About The Precise "Systemic" QS Issues Cited By The FDA Inspectors In The November 2016 North Campus FDA 483, And Knew That ZBH Was Not Taking Prompt And Meaningful Steps To Fully Remediate The QS Issues

172. The "systemic issues" identified by the FDA during the September 2016 North Campus Inspection, as well as the scope of the remediation and corrective actions that were necessary to fully address the issues, had been known by ZBH and the Officer Defendants at all times during the Class Period.

173. This was disastrous because ZBH and the Officer Defendants also knew that an inspection of the North Campus was imminent and that it was effectively impossible for ZBH to remediate the extensive QS deficiencies at the North Campus prior to the FDA inspection without completely shutting down the North Campus. Despite knowing these issues, ZBH and ZBH corporate management did not take prompt or meaningful actions to fully remediate or address the QS deficiencies.

1. ZBH Knew At The Start Of The Class Period That An Inspection Of The North Campus Was Imminent Because The North Campus Was Due For Its Mandated Biennial Inspection

174. As set forth in detail above in Section VI.B, because the North Campus

manufactured Class II and Class III medical devices, the North Campus was subject to biennial inspections.

175. Prior to the Class Period, the FDA had conducted an inspection of the North Campus between June 16, 2014 and June 30, 2014 (the "June 2014 North Campus Inspection"). As a result, ZBH and the Officer Defendants (who were seasoned veterans of the medical device industry) were well aware that an inspection of the North Campus was to occur around June 30, 2016, or soon thereafter.

176. At the conclusion of the June 2014 North Campus Inspection, the FDA inspectors had issued an FDA 483 to then Legacy Biomet (the "June 2014 North Campus FDA 483"). ZBH and the Individual Defendants also knew that the FDA would conduct a follow up inspection to ensure that ZBH had taken adequate responsive actions to address the prior observations from the June 2014 North Campus FDA 483. ZBH had not taken sufficient actions to address at least two observations from the prior June 2014 North Campus FDA 483.

177. ZBH and the Officer Defendants also knew that a follow inspection of the North Campus would be a high priority for the FDA because of, among others: (i) the high-profile Merger between two massive medical device manufacturers; (ii) the fact that ZBH was manufacturing Class II and Class III devices at the North Campus; and (iii) the extensive quality issues that had not been corrected at the Legacy Zimmer West Campus and quality issues at facilities in Puerto Rico and Montreal.

2. ZBH "Corporate Management" Had Already Known About The Precise "Systemic" QS Issues At The North Campus Because Of Corporate Audit Reports Issued On March 31, April 13, And June 7, 2016

178. In the December 21, 2016 Letter, ZBH candidly admitted that the issues identified in the November 2016 North Campus FDA 483 had not been a surprise to ZBH corporate

management. Rather, ZBH admitted that it had known about the precise issues and their magnitude since the Spring of 2016.

179. Specifically, in the December 21, 2016 Letter, ZBH admitted that its "corporate management" ***knew*** of these "systemic issues" because of corporate audits conducted after the Merger. ZBH admitted that "[u]ntil the Zimmer Biomet merger on June 24, 2015, North Campus had been operating independently and with indications that its quality system was in substantial compliance," but "[o]nce the merger was completed, ***the new Zimmer Biomet corporate management team conducted audits, learned of issues through the audits***, and promptly initiated corrective actions."

180. ZBH admitted that the "systemic issues" corporate management became aware of included: "***self-identified major compliance-related issues*** in areas such as design controls, sterile packaging, complaint handling, nonconforming material, and CAPAs." This list of issues effectively mirrored the issues cited by the FDA in the November 2016 North Campus FDA 483.

181. ZBH also admitted that these "systemic issues" were substantially the same issues as the issues identified by the FDA during the September 2016 North Campus Inspection:

> After the merger was closed, Zimmer Biomet Corporate directed corporate quality audits to be performed at the North Campus in the first half of 2016. ***These audits self-identified major compliance-related issues in areas such as design controls, sterile packaging, complaint handling, nonconforming material, and CAPAs.*** A remediation program with approved[44] funding [redacted] was established in July 2016 to address the systemic issues at the North Campus. ***This program self-identified CAPAs related to 7 of the 483 observations and 6 of the discussion points prior to the start of the inspection***. At the start of the FDA inspection, the remediation program was in the initial phase of execution. Remediation efforts were accelerated as additional issues were identified by FDA

[44] The information in the letter was redacted by the FDA's freedom of information staff. Based on partially un-redacted information on page 3 of that letter ("Remediation funding for the North Campus of [redacted] was approved in [redacted] by the CEO"), Plaintiffs are informed and believe that the July 2016 funding was approved directly by the Company's CEO, Defendant Dvorak.

> during the inspection. Rather than wait for the issuance of the FDA 483 to plan and take action, we immediately took steps to correct and improve various aspects of the North Campus quality management system. Immediate containment and investigation actions to date included the initiation of [redacted] product holds, [redacted] health hazard safety evaluations, and [redacted] interim control documents. [Redacted] were greatly expanded and will be covered under a master CAPA program called [redacted], discussed in Section 4.0 below.

182. The December 21, 2016 Letter also provided specific details about the dates and findings of the three North Campus corporate audit reports in the first half of 2016. These audits included: (i) a "Corporate Complaints Process Audit" that resulted in a report being issued on March 31, 2016, which identified "6 major and 2 minor observations"; (ii) a "Corporate Design Controls Audit" that resulted in a report being issued on April 13, 2016, which identified "4 critical and 15 major observations"; and (iii) a "Corporate General QMS[45] Audit" that resulted in a report being issued on June 7, 2016, which identified "15 major and 5 minor observations."

183. Additionally, the December 21, 2016 Letter admitted in multiple instances that there was a fundamental issue with the "quality culture" at the North Campus. ZBH also purportedly took the drastic measure of implementing major top level management changes at the North Campus to "address the Quality Management System performance issues noted at the Warsaw North Campus, along with the underlying quality culture issues now identified."

184. ZBH claimed to the FDA that it had made management changes in the following positions to address Quality Management System issues at the North Campus, along with underlying quality issues: (i) SVP of Global Operations and Logistics Team;[46] (ii) Vice President of Quality Assurance responsible for the Warsaw sites; (iii) Quality Assurance Director

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[45] QMS is an abbreviation for Quality Management System.

[46] As detailed below in Section VII.E, this was the position held by Barney. In the December 21, 2016 Letter, ZBH did not disclose to the FDA that, according to Barney, Barney had resigned from the Company following a request from Defendant Florin to concoct a story to mislead ZBH investors about the cause of the sales shortfall in Q3'16..

responsible for the North Campus; (iv) Compliance Director responsible for the Biomet Network; and (v) Quality Assurance Director responsible for the Warsaw Post Market Surveillance (PMS) and Complaint Handling Group.

185. ZBH admitted that it was not until July 2016 that "[a] remediation program with approved funding [redacted] was established … to address the systemic issues." On the next page of the December 21, 2016 Letter, ZBH also indicated, "Remediation funding for the North Campus of [redacted] was approved in [redacted] by the CEO." Based on the information in both sentences, Plaintiffs are informed and believe that the redacted language indicates that the July 2016 funding was approved directly by Defendant Dvorak, the Company's then CEO.

186. ZBH also made a stunning concession in the December 21, 2016 Letter that the Company knew at the start of the inspection that the issuance of a serious FDA 483 was both a foregone conclusion and the best case scenario for the Company:

> ***Rather than wait for the issuance of the FDA 483 to plan and take action, we immediately took steps to correct and improve various aspects of the North Campus quality management system.*** Immediate containment and investigation actions to date included the initiation of [redacted] product holds, [redacted] health hazard safety evaluations, and [redacted] interim control documents.

187. Among the "[i]mmediate [a]ctions taken during the Inspection to address FDA Observations," ZBH admited that ***on Sepember 29, 2016 (the second to last day of Q3'16)***, ZBH undertook the drastic and severe measure of implementing a major product hold of all products cleaned and packed at the facility:

> ***Product ship hold (16-064) was issued on September 29, 2016 to stop shipments of all final product cleaned, sterile packed, and sterilized at the Warsaw North Campus.*** After investigations were completed and documented justifications were prepared and approved, initial product ship hold releases under interim controls first began on October 21 , 2016. Product holds were released only after detailed justifications were documented to address product safety and effectiveness using the enhanced hold process implemented during the inspection.

3. Contrary To ZBH's Assertions, ZBH Did Not Take Prompt Remedial Actions To Address The "Systemic Issues" That ZBH Corporate Management Had Learned Of In The Spring Of 2016

188. While in the December 21, 2016 Letter, ZBH self-servingly claimed to have "promptly" taken corrective action upon learning of the "systemic issues," it is clear that ZBH did not promptly take corrective action. For example, although the issues were raised by corporate audit reports issued on March 31, April 13, and June 7, 2016, ZBH (purportedly) did not establish a comprehensive remediation program until sometime in July 2016 to address the systemic issues. Moreover, ZBH admits that this program was only "in the initial phase of execution" when the FDA inspection commenced on September 12, 2016. All the while, ZBH nevertheless continued to manufacture, sterile pack and distribute products from the facility in the Spring and Summer of 2016 without addressing these issues (*e.g.*, the issues were identified in the Spring of 2016 but remediation was only in the "initial phase" by September). ZBH admitted that "[r]emediation efforts were accelerated as additional issues were identified by FDA during the inspection."

189. The discussion points raised by the FDA at the conclusion of the inspection on November 22, 2016, contradict ZBH's assertion that the Company took prompt action upon learning of the "systemic" issues. Discussion point Number 15 appears to relate to ZBH's failure to timely issue CAPAs resulting from certain findings in the corporate audit reports:[47]

> The Investigators made two points regarding internal audits. First, ***they noted that Zimmer Biomet should be timely in*** concluding internal audits and ***initiating corrective actions***. Second, the Investigators stated that Zimmer Biomet should be certain to follow the procedures in CP1700 "Internal Audit Program."

190. ZBH's failure to take "prompt" action is magnified by the fact that when the

[47] ZBH's response notes that on October 20, 2016 (*i.e.*, during the September 2016 FDA Inspection), ZBH ironically "initiated CAPA CA-02976 to investigate the lack of timely issuance of CAPAs resulting from the audit report from a March, 2016 Design Control Audit . . ."

Corporate General QMS Audit report was issued on June 7, 2016, ZBH corporate management knew that an FDA inspection of the North Campus was imminent (as discussed above).

191. Given the amount of time[48] and the $300 million that was necessary to remediate the "systemic" regulatory and quality deficiencies at the North Campus between September 2016 and 2017 (as well as the substantial impact on its manufacturing operations and the substantial supply shortages in the second half of 2016 and first half of 2017), if ZBH had taken prompt action to fully address the systemic issues in June 2016, it would have effectively required a complete shutdown of the facility and had a grave impact on ZBH's financial performance.

192. As alleged in more detail below, CW1 said that ZBH was waiting until November 2016 to convert to Legacy Zimmer policies and procedures over a six to eight month process but after the FDA inspection commenced, the poly bearing clean room was completely shut down and production was mostly shut down for approximately six weeks to conduct this conversion. CW1 also said that new procedures were put in place that included more documentation than the Legacy Biomet procedures and that it took longer to produce because of the paperwork. CW1 said that the additional processes (documentation) cut production by one-third.

4. Former ZBH Employees Confirm That ZBH Waited Until The September 2016 North Campus Inspection To Take Serious Remedial Actions, Which Devastated The Output At The North Campus

193. CW1, a Production Supervisor of the poly bearing department at the North Campus, explained that his department manufactured the poly bearings for Biomet devices. According to CW1, poly bearings are used for hip, knee and shoulder devices and poly bearings are both incorporated into devices but also separate devices. CW1 also explained that the

[48] For example, a Wells Fargo analyst indicated that their FDA consultant had reviewed the November 2016 North Campus FDA 483 and "believe[d] it will take ZBH at least a year to address all the issues" cited by the FDA in the 14 observations. *See* ¶243.

production area included a manufacturing area, as well as a "clean room" where products were sterilized and packaged.

194. CW1 indicated that ZBH knew from the "get go" (*i.e.*, the time of the merger) that the two companies employed different policies and procedures in the clean room as well as manufacturing. CW1 said the plan from the beginning was to convert Biomet to Zimmer policies and procedures. CW1 indicated that the plan was to begin this ***approximately six to eight month process in November 2016***. CW1 explained that the plan to convert [the North Campus] to [Legacy] Zimmer procedures changed soon after the FDA started its inspection.

195. CW1 recalled that the FDA inspection began in the Sports Medicine department and then the FDA began looking at poly because it shared some area with Sports Medicine. CW1 noted that the FDA inspection was primarily focused on the cleaning area but also included the manufacturing area.

196. CW1 said the FDA inspection "devastated" his department, which was almost completely shut down for six weeks beginning at the end of September 2016, though CW1 could not be specific about the date.

197. Though CW1 was not involved in communications with the FDA nor privy to the specifics of the decision, CW1 understood that ZBH executives actually made the decision to shut down production in the poly bearing department instead of waiting for the FDA to order it.[49] CW1 explained that it would have looked worse to have to announce that the FDA shut down production.

198. CW1 said that instead of waiting until November 2016 as planned and converting [the North Campus] to [Legacy] Zimmer policies and procedures over a six to eight

[49] CW1's account is independently corroborated by the Company's admissions in the December 21, 2016 Letter.

month process, the poly bearing clean room was completely shut down and production was mostly shut down for approximately six weeks to conduct this conversion. CW1 recalled that production started again at the end of October 2016/beginning of November 2016, meaning that the shutdown would have had to start in September 2016.

199. CW1 understood that the main reason for the shutdown was to convert [the North Campus to Legacy] Zimmer's processes and procedures. CW1 also said there were concerns about cleanliness and sterilization in the clean room and the manufacturing areas. In addition to the clean room, CW1 said production was shut down but not completely. CW1 said that the department tried to keep at least a couple of machines running through the shutdown to have some supply available. However, CW1 said it was risky because the product just piled up waiting to be processed through the clean room, which was completely shut down. Also, CW1 further stated that, if the FDA found contamination then the product would have to be thrown out. CW1 said the company cut off the supply of materials to the poly bearing manufacturing after a couple weeks and then the manufacturing area was also completely shut down.

200. CW1 indicated that once the shutdown was over, the poly bearing department had to run constant shifts in order to replenish inventories. CW1 worked 31 or 32 days in a row once it was operational again. CW1 then took a week off and upon returning continued to work six days a week and every weekend. In early 2017, CW1 left the Company because he did not see a light at the end of the tunnel and was burned out.

201. CW1 also said the new procedures put in place included more documentation than the [Legacy] Biomet procedures. As such, CW1 said that it took longer to produce because of the paperwork. CW1 said that the additional processes (documentation) cut production by one-third. CW1 explained that in a typical shift, one of CW1's employees would complete 185 parts

a night but with the documentation, a person was lucky to complete 24 to 25 parts in a shift.[50] With the additional paperwork, CW1's department had difficulty keeping up with demand and thus, there were constant shifts running even through the Thanksgiving holiday weekend.

202. Although CW2 was a Legacy Zimmer employee and based in the Warsaw West Campus (*i.e.*, the Legacy Zimmer facility) after the merger, CW2 was aware of information pertinent to the issues at the North Campus before, during and after the Class Period.

203. CW2 said that the most significant supply constraint CW2 was aware of was when the company stopped shipping product due to the ongoing FDA inspection.

204. Like CW1, CW2 understood that ZBH made the decision to hold product shipments because of the ongoing FDA inspection. CW2 similarly explained that if ZBH had continued shipping product during the inspection and the FDA found issues, then the Company would have to issue a recall, which would be much worse than a shipment hold.

205. CW2 had been aware that the FDA was conducting an inspection. CW2 said that everyone was aware of the inspection because many people were moved from the West Campus to the North Campus to help with the audit. CW2 said there were three or four people in CW2's immediate working area (not within CW2's department) that were temporarily assigned to help with the FDA inspection. As such, CW2 said the inspection caused a disruption at the West Campus as well because of the reassignment of employees.

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[50] CW1's account in this respect is significant. As noted above, according to CW1 poly bearings are used for hip, knee and shoulder devices and that poly bearings are both incorporated into devices but also separate devices. The obvious implication of CW1's account is that the drastic decrease in manufacturing resulting from the implementation of adequate procedures would result in an exponential impact on the manufacturing of hip, knee and shoulder products at the North Campus, which rely on poly bearings. If ZBH had implemented the proper procedures immediately in June 2016, ZBH would not have been able to manufacture sufficient supply to support market level organic revenue growth. As noted above, Defendant Dvorak later admitted that the products manufactured at the North Campus were "a very important set of brands and strategically relevant to acceleration of the top line" [*i.e.*, revenue]. *See* ¶256.

206. CW2 understood from discussions with people working in CW2's area that the main issues at North Campus were that the processes in place were not validated properly. In addition, CW2 indicated that it was found that management signed off on the improperly validated processes. According to CW2, ZBH determined that high management encouraged or endorsed the sign off of improperly validated processes. As such, CW2 indicated that Legacy Biomet senior management were fired or resigned as a result of these findings.[51] CW2 noted certain Biomet senior personnel that were fired or resigned.

207. CW2 explained that it was known that [Legacy] Biomet was quite profitable and it was suspected at the time of the merger that the high profitability might have been because [Legacy] Biomet took short cuts. In addition, CW2 said [Legacy] Zimmer knew that if the FDA arrived to conduct an inspection there would be a problem with the [Legacy] Biomet campus [*i.e.*, the North Campus]. CW2 said it was common knowledge there were cleanliness and quality issues at the [Legacy] Biomet campus and while CW2 did not witness it first-hand, CW2 was not that far removed in CW2's reporting chain from individuals in the know such as Adrian Furey (who previously held the position of VP of North America)[52] and Sam Stutzman (a Legacy Biomet employee at the North Campus who was moved to the West Campus after the Merger).[53]

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[51] Although CW2's account is based on discussions with people working in CW2's area, his account is sufficiently reliable because it is independently corroborated by ZBH's own admissions. For example, ZBH cryptically admitted in the December 21, 2016 Letter that actions had been taken "to address the quality culture" at the North Campus and that "management changes had been implemented by ZBH to address Quality Management System performance issues noted at the Warsaw North Campus, along with underlying quality culture issues now recognized." CW2's account is also independently corroborated by the information in the November NCR Report.

[52] The December 21, 2016 Letter, at 3, notes that "Furey, a legacy Zimmer leader, was named the interim leader" of the North Campus after the departure of the prior Senior Vice President of Global Operations and Logistics Team.

[53] On the internet, Mr. Stutzman identifies himself as the Senior Director of Operations at ZBH.

E. Defendants Dvorak And Florin Instruct Barney To Concoct A Story To Mislead Investors About The Root Cause Of The Q3'16 Supply Shortages And To Terminate Employees For Cause Under A False Pretext

208. After assisting the Private Equity Defendants in selling $2.25 billion of ZBH stock (in the June 2016 Offering and the August 2016 Offering) to the unsuspecting public – *without disclosing the known "systemic issues"* with the QS at the North Campus – ZBH, Defendant Dvorak and Defendant Florin faced substantial liability when having to report the Company's dismal Q3'16 organic revenue growth rate and to finally disclose/explain the dire issues plaguing the North Campus, as well as the ongoing FDA inspection of the North Campus.

209. Rather than disclose these issues, Defendants Dvorak and Florin "doubled-down" on their efforts to conceal the North Campus quality issues from investors and the public. Specifically, Defendants Dvorak and Florin crafted a plan to further cover up these issues, as well as the impact these issues would continue to have on the Company's ability to maintain adequate supply of key/strategic products for the rest of 2016 and 2017. In furtherance of this plan, in October 2016, Defendants Dvorak and Florin concocted a false and/or misleading narrative about what had caused the Company's supply issues and sales shortfall in Q3'16.

210. Defendants Dvorak and Florin proceeded to execute their cover-up scheme by making materially false and/or misleading statements and omitting material information when reporting the Company's Q3'16 financial results to investors and securities analysts on October 31, 2016. In furtherance of this scheme, Defendants Dvorak and Florin engaged in additional acts, including, providing materially false/misleading information and omitting material information in reports filed with the SEC and in correspondence with the FDA.

211. As alleged below, Defendants Dvorak and Florin's actions to mislead investors on and around October 31, 2016, were premeditated. In October 2016, Defendants Dvorak and

Florin took substantial and overt steps of preparation, including attempts to enlist the assistance of other ZBH senior leadership. As alleged below, Defendants Dvorak and Florin faced opposition and objections from at least one high ranking member of the ZBH's senior leadership team who reported directly to Defendant Dvorak. Defendants Dvorak and Florin recklessly disregarded the objection and when discussing ZBH's Q3'16 financial results during a conference call with investors on October 31, 2016, Defendants Dvorak and Florin proceeded to omit material information about, among others, the ongoing FDA inspection of the North Campus and the "systemic issues" with the North Campus' QS, which had been well documented in corporate audit reports dated March 31, April 13, and June 7, 2016. During the conference call on October 31, 2016, Defendants Dvorak and Florin made numerous false and/or misleading statements indicating, among others, that the "unanticipated supply constraints" in Q3'16 "related to our transitioning supply chain infrastructure."

212. After the Class Period, on August 11, 2017, two high ranking former ZBH employees, Robin Barney and Terry Martin ("Martin") filed separate complaints against ZBH in the United States District Court for the District of Indiana: *Barney v. Zimmer Biomet Holdings, Inc.*, 3:17-cv-00616-JD-MGG (N.D. Ind.) (the "Barney Complaint"); and *Martin v. Zimmer Biomet Inc.*, et al., 3:17-cv-00615-JD-MGG (N.D. Ind.) (the "Martin Complaint").[54]

213. The Barney Complaint and the Martin Complaint assert claims against the Company arising from the circumstances under which their employment with the Company ended. The Barney complaint alleges that she was constructively terminated by ZBH when she was effectively forced to resign from the Company after objecting to Defendants Dvorak and Florin's plans to misrepresent to investors the true cause of the sales shortfall in Q3'16.

[54] A copy of the Martin Complaint is attached hereto as "Ex. G."

214. At all times during the Class Period and until her departure from the Company on November 11, 2016, Barney held the position of SVP of Global Operations and Logistics.[55] As the SVP of Global Operations and Logistics, Barney served as one of ZBH's highest-ranking executives and was one of the approximately 12 ZBH executives/employees that reported directly to Defendant Dvorak.

215. On October 30, 2014, while the Merger was pending, Legacy Zimmer issued a press release entitled, "Zimmer Announces Executive Leadership Team and New Name of Combined Company Following Closing." Therein, Legacy Zimmer announced that upon the closing of the Merger, "[t]he executive leadership team of the new [ZBH] will comprise 12 executives reporting directly to [Defendant] Dvorak, and will be organized around three business units, three geographic regions and six functional areas." Therein, under the section, "Zimmer Biomet functional areas and leadership," the press release stated: "Robin T. Barney, Senior Vice President, Global Operations and Logistics. Barney has held the Global Operations and Logistics executive leadership position at Biomet for seven years."

216. Barney's position as SVP of Global Operations and Logistics was effectively as high-ranking and senior as that of Defendant Florin, ZBH's CFO, who during the Class Period also held the position of SVP. Legacy Zimmer's October 30, 2014, press release also identified Defendant Florin as one of the 12 member executive leadership team reporting directly to Defendant Dvorak.

217. According to the Barney Complaint, Barney was constructively discharged from ZBH, without cause, on November 11, 2016. Specifically, the Barney Complaint alleges that "[ZBH], in forcing Barney to terminate employees under false pretexts and to make material

[55] Prior to the Merger, Barney had been the SVP of Operations at Legacy Biomet and became the SVP of Operations and Logistics for ZBH when the Merger closed.

misrepresentations to investors, left Barney with no other choice but to resign." Ex. C at ¶40.

218. The Barney Complaint alleges that in August and September 2016, Barney was notified that her job was being moved overseas and that Defendant Dvorak needed an answer about whether Barney would relocate to Switzerland. Specifically, the Barney Complaint alleges:

> 14. Around August of 2016, Zimmer Biomet's Senior Vice President of Human Resources informed Ms. Barney that her job would be moved from Warsaw, Indiana to Switzerland, requiring her relocation by the end of 2017.
>
> 15. On September 9, 2016, Zimmer Biomet's Senior Vice President of Human Resources, Bill Fisher, asked Ms. Barney whether she would in fact relocate to Switzerland, indicating that the Chief Executive Officer needed an answer. Ms. Barney stated that she needed time to think about it.
>
> 16. Ms. Barney later informed Zimmer Biomet's Senior Vice President of Human Resources that she did not wish to relocate to Switzerland, and was left to conclude that her employment would therefore be terminated before the end of 2017, and that the company would pay her the lucrative severance package provided for in her Employment Agreement.

Ex. C at ¶¶14-16.

219. According to the Barney Complaint, in October 2016, Defendant Florin "demanded" that Barney "concoct" a story to mislead investors about the true cause of ZBH's Q3'16 sales shortfall. Barney also alleges that despite the demand, Barney refused to make such material misrepresentations to investors. Specifically, the Barney Complaint alleges:

> 17. Around October of 2016, Zimmer Biomet's Chief Financial Officer [(*i.e.*, Defendant Florin)] ***demanded that Ms. Barney concoct a "story" to mislead Zimmer Biomet investors about the root cause of the 2016 Q3 shortfalls in sales on an upcoming investor call that would take place on November 1, 2016.***
>
> 18. Ms. Barney ***refused to make material misrepresentations to the investors***.

Ex. C at ¶¶17-18.

220. The Barney Complaint alleges that Defendant Dvorak also participated in the scheme to cover up the true cause of the Q3'16 shortfall by pressuring Barney to terminate ZBH employees for cause under false pretext:

> 19. ***On October 29, 2016, Zimmer Biomet's Chief Executive Officer [(i.e., Defendant Dvorak)] called Ms. Barney's cellular telephone and instructed Ms. Barney to make immediate, significant organizational changes as a result of an ongoing U.S. Food and Drug Administration audit that began on September 12, 2016, which would result in employees being terminated for cause under a false pretext.***
>
> 20. Ms. Barney refused to terminate any employees for cause as a result of the FDA audit because she did not feel it would be ethical or truthful to do so. ***Zimmer Biomet's CEO [(i.e., Defendant Dvorak)] stated that he was not happy with her refusal, and that they would talk further about it.***

Ex. C at ¶¶19-20.

221. The Barney Complaint reveals that Barney subsequently submitted her notice of resignation:

> 21. ***After speaking to Zimmer Biomet's CEO [(i.e., Defendant Dvorak)] that day, on October 29, 2016, Ms. Barney submitted her two-week's notice of resignation via email, which would be effective November 11, 2016.***
>
> 22. ***Ms. Barney felt that she had no choice but to resign, or be forced to participate in unethical and fraudulent business practices, potentially exposing herself to personal legal liability for securities fraud, for example.***
>
> 23. Ms. Barney was constructively discharged and forced to resign from Zimmer Biomet, effective November 11, 2016.

Ex. C at ¶¶21-23.

222. The Barney Complaint is independently corroborated by Defendant Dvorak and Florin's false and misleading statements during ZBH's Q3'16 conference call on October 31, 2016. As alleged herein, during the conference call, Defendants Dvorak and Florin executed their premeditated plan (over Barney's objection and resignation), and affirmatively provided a false explanation for the Q3'16 sales shortfall and affirmatively omitted that the true cause of the

Company's Q3'16 financial performance had been related to the ongoing FDA inspection which was uncovering the internally known and well documented "systemic issues" with the QS at the North Campus.

223. For example, on the October 31, 2016, conference call, Defendants Dvorak and Florin omitted any reference to the FDA's ongoing inspection of the North Campus, as well as any reference to the product hold(s) that had caused the Q3'16 supply shortages and were continuing to cause severe supply shortages in October 2016 and Q4'16.

224. The fact that neither Defendant Dvorak nor Defendant Florin made a single reference to the catastrophic ongoing FDA inspection of the North Campus, strongly corroborates the allegations in the Barney complaint and is also powerful evidence that Defendants Dvorak and Florin acted in concert to mislead investors during the Q3'16 conference call. The complete omission of such a highly critical fact (*i.e.*, that an ongoing FDA inspection of the North Campus had resulted in devastating disruptions to production and distribution at a primary manufacturing facility) could not have been accomplished without concerted planning and action between Defendants Dvorak and Florin.

225. Rather, Defendants Dvorak and Florin falsely placed the blame for the Q3'16 sales performance on "[v]ariable commercial performances by our sales teams" that were "in part caused by unanticipated supply constraints, related to our transitioning supply chain infrastructure."

226. During the Q3'16 conference call, Defendants Dvorak and Florin affirmatively misrepresented and covered up the true cause of the Q3'16 sales performance by brazenly painting the misleading impression that the Company's problem involved a temporary supply shortage stemming from the Company failing to realize that it had ***too much demand*** for cross-

sales of certain products and not realizing that it was allegedly depleting its safety stock of inventory. This description was misleading and was also shocking because cross-selling was effectively the lynchpin for ZBH's plan to realize synergies from the Merger and return to market level growth. For example, during the Q3'16 conference call, Defendant Florin described the issue, as follows:

> ***As a consequence, we underestimated demand for certain key cross-sell brands within our existing customer base, leading to a depletion of our safety stocks, and also affecting our ability to capitalize on new customer opportunities.*** We are working diligently to enhance our supply chain processes and execution, particularly in the areas of demand forecasting, global inventory tracking, and asset deployment systems, while we replenish our safety stock levels. However, these issues have some carryover effect into the fourth quarter, which I will address shortly in the context of our updated Q4 guidance.

227. Defendants Dvorak and Florin were successful in their efforts to mislead investors about the true cause of the Company's Q3'16 supply shortages and sales shortfall, as well as to cover up the ongoing FDA inspection of the North Campus. For example, the Company's false explanation about what had caused the supply shortages caught analysts off guard who had trouble comprehending how the alleged supply chain issue described by Defendants Dvorak and Florin had gone undetected. For example, BMO Capital Markets promptly issued an analyst report on October 31, 2016, entitled, "What? Supply Chain Issues?" The report stated:

> **Key Points**
>
> ***What? Supply chain issues? To being to say that this was a surprise is an understatement.*** For a management team that has integrated many acquisitions, this was clearly not expected. ***As we understand it, the [interim] fixes put in place to help integrate the Zimmer and Biomet processes did not give management the line of sight in shifting product demand. This includes: 1) an inability to respond to shifting product mix; 2) underestimating demand in key brands (e.g., Persona Knee, Biomet's legacy hip portfolio, and the Comprehensive Total Shoulder System); and 3) a failure to monitor its inventory levels, which meant it needed to service existing accounts and missed the opportunity to penetrate competitive ones in some cases.*** In the 3Q16, this negatively affected revenue by about 100 basis points. It is estimated it will have

> a 200 basis point impact in the 4Q16 and roll into the 1Q17 before dissipating. ***In terms of taking action, fixes are coming in the form of an integrated global inventory data warehouse that will give visibility to finished goods inventory and is expected to be on line in 4Q16. Integrated demand and production planning tools are also being developed to aid in forecasting,*** which we expect to see implemented early 2017.

228. In the days that followed, Defendants Dvorak and Florin continued spreading their false narrative to investors by communicating directly and/or indirectly (through other ZBH employees) with research analysts from major securities firms and providing analysts with further false or misleading information about the supposed Q3'16 "supply chain" issues that had purportedly "caused" the Q3'16 sales shortfall and resulted in lowered Q4'16 guidance.

229. For example, J.P. Morgan issued a report on October 31, 2016, entitled, "We Spoke to Mgmt; Here's What We Learned." Therein, the analyst indicated that he had a call with ZBH "management" that "helped shed some light into exactly what drove the miss in 3Q." As the analyst noted, "The #1 question investors have is why didn't they see this coming and how could management have been so bullish on 3Q as late as the September investor conferences and an NDR [non-deal roadshow] in Boston on September 28th?"

230. According to the October 31, 2016, report from J.P. Morgan, ZBH management had explained to the analyst that ZBH management sees daily sales reports for the U.S. businesses and gets updated weekly sales projections from every business around the globe, including the U.S. According to the report, ZBH management told the analyst that ZBH management was receiving delayed supply chain reports and that ZBH management knew that ZBH had an inventory issue when the "August supply chain report came in to them in mid-September." As the J.P. Morgan analyst noted, the obvious question was "[w]hy did it take so long?" The report continued by revealing: "[w]ith Zimmer consolidating its inventory management systems, ***the monthly supply chain reports at this point are being crafted***

manually. As a result, it takes a lot longer than it usually would. Why no one raised an alarm prior to the report is unclear, and obviously an issue management is focused on."

231. The J.P. Morgan report also explained that " . . . the ongoing integration of the Biomet and Zimmer supply chains and ERP systems meant that the organization wasn't able to connect the dots on a number of red flags earlier in the quarter to prevent the situation." The report also highlighted the "complete disconnect between supply and demand" and ZBH's "broken" forecasting system:

> **The lack of visibility to safety stock across distributors and long lead times from production meant that there was just a complete disconnect between supply and demand.** Part of the problem was that the people providing directions to management didn't have a clear line of sight to instrumentation levels for Persona, while in Hips and Shoulders the issue was that the company has seen a big mix shift away from the Zimmer products towards the Biomet ones, and the necessary inventory wasn't there. This was partly due to a "broken" forecasting process and the fact that the supply chain couldn't adjust quickly enough to this shift in demand. By the time the problem was finally realized the last week in September, there just wasn't enough inventory on hand to fill demand as they had to curtail new account activity and shipments of certain products. And since they can't go after new business until they fill back orders and replenish their safety stocks, this issue will linger through 1Q17 with the worst of the impact (~200bps) in 4Q16.

(Emphasis in original).

232. Defendants Dvorak and Florin's attempt to cover up the true causes of the Q3'16 shortfall was foiled shortly thereafter by the November NCR Report, which disclosed that the North Campus had been negatively impacted by an FDA inspection, that the inspection had resulted in product being held at the facility, and that Barney was no longer at the Company.

233. The allegations in the Barney Complaint also contradict certain aspects of the narrative ZBH was attempting to provide to the FDA. In ZBH's correspondence with the FDA, ZBH attempted to place part of the blame for the North Campus compliance issues with the "quality culture" at the North Campus. For example, in ZBH's December 21, 2016 letter to the

FDA, ZBH noted that it had implemented management changes at the North Campus and even noted that ZBH had replaced the SVP of Global Operations and Logistics (*i.e.*, Barney) but ZBH did not disclose to the FDA that Barney had resigned in protest over the plan Dvorak and Florin had concocted to lie to investors and falsely blame ZBH employees for the issues at the North Campus, and to terminate these employees for cause under a false pretext.

234. The Martin Complaint further corroborates the allegations in the Barney Complaint, including the allegations from the Barney Complaint about Defendant Dvorak instructing Barney to terminate ZBH employees for cause under a false pretext.[56] The Martin Complaint alleges that ZBH wrongfully terminated Martin by claiming he was responsible for the issues at the North Campus when Martin alleges that he was not responsible for the issues cited by the FDA in connection with the inspection of the North Campus in the fall of 2016.

235. According to the Martin Complaint, Martin began his employment with Legacy Biomet in 1989 and following the acquisition of Legacy Biomet by private equity funds in 2007 his role and responsibilities as Vice President of Manufacture Engineering were aligned in accordance with the acquirer's business model. Ex. G at ¶14. According to the Martin Complaint, from 2007 until 2015 Martin served at the North Campus location. Ex. G at ¶15.

236. In connection with the 2015 Merger between Legacy Zimmer and Legacy Biomet, Martin alleges that he became the "Senior Director of Facilities and Maintenance" for ZBH and was relocated to the West Campus. Ex. G at ¶16.

237. Martin alleges that as a result of the FDA inspection of the North Campus in the fall of 2016, Martin was temporarily relocated to the North Campus to assist with remediation

[56] The Barney Complaint alleges that on October 29, 2016, Defendant Dvorak "instructed Ms. Barney to make immediate, significant organizational changes as a result of an ongoing U.S. Food and Drug Administration audit that began on September 12, 2016, which would result in employees being terminated for cause under a false pretext." Ex. C at ¶19.

efforts from October 2016 until January 2017:

> 17. In October of 2016, Mr. Martin was instructed to report to the Biomet North Campus to assist in remediating an ongoing FDA audit.
>
> 18. In January 2017, following his temporary job reassignment, Mr. Martin returned to the Zimmer West Campus and resumed his normal responsibilities as Senior Director of Facilities and Maintenance at Zimmer Biomet.

Ex. G at ¶¶17-18.

238. The Martin Complaint alleges that ZBH notified Martin in February 2017 that he was being terminated because he had "management accountability" for the issues cited by the FDA:

> 19. On February 1, 2017, Martin received a letter from Zimmer Biomet, stating that his employment would be terminated effective February 10, 2017.
>
> 20. Martin's termination letter states that his selection for separation is due to his "failure to ensure that the Warsaw North Campus facility was compliant with FDA requirements." The termination letter identifies Martin as a "key leader at that facility from 2006 to 2014 in a Vice President of Manufacturing Role," and states that Martin "had management accountability for many issues noted in the FDA inspection observations shared on November 22, 2016."

Ex. G at ¶¶19-20.

239. The Martin Complaint alleges that Martin was improperly blamed for the issues at the North Campus and alleges that Martin never held the position attributed to him in the above quoted portion of the letter notifying him of his termination:

> 21. Martin's termination letter states that he is not eligible for severance benefits under the terms of the Zimmer Biomet Severance Plan, because his termination is for "Any act or omission causing, or having potential to cause, significant harm or loss to the company."
>
> 22. ***Martin has never held the title, or performed the responsibilities, of Vice President of Manufacturing.***

23. Martin was not responsible for the November 22, 2016, FDA audit observations regarding the Biomet North Campus facility.

Ex. G at ¶¶21-23.

F. Securities Analysts' Reactions Confirm That The Issues Cited By The FDA In The November 2016 North Campus FDA 483 Were Serious And Highly Concerning

240. On December 14, 2016, one or more research analysts issued reports indicating that, in response to FOIA[57] requests, the analysts had received copies of the November 2016 North Campus FDA 483.

241. In response, that day ZBH issued the following statement acknowledging that the Company had received the November 2016 North Campus FDA 483 and that there were "regulatory compliance gaps at the legacy Biomet operation in Warsaw:"

> As an update to the Company's statement published on November 8, 2016 concerning product supply matters, Zimmer Biomet continues to make excellent progress enhancing certain aspects of its supply chain infrastructure as it harmonizes and optimizes its sourcing, manufacturing and quality management systems. The Company has been successfully addressing the previously disclosed temporary shipping delays involving certain products and, as expected, most of the impacted product lines have returned to full shipping capacity.
>
> Separately, on December 14, 2016, one or more investment analysts have published reports concerning a recent FDA inspection of a Zimmer Biomet manufacturing facility, and the Company is issuing this statement in response. Like all medical device companies, Zimmer Biomet is subject to periodic FDA inspections. Recently, the FDA completed an inspection of the legacy Biomet manufacturing site in Warsaw, Indiana. As is often the case, at the conclusion of the inspection, the FDA issued various inspectional observations on Form 483.
>
> Zimmer Biomet takes these matters very seriously and is in the process of

[57] As noted in a December 16, 2016, report issued by Morningstar: "Upon hearing rumors that Zimmer Biomet had been caught in the sights of the FDA last month, we'd filed a request under the [FOIA]. At the time, we were skeptical that any recent Form 483 directed at the firm existed, as in the past, we've seen other medical device firms take a more proactive stance in these situations to reassure investors that management was working decisively to resolve the FDA's issues. In the ensuing four-week period that was required to process our FOIA request a Form 483 had been issued to Zimmer Biomet."

> preparing its written response to the Form 483 observations. The Company has developed and is executing a remediation plan to fully address the issues cited by the FDA and this work is progressing well. Additionally, the Company will continue to communicate with the FDA regarding the status of the corrective actions and remediation work.
>
> Zimmer Biomet is committed to operating a first-rate quality management system across its global manufacturing network. While the Company is taking the necessary steps to address ***certain regulatory compliance gaps at the legacy Biomet operation in Warsaw***, it remains confident in the quality, safety and efficacy of all of its products. No patient safety concerns have been identified with any of the products manufactured at the site.
>
> ***In conclusion, the anticipated full impact of all of the above-described matters was included in the Company's sales and earnings guidance update issued on October 31, 2016.***

242. Analyst reports issued on December 14 and 16, 2016, confirmed the severity and magnitude of the issues raised by the FDA in the 57 page November 2016 North Campus FDA 483.

243. For example, a December 14, 2016, Wells Fargo report detailed the reaction of their FDA legal consultant to the November 2016 North Campus FDA 483: "The bottom line is, this is one of the longest and most serious 483s [the] consultant has ever seen" and their consultant "believes it will take ZBH at least a year to address all the issues in the 483."

244. Wells Fargo's FDA legal consultant deemed the magnitude of the issues raised by the FDA as "unusual" and "serious." For example, the report stated:

> . . . According to our consultant, this 483 is far longer than the average 483. The number of observations (14) is towards the upper end of 483s, but the length (57 pages) is quite unusual according to our consultant. While he assumes that other 483s have been issued that are as long or longer, ***this is the longest one he remembers seeing. The corollary is that FDA has gone to considerable efforts to document what the agency perceives as significant violations. The 483 does not simply provide an example or two of deficiencies, but it provides multiple examples. It is unusual to be so thorough in documenting a company's perceived shortcomings.***

245. Wells Fargo's legal consultant deemed FDA's concerns as "significant, both from

a regulatory perspective and from the standpoint of safety." For example, the report stated:

> . . . FDA has written the 483s in such a way as to argue that these are not just technical violations, ***but ones that potentially go to safety***, e.g., whether products were properly sterilized or steps adequately documented so that the safety is known. At a minimum, ***our consultant believes ZBH is going to have to spend a significant amount of time and effort addressing these issues.***

246. Wells Fargo's legal consultant also noted the fact that the FDA had dedicated 21 pages exclusively to a single observation was significant: "***Our FDA consultant does not recall ever seeing a 21 page single observation***. FDA not only documented that this was a repeat observation, but ***went to great lengths to document myriad manifestations that the company failed to comply with FDA's regulations***." The legal consultant opined that it was "very likely" that ZBH would receive a warning letter from the FDA relating to the North Campus:

> . . . Given the 15-day period for responding to 483s, our consultant does not believe ZBH will be able to provide objective evidence that it has corrected all of these issues in that 15-day window. Any corrective actions submitted after the 15-day period can be discounted by FDA in deciding whether to issue a warning letter. If there are any PMAs (premarket approvals) that are pending from the facility, these quality issues could substantially delay the approval of those PMAs. Fortunately for ZBH, we are not aware of any pending PMAs. Warning letters do not prevent the clearance of 510(k)s. Given the number and severity of issues, FDA could contemplate other actions, such as requesting a Regulatory Meeting at the District to emphasize to company management the agency's concerns. FDA could also pursue an injunction, although there have been relatively few injunctive proceedings recently and the change in administration may play a role here according to our consultant.

247. The seriousness of the November 2016 North Campus FDA 483 was echoed by other analysts as well. For example, Northcoast Research issued a report on December 16, 2016, after reaching out to "an independent consulting firm (not affiliated with the FDA) to seek their assessment[58] of the FDA's observations." Northcoast's consultant similarly expressed their view that the November 2016 North Campus FDA 483 was "unusual" and "intense:"

[58] The report also indicates that the "FDA consulting contact's feedback is based on the presently available data (the FDA's observations, but not ZBH's responses)."

> While Form 483 observations are fairly common following FDA inspections, ***our FDA consulting contact suggested the number of observations and items within each observation make Biomet's recent Form 483 an "intense" one.*** According to our contact, the FDA's most serious concerns are typically addressed in the initial observations of a Form 483. While our contact suggests inadequate CAPA (Corrective and Preventative Action) procedures commonly lead-off Form 483s, ***the Biomet document was somewhat unusual in having 21 pages addressing process validation (split into nine parts, including items such as sterilization validation, sterile packaging validation, and validation of various cleaning processes for implantable devices) before mentioning any CAPA items.***
>
> ***
>
> Most importantly, our contact thinks the observations in Biomet's Form 483 are fixable (with most being characterized as easily remediated) although ***this process is expected to take time (at least one year of remediation according to our contact). Our contact also believes remediation efforts will "significantly tie up (ZBH's) R&D and Quality Assurance departments" during this time.***

248. Similar concerns were also expressed in a December 16, 2016, Morningstar report about the "worrisome" November 2016 North Campus FDA 483:

> Compared with redacted Form 483s that we've seen issued to other medical device firms over the years, ***this one is substantially more extensive and serious***. For example, the FDA raised issues with water samples that failed to meet acceptable microbial and endotoxin tolerances, and the possibility of particulate contamination of some clean rooms. ***We are perhaps most troubled by this Form 483 because the FDA had already raised a number of these issues at least two years ago. Based on the FDA's current assessment, the firm has not adequately resolved these issues and it continued to ship product manufactured under these conditions during that period***.
>
> In most Form 483s that we've reviewed, the majority of the issues are related to quality control--specifically, documenting the processes and procedures in place to ensure quality-related aspects of how products are manufactured. ***It is unusual, in our experience, to see specific issues raised with direct implications for the sterility of the manufactured product, for example. This is why we find Zimmer-Biomet's Form 483 to be so worrisome.***

249. The Morningstar analyst opined, "Considering the extensive issues the FDA has identified and that ***some of them may actually require Zimmer Biomet to construct or remodel parts of the physical plant, we think it could take 12 to 18 months to ameliorate conditions*** to

the FDA's satisfaction."

G. ZBH's Post-Class Period Disclosures Reveal That The North Campus Remediation Will Cost $300 Million And Cause Continued Supply Shortages Throughout 2017 Of Key Products "Strategically Relevant" To Accelerating Revenue

250. Ultimately, ZBH and the Individual Defendants were unable to continue hiding the severe QS issues at the North Campus and the drastic impact that the remediation efforts would have on the Company's ability to maintain sufficient supply to meet demand for its products. The extensive remediation work that was needed to bring the QS at the North Campus up to date and in compliance with FDA regulations would ultimately cost the Company hundreds of millions of dollars and cripple the Company's organic revenue growth rate into late 2017 and possibly into 2018.

251. When ZBH reported its Q4'16 financial results, the Company indicated that in Q4'16 it had spent approximately $145 million related to "integration activities" and at least $38 million of quality remediation expenses.[59]

252. During the January 31, 2017, conference call to discuss the Company's Q4'16 financial results, Defendant Florin also noted that in 2017, the Company expected to spend "approximately $170 million of cost to harmonize and optimize our supply chain and manufacturing and quality systems," which would be generally related to ZBH's efforts to address the issues raised by the corporate audits and the observations in the November 2016 North Campus FDA 483.

---

[59] A significant undisclosed portion of the "integration" expenses was seemingly spent on remediation efforts. As explained during a January 31, 2017 conference call to discuss the Company's Q4'16 financial results, Defendant Florin stated: "[T]o the extent we're incurring remediation expenses, that's running through as a special charge. To the extent we're making permanent investments in the quality infrastructure and manufacturing overhead infrastructure, that's running through the adjusted P&L [*i.e.*, profit and loss]."

253. When the Company subsequently reported its financial results for Q1'17, Defendant Florin revealed that the Company was increasing its expected expenditures to address the quality and remediation issues (by another $40 million) to $210 million in 2017.

254. During an analyst conference on May 3, 2017, Defendant Florin indicated that the Company expected additional remediation efforts and costs to continue into 2018 and that ZBH presently expected "the full remediation spend to approach $300 million before its complete."

255. When ZBH announced its Q1'17 financial results on April 27, 2017, ZBH revealed that it was still experiencing supply shortages because of the remediation activities at the North Campus, which would continue into the second half of 2017. During a conference call to discuss the Company's Q1'17 results, Defendant Dvorak acknowledged that in Q1'17 ZBH "experienced a greater-than-expected number of temporary and occasional production delays," and that "[w]hile our overall production throughput improved during the quarter, these delays resulted in lower-than-expected levels of finished goods and strained inventory availability of key brands throughout" Q1'17.

256. During the conference call, Defendant Dvorak was asked about the root cause of the quality problems at the North Campus and the supply shortages. Dvorak admitted that the issue stemmed from the above discussed corporate audit reports and subsequent remediation work that was undertaken in response. Dvorak conceded that the products impacted at the North Campus were crucial to ZBH's ability to drive top line revenue growth from cross-selling:

> [*Defendant Dvorak*:] … [A]s we explained in the last call, ***we have been working through the integration process to harmonize and optimize our quality and manufacturing systems as part of the integration. Those efforts as it relates to the Warsaw North Campus were greatly accelerated as a consequence of both internal audit findings as well as the FDA's inspection that concluded in the fourth quarter of last year.*** So we had a pretty fluid situation in the fourth quarter leading into the beginning of this year. We've made accelerated changes to those operations. And obviously, in addition to implementing operational improvements

> at the facility as part of these regulatory compliance enhancement efforts, we were focused on ensuring that the production was coming back up to satisfy, in a prioritized way, existing customer demand and then working towards replenishing safety stocks that would allow us to go back on offense. ***Because some of these key brands that come out of that facility provide us with some of our best competitive opportunities, so they're a very important set of brands and strategically relevant to the acceleration of the top line. And so it really is a matter that is focused on that facility.*** And as we got into the beginning of the year and production began to accelerate back up, it just took us longer to ramp that production back up. You can understand why we'd be operating with an abundance of caution, most importantly, with the interest of the patients that are served by these products in mind. These are high-quality products. We want to make sure that we're putting them out without any compromise, and so the monitoring processes are very sensitive. The implementation of these processes, as I said, this was done on a very accelerated basis for obvious reasons, and it just took us longer to ramp up that production in the first quarter than we originally anticipated. As we exited the quarter and in most recent weeks, those production levels have been brought up to a point where we're going to be able to begin to more fully satisfy existing customers and, as the second quarter progresses, work towards replenishing those safety stocks. So in the summer months, we expect, in particular, to make a lot of progress on that front and to put ourselves in a position then to not only fully satisfy existing customer demands but then to go back on offense.

257. The magnitude of the necessary remediation and the resulting impact on ZBH's ability to generate sufficient supply of key products was extremely frustrating to investors and analysts. An April 27, 2017, J.P. Morgan report entitled, "Patience Wearing Thin" noted, "While the rest of the industry is posting quarter after quarter mid-single digit or better top-line growth, Zimmer is struggling and ***the pitchforks are out***." Further, the report noted:

> **The weak start to the year was caused by a greater than expected number of process monitoring failures at the Warsaw facility.** These process enhancements were more expansive overhauls of manufacturing lines that took place in 4Q-1Q in a bid to address concerns raised by the 483s issued to Zimmer in December last year. Given the broad scope of these line changes, monitoring failures led to manufacturing lines being shut down, remediated, and brought back up. While Zimmer initially thought they could make up for initial delays in the quarter itself, new process monitoring failures and corresponding field actions led Zimmer to fall further behind.
>
> **These delays led Zimmer to fall even further behind schedule.** As a reminder, Zimmer was already playing catch-up on the back of the 3Q16 supply issue and

> the 483s added another layer of delays on top of that. While management sees current output as being sufficient for their needs, Zimmer still has multiple tiers of demand they need to work through: (1) clearing back orders left over from the end of 2016 and 1Q17; (2) creating enough product to satisfy existing demand; (3) replenishing safety stocks; and (4) building up enough inventory to begin aggressively taking share.
>
> **With that as the backdrop, management lowered full year organic growth guidance to 2.0-3.0%.**

(Emphasis in original).

258. At a May 17, 2017, analyst conference, Defendant Florin was asked how the Company went from 40 years of having no problems to $300 million of needed investments to fix the issues. Florin admitted the 483s are deep and broad, running the gamut of an FDA 483:

> [*Analyst:*] …[H]how do you go from 40 years of no problems to $300 million of needed investment to fix the issues and just we're having a hard time understanding how we got from here to here?
>
> [*Defendant Florin*:] It's – Bob, I would just say the ***483s are deep and broad***, much deeper and broader than we expected, observation noted. …
>
> So again, at this juncture, our focus is executing the plan that we've laid out. It is an – it's very expensive. ***It runs the gamut between, across all the major subsystems of a quality system, production and process control, design history file remediation, how we clean, pack, sterilize products, cap our systems, complaint handling systems, supplier certifications.*** It really, it runs the gamut and that's out in the public domain in terms of the 483. So, it's a very expensive remediation plan and we're executing to that. We know how to do this. We're spending the money necessary with a lot of outside help, that was quite the biggest reason for the increase in spend. We've had to go outside, Warsaw is a pretty small place. So, to get the quantity of people that we needed to execute the plan, we had to bring in more outside consultants. And to execute it with excellence, do that – do it right the first time and get it done by the end of 2018, thus the price tag.

259. Defendant Florin went on to explain that the $40 million increase to anticipated remediation costs was due to the significant time and expense associated with remediating observations related to design controls and design history files:

> It was a $40 million bump and it was again a combination of having to spend

> more money with outside consultants, which comes at a premium, just because of the sheer numbers of people that we needed, as well as during the first quarter, as we looked at a particular remediation area, such as design controls and design history file remediation. We found that it was far more significant. So just for perspective, a design history file in order to take a file that's been in existence for in some cases, decades. So open that file up and to bring it to the standards that we've agreed to with FDA, we're going to have to spend 700 hours per file to remediate that design history file. So that's just – in terms of order magnitude I think that just shows you the what we have to go through.

260. ZBH's inability to satisfy the demand for its products while remediating the systemic issues at the North Campus continued to devastate the Company's ability to compete. For example, on June 21, 2017, RBC issued an analyst report noting that as a result of North Campus remediation efforts, "Management recently estimated that 3 out of every 10 knee cases had been going to a competitor because the company did not have enough Vanguard inventory to meet demand and as some surgeons did not want to switch over to Persona."

261. On July 11, 2017, the Company issued two press releases. In the first press release, the Company announced that Defendant Dvorak had stepped down as president, CEO, and director, of the Company. Therein, the Company announced that Defendant Florin would serve as the Company's interim CEO while the board conducted a search for a replacement.

262. In the second press release issued on July 11, 2017, the Company announced preliminary financial results for Q2'17. Therein, the Company indicated that (excluding the contribution from the recent acquisition of LDR) "second quarter 2017 revenues are expected to decrease by 1.3%, or a decrease of 0.3% on a constant currency basis, from the second quarter of 2016." Additionally, therein, the press release stated:

> While production output increased at our legacy Biomet manufacturing site in Warsaw, Indiana during the second quarter, certain brands did not achieve targeted production levels as quickly as anticipated. We also experienced slower than expected sales recapture from previously affected customers in the United States," said Dan Florin, Interim Chief Executive Officer, Senior Vice President and Chief Financial Officer. "As we look toward the second half of 2017, we are

> focused on restoring full product supply and improving customer engagement, while continuing to progress on our quality enhancement efforts.

263. On July 28, 2017, the Company reported its financial results for Q2'17 and held a conference call to discuss its financial results with investors, securities analysts, and the public. Therein, Defendant Florin spoke candidly about the extent to which these issues would continue hindering the Company's ability to meet demand for its products throughout 2017:

> As we've highlighted previously, there are two primary factors that contributed to top line results being below our expectations. First, production delays within certain key brands impacted our ability to reduce back orders at the targeted rate. Second, sales recapture for previously affected customers in the United States was impacted by our delayed production output. As a consequence of lower than anticipated second quarter results as well as updated assumptions on production levels and sales recapture, we are revising our 2017 sales and earnings guidance, which I will detail later in my remarks.
>
> I'd like to now spend a few minutes providing more detail on our key focus areas to address these challenges going forward, as well as some of the initiatives already underway.
>
> During the quarter, we delivered production consistency with significantly less disruption than we saw in the first quarter. Notably, we delivered the highest quarterly output on record from our Warsaw North Campus manufacturing facility, allowing for some of our brands to achieve the full production levels that we had previously anticipated.
>
> ***However, reaching full production of certain brands has proven to be more challenging than initially anticipated due to the complexity of validating certain material types and production processes as well as ensuring quality control with regard to sourcing. This resulted in lower than anticipated supply availability of these brands during the second quarter, and we have, therefore, updated our expectations for the second half of the year.***
>
> ***We continued to make progress meaningfully reducing back orders on many of the brands manufactured at the Warsaw North Campus, and we expect to continue building safety stock of these products through the third quarter. For those brands that were delayed in the second quarter, we anticipate that we will substantially reduce back orders through the third quarter and early into the fourth quarter.***
>
> ***Importantly, we expect to reach sufficient safety stock levels across our entire portfolio as we exit 2017. Clearing backorders allows us to more fully meet***

existing customer demand, and we expect that achieving sufficient levels of safety stock will enable us to return to greater sales offense and bring on new customers.

VIII. DEFENDANTS' VIOLATIONS OF THE EXCHANGE ACT[60]

264. During the Class Period, ZBH and the Officer Defendants made materially false and/or misleading statements and omissions of material fact to investors in violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder.

265. Among others, ZBH and the Officer Defendants falsely and misleadingly represented to investors that ZBH's organic revenue growth was accelerating and that organic revenue growth would continue to accelerate above market level in the second half of 2016 due to cross-selling opportunities, while also failing to disclose, among other things: (i) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming and costly remediation and corrective activities; (ii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iii) that an FDA inspection of the Legacy Biomet North Campus was imminent; (iv) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus; and (v) that as a result of the foregoing, ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016.

266. Additionally, during the Class Period, ZBH purported to warn investors of unmaterialized risks relating to its business and had represented to investors that certain "risks" were mere uncertainties that had not materialized. However, these purported risk warnings were materially false and/or misleading because ZBH omitted, among others, the following risks: (i) that ZBH would be unable to satisfy demand for its products while remediating the QS

[60]For purposes of this section only, any references to "Defendants" is limited to Defendant ZBH, the Officer Defendants, and the Private Equity Defendants.

deficiencies at the North Campus; and (ii) that ZBH would have to disrupt production/distribution of key products because ZBH was manufacturing, sterile packing, and distributing products from the North Campus despite knowing that "systemic issues" with the QS had not been adequately remediated and knowing that an FDA inspection of the facility was imminent.

267. Additionally, these purported risk warnings were materially false and/or misleading because ZBH failed to disclose that certain of the potential uncertainties/risks that ZBH was warning about, had in fact actually occurred or were very likely to occur, including: (i) that integration of Legacy Biomet was going to be far more expensive, take far more time, and cause far more disruption because of the "systemic issues" with the North Campus' QS; (ii) that an FDA inspection of the North Campus was imminent and would result in negative consequences and disruptions to the manufacturing and supply of key products; and (iii) that the Company was actually manufacturing and distributing products from the North Campus despite ZBH corporate management knowing about "systemic issues" with the quality management systems that had not been remediated.

268. Each of the statements and omissions identified below (in this Section VIII.A) as false and/or misleading was made with scienter because ZBH and the Individual Defendants knew and/or recklessly disregarded that their statements were false and/or misleading and/or omitted material information required to be stated therein to make their statements not misleading. Specifically, among other reasons (including those referenced in Section VIII.B), ZBH and the Individual Defendants knew and/or recklessly disregarded, the following:

(a) that, in the first half of 2016, corporate audit reports issued on March 31, April 13, and June 7, 2016, had revealed to ZBH corporate management that, contrary to

their prior beliefs, the QS at the North Campus was not in substantial compliance with FDA regulatory requirements and alerted ZBH corporate management to "systemic" quality and compliance issues at the North Campus (*see* Section VII.D.2);

(b) that ZBH knew an FDA inspection of the North Campus was imminent and that the "systemic" QS issues were of such a magnitude that ZBH would not be able to remediate or correct these issues prior to the FDA inspection of the North Campus (*see* Sections VII.D.1 and VII.D.2);

(c) that the FDA was carefully scrutinizing ZBH's manufacturing facilities following disastrous inspections around the world, including a highly critical inspection of the Legacy Zimmer West Campus in late 2015 (Section VI.E); and

(d) that despite learning of "systemic" issues with the North Campus' quality management system, knowing that prior FDA observations had not been adequately addressed, and knowing that an FDA inspection of the North Campus was imminent, ZBH was not taking prompt action to address the quality and compliance issues at the North Campus and was continuing to distribute products, including key products/brands, that were manufactured, cleaned, sterile packed, and/or sterilized at the North Campus (*see* Sections VII.D.3 and VII.D.4).

A. ZBH And The Officer Defendants' Material Misstatements And Omissions In Violation Of The Exchange Act

1. The June 7, 2016 Statement

269. The Class Period starts on June 7, 2016. On this day, ZBH held a conference call in connection with the Company's announcement of the LDR acquisition. During the conference call, an analyst noted, "I guess one concern I have is the timing of this deal, given that you have a lot left to accomplish with the Biomet integration and that you have yet to return your core hip

and knee business to market growth rates." The analyst then noted that ZBH had reiterated its guidance for the year and asked, "[A]re you also comfortable reiterating the second quarter revenue growth guidance for Zimmer Biomet," and "just broadly, how confident are you in the Q2 and 2016 revenue growth outlook for your Company today?" In response, Defendant Dvorak, stated:

> ***We are highly confident and we are reiterating guidance for the year***, and in response to your question, comfortable reiterating guidance for the second quarter just the same. ***I think you ought to interpret this announcement as being confidence in the state of the integration, the progress that we've made on the Biomet side***, we obviously feel like we're well-positioned to be able to put the right integration plan together and realize the full benefits of this LDR combination that we announced this morning, otherwise we wouldn't be putting ourselves in a position to overlay an integration that we weren't comfortable with. ***So, highly confident in the tracking of synergies and realization of all the benefits that we've described previously from the [Legacy] Biomet*** combination and believe that this is going to be a top-line accelerator and create a growth engine for the future on the Spine side.

270. The above statement was materially false and/or misleading and/or omitted material facts necessary to make the statement not misleading. Specifically, the statement was materially false and/or misleading when made because it failed to disclose: (i) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming and costly remediation and corrective activities; (ii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iii) that an FDA inspection of the Legacy Biomet North Campus was imminent; (iv) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus; and (v) that as a result of the foregoing, ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016.

2. The June 2016 SPO Materials

271. On June 13, 2016, ZBH and the Private Equity Funds offered for sale 11,116,533

shares of ZBH common stock in the June 2016 Offering. The Private Equity Funds received all of the proceeds from the offering and ZBH did not receive any of the proceeds. Ultimately, the selling shareholders sold the 11,116,533 shares of ZBH common stock at a price of $115.85 per share, for net proceeds of approximately $1.28 billion.

272. The June 2016 Offering was conducted pursuant to a registration statement on Form S-3 that ZBH filed with the SEC on February 4, 2016 (the "Registration Statement"). The Registration Statement was signed by Defendants Dvorak, Florin and Collins.

273. ZBH supplemented the Registration Statement with a Preliminary Prospectus Supplement filed with the SEC on June 13, 2016 (the "June Preliminary Prospectus") and a Final Prospectus Supplement filed with the SEC on June 15, 2016 (the "June Final Prospectus" and together with the Registration Statement and the June Preliminary Prospectus, the "June SPO Materials").

274. The June SPO Materials incorporated by reference, among others: (i) ZBH's Annual Report on Form 10-K for the year ended December 31, 2015 (filed on February 29, 2016) (the "2015 10-K"); and (ii) ZBH's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (filed with the SEC on May 10, 2016) (the "Q1'16 10-Q").

275. The June SPO Materials were defective because they contained untrue statements of material facts and/or omitted to state facts necessary to make the statements made therein not misleading and the June SPO Materials were not prepared in accordance with the rules and regulations governing their preparation.

276. The June Preliminary Prospectus and the June Final Prospectus, both represented that any "forward-looking statements are based upon the current beliefs and expectations of our management" and purported to identify, among others, the following generic and boilerplate

"risks and uncertainties:" (i) "the risks and uncertainties related to our ability to successfully integrate the operations, products, employees and distributors of the legacy companies;" (ii) "our ability to remediate matters identified in any inspectional observations or warning letters issued by the FDA;" and (iii) "the success of our quality and operational excellence initiatives."

277. The above (purported) risk warning was materially false and/or misleading and/or omitted material facts necessary to make the statement not misleading. Specifically, the (purported) risk warning was materially false and/or misleading when made because it failed to warn investors: (i) that ZBH would be unable to satisfy demand for its products while remediating the QS deficiencies at the North Campus; and (ii) that ZBH would have to disrupt production and distribution of key products because ZBH was manufacturing, sterile packing, and distributing products from the North Campus despite knowing that "systemic issues" with the QS had not been adequately remediated and knowing that an FDA inspection of the facility was imminent.

278. Additionally, the statement set forth above in ¶276 was materially false and/or misleading because it failed to disclose: (i) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming and costly remediation and corrective activities; (ii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iii) that an FDA inspection of the Legacy Biomet North Campus was imminent; (iv) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus; and (v) that as a result of the foregoing, ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016.

279. The 2015 10-K, which was incorporated by reference into the June SPO

Materials, contained a number of stale risk factors that purported to caution investors about risks and uncertainties that had not occurred. Additionally, the Q1'16 10-Q, which was also incorporated by reference into the June SPO Materials, directed investors to the same stale risk warnings contained in the 2015 10-K and added: "***There have been no material changes in our risk factors from those disclosed in our Annual Report*** on Form 10-K for the year ended December 31, 2015."

280. The June SPO Materials incorporated the following risk factor from the 2015 10-K and the Q1'16 10-Q (which had been incorporated from the 2015 10-K):

> **Successful integration of Biomet and anticipated benefits of the Biomet merger are not assured and integration matters could divert attention of management away from operations. Also, the merger could have an adverse effect on our business relationships.**
>
> Although Biomet has become an indirect wholly owned subsidiary of ours, it is initially continuing its operations on a basis that is separate from the legacy Zimmer operations. There can be no assurance that Biomet will be able to maintain and grow its business and operations . . .
>
> Our ability to realize the anticipated benefits of the Biomet merger will depend, to a large extent, on our ability to integrate the legacy businesses. Integrating and coordinating certain aspects of the operations and personnel of Biomet with ours involves complex operational, technological and personnel-related challenges. This process is time-consuming and expensive, disrupts the businesses of both companies and may not result in the full benefits expected by us, including cost synergies expected to arise from supply chain efficiencies and overlapping general and administrative functions. The ***potential difficulties, and resulting costs and delays***, include:
>
> • managing a larger combined company;
> • consolidating corporate and administrative infrastructures;
> • ***issues in integrating manufacturing, warehouse and distribution facilities***, research and development and sales forces;
> • difficulties attracting and retaining key personnel;
> • loss of customers and suppliers and inability to attract new customers and suppliers;
> • unanticipated issues in integrating information technology, communications and other systems;

> • incompatibility of purchasing, logistics, marketing, administration and other systems and processes; and
> • unforeseen and unexpected liabilities related to the merger or Biomet's business.
>
> Additionally, the integration of our and Biomet's operations, products and personnel may place a significant burden on management and other internal resources. The attention of our management may be directed towards integration considerations and may be diverted from our day-to-day business operations, and matters related to the integration may require commitments of time and resources that could otherwise have been devoted to other opportunities that might have been beneficial to us. The diversion of management's attention, and any difficulties encountered in the transition and integration process, could harm our business, financial condition and operating results.
>
> Even if our businesses are successfully integrated, we may not realize the full benefits of the merger, including anticipated synergies, cost savings or growth opportunities, within the expected timeframe or at all. In addition, we expect to incur significant integration and restructuring expenses to realize synergies. However, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. These expenses could, particularly in the near term, exceed the savings that we expect to achieve from elimination of duplicative expenses and the realization of economies of scale and cost savings. Although we expect that the realization of efficiencies related to the integration of the businesses may offset incremental transaction, merger-related and restructuring costs over time, we cannot give any assurance that this net benefit will be achieved in the near term, or at all.
>
> Any of these matters could adversely affect our businesses or harm our financial condition, results of operations or business prospects.

281. The statements in ¶¶279-280 were materially false and/or misleading when made for the same reasons set forth above in ¶¶277-278. Additionally, those statements were knowingly and/or recklessly materially false and/or misleading because, despite warning about "potential difficulties, and resulting costs and delays" relating to "issues in integrating manufacturing … facilities," ZBH did not update its risk disclosure in light of the new information from the corporate audit reports (issued on March 31, April 13, and June 7, 2016) alerting ZBH management to the fact that the QS at the Legacy Biomet North Campus were not compliant with FDA standards/regulations and it would require substantial time and money (in

excess of one year and $300 million) to remediate the "systemic issues" and result in substantial disruption to the supply of essential Legacy Biomet products.

282. The June SPO Materials incorporated the following stale risk factor from the 2015 10-K and the Q1'16 10-Q (which had been incorporated from the 2015 10-K):

> **We are subject to various governmental regulations relating to the manufacturing, labeling and marketing of our products, non-compliance with which could adversely affect our business, financial condition and results of operations.**
>
> ***
>
> ***Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. Compliance with the FDA's requirements, including the Quality System regulation,*** recordkeeping regulations, labeling and promotional requirements and adverse event reporting regulations, ***is subject to continual review and is monitored rigorously through periodic inspections by the FDA, which may result in observations on Form 483, and in some cases warning letters, that require corrective action, or other forms of enforcement. If the FDA were to conclude that we are not in compliance with applicable laws or regulations,*** or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of payment of such devices, refuse to grant pending premarket approval applications, refuse to provide certificates to foreign governments for exports, and/or require us to notify healthcare professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions on a company-wide basis, enjoin and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees or us. The FDA may also recommend prosecution to the DOJ. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and could have a material adverse effect on our business, financial condition and results of operations.
>
> In 2012, we received a warning letter from the FDA citing concerns relating to certain processes pertaining to products manufactured at our Ponce, Puerto Rico manufacturing facility. In June 2015, Biomet received a warning letter from the FDA that requested additional information to allow the FDA to evaluate the adequacy of Biomet's responses to certain Form 483 observations issued following an inspection of Biomet's Zhejiang, China manufacturing facility in January 2015. As of December 31, 2015, these warning letters remained pending. Until the violations are corrected, we may become subject to additional regulatory action by the FDA, the FDA may refuse to grant premarket approval applications and/or the FDA may refuse to grant export certificates, any of which could have a

> material adverse effect on our business, financial condition and results of operations. Additional information regarding these and other FDA regulatory matters can be found in Note 20 to the consolidated financial statements.

283. The above statement was materially false and/or misleading when made for the same reasons set forth above in ¶¶277-278.

284. The June SPO Materials incorporated the following stale risk factor from the 2015 10-K and the Q1'16 10-Q (which had been incorporated from the 2015 10-K):

> **Interruption of our manufacturing operations could adversely affect our business, financial condition and results of operations.**
>
> We have manufacturing sites all over the world. In some instances, however, the manufacturing of certain of our product lines is concentrated in one or more of our plants. Damage to one or more of our facilities from weather or natural disaster-related events, or ***issues in our manufacturing arising from*** failure to follow specific internal protocols and procedures, ***compliance concerns relating to the Quality System regulation and Good Manufacturing Practice requirements***, equipment breakdown or malfunction or other factors ***could adversely affect our ability to manufacture our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing affected products or to meet customer demand. In the event of a significant interruption, for example, as a result of a failure to follow regulatory protocols and procedures, we may experience lengthy delays in resuming production of affected products*** due primarily to the need for regulatory approvals. As a result, we may experience loss of market share, which we may be unable to recapture, and harm to our reputation, which could adversely affect our business, financial condition and results of operations.

285. The above statement was materially false and/or misleading when made for the same reasons set forth above in ¶¶277-278.

286. The Company's 2015 10-K, under the heading "Government Regulation and Compliance," contained the following statement:

> . . . [W]e have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. ***We are also subject to periodic inspection by the FDA for compliance with the FDA's Quality System regulations among other FDA requirements***, such as restrictions on advertising

> and promotion. ***The Quality System regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use.*** If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could require us to notify healthcare professionals and others that the devices present unreasonable risks of substantial harm to the public health, order a recall, repair, replacement, or refund payment of such devices, detain or seize adulterated or misbranded medical devices, or ban such medical devices.

287. The Company's Q1'16 10-Q contained the following statement (which was substantially the same as a statement contained in the 2015 10-K) under the heading "Regulatory Matters, Government Investigations and Other Matters:"

> *FDA warning letters*: In September 2012, Zimmer received a warning letter from the U.S. Food and Drug Administration ("FDA") citing concerns relating to certain processes pertaining to products manufactured at our Ponce, Puerto Rico manufacturing facility. In June 2015, Biomet received a warning letter from the FDA that requested additional information to allow the FDA to evaluate the adequacy of Biomet's responses to certain Form 483 observations issued following an inspection of Biomet's Zhejiang, China manufacturing facility in January 2015. We have provided detailed responses to the FDA as to our corrective actions and will continue to work expeditiously to address the issues identified by the FDA during inspections in Ponce and Zhejiang. As of March 31, 2016, these warning letters remained pending. Until the violations are corrected, we may be subject to additional regulatory action by the FDA, including seizure, injunction and/or civil monetary penalties. Additionally, requests for Certificates to Foreign Governments related to products manufactured at the Ponce and Zhejiang facilities may not be granted and premarket approval applications for Class III devices to which the quality system regulation deviations at these facilities are reasonably related will not be approved until the violations have been corrected. ***In addition to responding to the warning letters described above, we are in the process of addressing various FDA Form 483 inspectional observations at certain of our manufacturing facilities.*** The ultimate outcome of these matters is presently uncertain.

288. The 2015 10-K contained the following statement about the Company's outlook for 2016: "We expect pro forma sales growth will improve in the last half of the year compared to the first half as our sales force stabilizes, we take advantage of cross-selling opportunities and we anniversary out of many sales force dissynergies caused by the merger."

289. Under the heading "2016 Outlook," the Company's Q1'16 10-Q also contained the following statement that was substantially similar to the above statement from the 2015 10-K: "We expect pro forma sales growth will improve in the second half of the year compared to the first half as our sales force stabilizes, we take advantage of cross-selling opportunities and we anniversary out of the impact of product line divestitures and certain sales force dissynergies caused by the merger."

290. The statements in ¶¶286-289 incorporated by reference into the June SPO Materials were materially false and misleading and/or omitted material facts necessary to make the statement not misleading. Specifically, the statements were materially false and/or misleading when made because they failed to disclose: (i) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming and costly remediation and corrective activities; (ii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iii) that an FDA inspection of the Legacy Biomet North Campus was imminent; (iv) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus; and (v) that as a result of the foregoing, ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016.

291. The June SPO Materials also failed to provide material information required by Item 303 of SEC Regulation S-K ("Item 303"), 17 C.F.R. §229.303(a)(3)(ii), which mandates that registration statements disclose "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." Similarly, the regulation requires that registration statements disclose events that the registrant knows would "cause a material change

in the relationship between costs and revenues" and "any unusual or infrequent events or transactions or any significant economic changes that materially affected the amount of reported income from continuing operations and, in each case, indicate the extent to which income was so affected." 17 C.F.R. §229.303(a)(3)(i), (ii).

292. The June SPO Materials were materially false and misleading because they failed to disclose the following known adverse trends and/or uncertainties that ZBH was required to disclose under Item 303, including: (i) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming and costly remediation and corrective activities; (ii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iii) that an FDA inspection of the Legacy Biomet North Campus was imminent; (iv) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus; and (v) that as a result of the foregoing, ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016.

293. Additionally, the June SPO Materials were also materially false and misleading because they failed to disclose the additional known adverse trend and/or uncertainty in violation of Item 303: that the Legacy Biomet North Campus required substantial remediation, which would take considerable time and money (which would exceed more than a year and cost upwards of $300 million), which was particularly evident to ZBH and Defendants Dvorak, Florin and Collins in light of the significant time and funds that were being expended for the purported ongoing remediation activities for the Legacy Zimmer West Campus.

3. The July 28, 2016 Statements

294. On July 28, 2016, ZBH issued a press release entitled, "Zimmer Biomet Reports

Second Quarter 2016 Financial Results." For the Company's second quarter ending June 30, 2016, the Company reported net sales of $1.934 billion and provided updated/increased revenue guidance for 2016.

295. The July 28, 2016, press release also provided materially false and misleading "updated" guidance, which ***increased*** ZBH's revenue guidance for 2016: "Organic revenue growth . . . is now expected to be in a range of 2.5% to 3.0%. Previously, the Company estimated full-year revenue growth to be in a range of 2.0% to 3.0% on a similar basis."

296. The above statement in the July 28, 2016, press release was materially false and/or misleading and/or omitted material facts necessary to make the statement not misleading. Specifically, the statements were materially false and/or misleading when made because they failed to disclose: (i) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming and costly remediation and corrective activities; (ii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iii) that an FDA inspection of the Legacy Biomet North Campus was imminent; (iv) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus; and (v) that as a result of the foregoing, ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016.

297. On July 28, 2016, the Company held a conference call with investors, analysts, and the public, to discuss the Company's Q2 2016 financial results (the "July 28th Call") announced that day. Defendants Dvorak, Florin and Marshall participated in the conference call.

298. On the July 28th Call, Defendant Dvorak made the following statement in which he falsely represented, among others, that the Company had reached an inflection point and had

successfully reestablished top-line (*i.e.*, revenue) momentum:

> … I would like to take a moment to reflect on the one-year anniversary of the formation of [ZBH]. …
>
> ***We successfully integrated and leveraged the combined expertise and cultures of the two organizations***, while executing on a highly complementary portfolio of technologies, services and solutions. Our financial results have provided the tangible proof points that Zimmer Biomet reflects our initial vision of an ideal fit.
>
> ***Our Company has reached an important inflection point, having successfully reestablished top-line momentum by beginning to capture the promise of the attractive cross-selling opportunities inherent in our merger, in addition to successfully delivering on our synergy commitments.***
>
> ***
>
> Consistent with this progress, ***Zimmer Biomet generated solid revenue acceleration in the second quarter, again above the top end of our expectations, further validating our strategies to achieve above-market revenue growth by the close of 2016. Our steady advance towards this goal demonstrates the increasing productivity and focused execution of our commercial organization and for the balance of the year, will continue to exploit the opportunities presented by our differentiated musculoskeletal portfolio.***

299. The above statement was materially false and/or misleading when made for the same reasons set forth above in ¶296. Additionally, Defendant Dvorak's statement was knowingly and/or recklessly false or misleading because: (i) ZBH had not "reached an important inflection point" and did not have the ability to "capture the promise of the attractive cross-selling opportunities" because ZBH was facing substantial remediation work at the North Campus that would limit production of key brands/products strategically relevant to accelerating revenue in the second half of 2016; and (ii) ZBH had not "successfully integrated and leveraged the combined expertise and cultures of the two organizations," because (a) ZBH had to remediate "systemic issues" with the QS at the Legacy Biomet North Campus, which required substantial time and expense, and (b) ZBH had identified "quality culture issues" with the North Campus.

300. On the July 28th Call, Defendant Dvorak made the following statement: "As

anticipated, the cross-selling opportunities of our market-leading knee portfolio continue to drive growth, led by the ongoing sales performance of premium reconstructive systems such as our flagship Persona, the Personalized Knee System and the Vanguard 360 Revision Knee System."

301. The above statement was materially false and/or misleading when made for the same reasons set forth above in ¶296. Additionally, Defendant Dvorak's statement was knowingly or recklessly false or misleading because: (i) supply of the Vanguard product was limited or would be substantially limited because of the required remediation work at the North Campus; and (ii) because ZBH had continued to knowingly distribute Vanguard product manufactured, cleaned, sterile packed, and sterilized at the North Campus while knowing of "systemic issues" with the QS at the North Campus, and there was a near certainty that when the FDA inspected the North Campus, the FDA would take action, or the Company would have to voluntarily take preemptive action, to limit the further distribution of any Vanguard product previously manufactured, cleaned, sterile packed, and sterilized during that time.

302. On the July 28th Call, Defendant Florin made the following statement: "We ***remain on track to deliver cumulative net EBIT merger synergies of $225 million by the end of 2016*** which is ahead of our expectations at the time of the merger closing and consistent with our full year of guidance."

303. The above statement was materially false and/or misleading when made for the same reasons set forth above in ¶296. Additionally, Defendant Florin's statement was knowingly and/or recklessly false or misleading because Defendant Florin omitted that despite being purportedly on track to deliver the synergies, the Company had also approved significant remediation funding (approved by Defendant Dvorak) to address the "systemic" issues with the North Campus and that even more substantial time and funding would be necessary to fully

address the issues (which would later cost upwards of $300 million). Touting being on track to achieve the stated synergies was materially misleading without also disclosing the unexpected expenses the Company was facing to remediate the QS at the North Campus and that would likely offset a substantial or majority of the synergies that Defendant Florin was touting.

304. On the July 28th Call, Defendant Florin made the following statement:

> I will provide updated revenue and adjusted earnings per share guidance for the full year as well as our expectations for the second half of the year. ***Our guidance reflects continued accelerating sales momentum, consistent with our prior expectations*** . . . .
>
> . . . [O]***rganic revenue growth, on a constant currency adjusted pro forma basis, is now expected to be in a range of 2.5% to 3.0%. Previously, the Company estimated full-year revenue growth to be in a range of 2.0% to 3.0% on a similar basis.***

305. During the July 28th Call, Defendant Florin also stated: "As we look to the second half of the year, revenue growth is expected to be in a range of 4.0% to 5.0% for both the third and fourth quarter . . . ."

306. The above statements in ¶¶304-305 were materially false and/or misleading when made for the same reasons set forth above in ¶296.

307. On the July 28th Call Defendant Florin also stated: "… [I]mportantly, as we said in our prepared remarks, ***with the Biomet integration, solidly on track and accelerating revenue growth that it really does put us in a position to make important strategic investments*** . . . ."

308. The above statements in ¶307 were materially false and/or misleading when made for the same reasons set forth above in ¶296. Additionally, Defendant Florin's statement was knowingly or recklessly false and misleading because: (i) organic revenue growth was not accelerating; and (ii) the integration of Legacy Biomet was not "solidly on track" because ZBH corporate management had learned of substantial regulatory gaps at the North Campus (which

necessitated Defendant Dvorak approving special remediation funding in July 2016) and would require substantial time and expense to bring the North Campus QS and procedures in line with regulatory standards.

4. The August 8, 2016 Quarterly Report On Form 10-Q

309. On August 8, 2016, ZBH filed its Quarterly Report on Form 10-Q for the 2016 second quarter (the "Q2'16 10-Q") with the SEC. The Company's Q2'16 10-Q reaffirmed the Company's financial results previously announced on July 28, 2016, and was signed by Defendants Florin and Collins.

310. Under the heading "Regulatory Matters, Government Investigations and Other Matters," the Q2'16 10-Q contained the following statement:

> *FDA warning letters*: In September 2012, Zimmer received a warning letter from the U.S. Food and Drug Administration ("FDA") citing concerns relating to certain processes pertaining to products manufactured at our Ponce, Puerto Rico manufacturing facility. In June 2015, Biomet received a warning letter from the FDA that requested additional information to allow the FDA to evaluate the adequacy of Biomet's responses to certain Form 483 observations issued following an inspection of Biomet's Zhejiang, China manufacturing facility in January 2015. In May 2016, Zimmer received a warning letter from the FDA related to observed non-conformities with current good manufacturing practice requirements of the Quality System regulation at our facility in Montreal, Quebec, Canada. We have provided detailed responses to the FDA as to our corrective actions and will continue to work expeditiously to address the issues identified by the FDA during inspections in Ponce, Zhejiang and Montreal. As of June 30, 2016, these warning letters remained pending. Until the violations are corrected, we may be subject to additional regulatory action by the FDA, including seizure, injunction and/or civil monetary penalties. Additionally, requests for Certificates to Foreign Governments related to products manufactured at the Ponce facility may not be granted and premarket approval applications for Class III devices to which the quality system regulation deviations at these facilities are reasonably related will not be approved until the violations have been corrected. ***In addition to responding to the warning letters described above, we are in the process of addressing various FDA Form 483 inspectional observations at certain of our manufacturing facilities.*** The ultimate outcome of these matters is presently uncertain.

311. The Q2'16 10-Q also contained the following statement:

Results for the Three and Six Month Periods ended June 30, 2016

> Our results have been significantly impacted by the Biomet merger. In 2016, ***we have continued to make progress in our*** commercial and ***operational integration across all geographies and functions***. As we expected, our sales growth rates were below market growth rates in the first half of 2016, ***but we saw sequential improvement from the second half of 2015 and expect to end 2016 at or above market growth rates***.

312. The above statements in ¶¶310-311 were materially false and/or misleading and/or omitted material facts necessary to make the statement not misleading. Specifically, the statements were materially false and/or misleading when made because they failed to disclose: (i) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming and costly remediation and corrective activities; (ii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iii) that an FDA inspection of the Legacy Biomet North Campus was imminent; (iv) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus; and (v) that as a result of the foregoing, ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016.

313. The Q2'16 10-Q also directed readers to risk warnings in the 2015 10-K and contained the following statement: "Except as set forth below, ***there have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015***."[61]

314. The above statement, along with the incorporated risk warning statements from

[61] The Q2'16 10-Q added one risk warning purporting to caution investors that "[w]e may not be able to effectively integrate newly acquired businesses into our operations or achieve expected cost savings or profitability." Three other changes/updates to the risk warnings pertained to unrelated matters such as the United Kingdom's referendum on whether to leave the European Union, future sales by stockholders (*i.e.*, KKR and TPG) into the public market, and a prior governmental investigation of Biomet by the SEC and DOJ.

the 2015 10-K quoted above in ¶¶279, 280, 282, 284 were materially false and/or misleading when made for the same reasons set forth above in ¶¶277-278. As explained above, these (purported) risk warnings were materially false and/or misleading when made because they failed to warn investors that, among others: (i) the Company would have to disrupt production/distribution of products because ZBH was manufacturing and distributing products from the North Campus – despite "systemic issues" with the QS – when an FDA inspection of the facility was imminent; and (ii) the Company would be unable to continue satisfying the demand for its products while remediating the "systemic issues" with the North Campus' QS identified in corporate audit reports on March 31, April 13, and June 7, 2016.

5. The August 2016 SPO Materials

315. On August 9, 2016, ZBH and certain ZBH investors, consisting of affiliates of KKR and TPG, offered for sale 7,440,675 shares of ZBH common stock in an underwritten public offering. Those selling shareholders received all of the proceeds of the offering and ZBH did not receive any of the proceeds even though ZBH participated in offering the shares. Ultimately, the selling shareholders sold the 7,440,675 shares of ZBH common stock at a price of $129.75 per share, for net proceeds of approximately $960 million.

316. On February 4, 2016, ZBH filed the Registration Statement on Form S-3 with the SEC in connection with the August 2016 Offering. The Registration Statement was signed by Defendants Dvorak, Florin and Collins.

317. ZBH supplemented the Registration Statement with a Preliminary Prospectus Supplement filed with the SEC on August 9, 2016 (the "August Preliminary Prospectus") and a Final Prospectus Supplement filed with the SEC on August 11, 2016 (the "August Final Prospectus" and together with the Registration Statement and the August Preliminary Prospectus,

the "August SPO Materials").

318. The August SPO Materials incorporated by reference, among others: (i) ZBH's Annual Report on Form 10-K for the year ended December 31, 2015 (filed on February 29, 2016); (ii) ZBH's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (filed with the SEC on May 10, 2016); and (iii) ZBH's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 (filed with the SEC on August 8, 2016).

319. The August SPO Materials were defective because they contained untrue statements of material facts and/or omitted to state facts necessary to make the statements made therein not misleading and the August SPO Materials were not prepared in accordance with the rules and regulations governing their preparation.

320. The August SPO Materials repeated and incorporated the false/misleading statements from the June SPO Materials (which were incorporated by reference from the Company's 2015 10-K and Q1'16 10-Q) contained above in ¶¶279, 280, 282, 284, 286-288. Those statements were materially false or misleading and/or omitted material facts required to be stated therein, for the same reasons set forth in ¶¶277-278, 290.

321. The August SPO Materials incorporated the same statements from the Q2'16 10-Q contained in ¶¶310, 311, 313, 314, which were materially false or misleading and/or omitted material facts required to be stated therein, for the same reasons set forth in ¶¶312, 315.

322. The August SPO Materials were also materially misleading because ZBH and Defendants Dvorak, Florin, and Collins, knowingly and/or recklessly omitted material information required to be disclosed under Reg. S-K Item 303. As alleged above in ¶¶291-293, with respect to the June SPO Materials, the August SPO Materials failed to disclose the same known adverse trends and/or uncertainties identified above in ¶¶292-293 that were omitted from

the June SPO Materials.

6. The September 7, 2016, Wells Fargo Securities Healthcare Conference Statement

323. On September 7, 2016, ZBH participated in the Wells Fargo Securities Healthcare Conference. Defendant Marshall was present to represent ZBH.

324. During the September 7, 2016 Wells Fargo conference, an analyst from Wells Fargo asked: "***And given that you plan to exit 2016 growing at 3.5% to 4.5%, it would seem reasonable to expect you to grow at least 4% in 2017 on an organic basis. Is there anything that you'd point to that would make that a challenge***? The push back I get on 2017 is that the comps get tougher."

325. In response to the above question, Defendant Marshall made the following statement:

> Well, I mean, it would have -- and ***it's true, we have put out a longer-range goal for sustainable long-term growth. And we do believe that that is in that 4%-plus for just kind of the same reasons we were just talking about. And yes, the back half is a range of 2.5% to 4.5% on an organic basis. So it's reasonable to think that we can build on that momentum.***
>
> But as we think in terms of we're not here to give guidance on 2017, going to a strategic planning process at this point in time, so obviously during that planning process you evaluate the markets in which you're playing. ***So I do think that it does seem reasonable to think in terms of building on the momentum that we exit the year. So I think that that's -- particularly as you get more productivity out of your sales channels and you get all of your different categories and geographies growing at market***, that even though the comps may be different next year, you don't have a full year of any sort of building back towards market.

326. The above statement was materially false and/or misleading and/or omitted material facts necessary to make the statement not misleading. Specifically, the statements were materially false and/or misleading when made because they failed to disclose: (i) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming

and costly remediation and corrective activities; (ii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iii) that an FDA inspection of the Legacy Biomet North Campus was imminent; (iv) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus; and (v) that as a result of the foregoing, ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016.

7. The September 12, 2016 Morgan Stanley Global Healthcare Conference Statements

327. On September 12, 2016, ZBH participated in the Morgan Stanley Global Healthcare Conference. Defendants Dvorak and Florin participated on behalf of ZBH.

328. At the start of the session involving ZBH, an analyst from Morgan Stanley started off by stating:

> We had a really interesting morning presentation. We talked about how Medtech has been the outperforming sector of healthcare for the first time in several years, and Zimmer is one of the companies leading the charge in doing that. So it's my pleasure to have with us here morning both the CEO and CFO of Zimmer Biomet, David Dvorak and Dan Florin. ***David has said we can dispense with preamble commentary.*** We're going to jump right into Q&A.

329. As noted above, during the September 12, 2016, Wells Fargo conference, Defendant Dvorak instructed the Morgan Stanley analyst to "dispense with the preamble" and during their presentation at the conference, Defendants Dvorak and Florin neither identified their subsequent statements as forward looking nor provided any meaningful cautionary language.

330. At the outset of the September 12, 2016, Morgan Stanley conference, the analyst from Morgan Stanley asked Defendant Dvorak the following question: "I want to give you a chance to review. We sat here a year ago. It was a fundamentally different time for Zimmer Biomet. A deal had just closed, there was a dramatic amount of concern around growth rates.

Growth rates have begun to recover. It's a fundamental different investor perception now versus a year ago. How do you think the deal has gone?"

331. In response to the above question, Defendant Dvorak made the following statement:

> Yes, I think that the deal has validated the major premises that led us to the transaction in the first instance and our execution. And that was why, when we were sitting here last year, David, we were highly confident in our ability to deliver an improved top-line growth trajectory. ***We've reestablished that momentum.*** And part of the basis for that belief and the confidence was that these businesses independently had each generated mid-4% top-level growth prior to the combination.
>
> There was a long pendency period because of the antitrust regulatory review; that went on for 14 months. And so we were just coming off of that, had closed the deal maybe a month or two prior to getting together with you last year, and ***since then we've executed our synergy plans. We've been very successful; actually increased from the initial predictions what we would generate by way of operating synergies. And we've been at or above expectations this year on top-line resurgence. The team is executing very well.*** But as I said, I think fundamentally the major premises for the deal are validated with the performance that we've delivered so far this year.

332. During the September 12, 2016, Morgan Stanley conference, the analyst from Morgan Stanley asked the following question:

> So, it's a complicated integration and company. From a stock perspective, though, we think it's a pretty simple thesis, right? Organic growth acceleration and then earnings growth inflection. Those two things should drive the stock, and they are and we think they'll continue. So, let's talk about this first component, which is organic growth acceleration.
>
> I think at the time of the LDR transaction a few months back you had a lot of conviction that that second quarter was going to see acceleration. ***Talk to us about what's driving that near-term acceleration of organic growth and what your conviction is that that pathway to further growth acceleration continues into the back half of this year and 2017.***

333. In response to the above question, Defendant Dvorak made the following statement:

> Sure. The advantage that the government provided us with the long pendency period prior being able to close the deal was we were able to do a lot of planning. ***So we put together very detailed integration plans. In fact, there were in excess of 8,000 milestones, the majority of which have now been fully executed and realized.***
>
> But right on the front-end, priority wise, was the commercial channel integration. So we appointed the leaders throughout the globe at the senior level. That process cascades down all the way to sales representatives being reappointed by way of territories; compensation programs; clarity as to what product bag they are going to be carrying. Cross training on the product bag, because we've had gabs, relatively speaking, in each of the legacy Zimmer and Biomet organizations.
>
> ***And so as a consequence, the scale and the breadth and the comprehensiveness of the product bag is greatly enhanced by the combination. And so, we knew that it was just a matter of time if we were executing the right plans that we were going to see the cross-sell start to take place. Some of the understood and forecasted revenue dissynergies were going to dissipate, and that's exactly what you've seen as this year has progressed.***
>
> ***We began executing those synergy plans, the cross-sell with the products. We're kicking in in Q1, Q2; continuing into the second half of the year. Meanwhile, the revenue dis-synergies that were fully expected start dissipating and anniversarying out. That's why we are confident we're going to get back to at or above market growth rate as we exit this year.***

334. The above statements in ¶¶331-333 were materially false and/or misleading and/or omitted material facts necessary to make the statement not misleading. Specifically, the statements were materially false and/or misleading when made because they failed to disclose: (i) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming and costly remediation and corrective activities; (ii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iii) that an FDA inspection of the Legacy Biomet North Campus was imminent; (iv) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus; and (v) that as a result of the foregoing, ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016.

335. During the September 12, 2016, Morgan Stanley conference, the analyst from

Morgan Stanley asked the following question to Defendant Florin:

> So Dan, the second quarter took a step forward on organic growth. I think the investors were happy the stock has been inflecting . . . That being said, I felt the second quarter message harshed my mellow to a certain extent on my earnings thesis. Because you talked about lower buybacks because of LDR and some other headwinds in the business, most notably currency, less hedging gain.
>
> ***So, I kind of left the second quarter a little more nervous about earnings outlook, even though our thesis is a very powerful one about earnings. So talk to us about why we heard more about headwinds on the second-quarter call than potential tailwinds***?

336. In response to the above question, Defendant Florin made the following statement:

> Well, I think first, David, you have to keep in mind that we've grown earnings 22% year-on-year since the merger closed. And for 2016, we're going to deliver 15% or so earnings growth. So, that very much is intact. ***Our synergy program is absolutely -- continues to provide tailwinds from an earnings perspective. We talked about $225 million of net EBIT synergies by the end of this year, and then $350 million of net EBIT synergies by the middle of 2018. So that's very much intact.***
>
> ***At the same time you've seen -- with that earnings growth, you've also seen this accelerating top line.*** And that really is by virtue of what David [Dvorak] has described. And also the investments that we continue to make back into the business: the sales force specialization; medical training and education; instrument deployments. Our signature solutions platform, which is all about the continuum of care and innovating across that whole continuum of care are important investments that we continue to make into the business.
>
> ***As we look at the back half of the year, we've reiterated our earnings guidance for the full year.*** LDR, as we've described, is a company with a high growth profile but with some operating losses. So we're absorbing that while making these strategic investments, and then delivering earnings at the high-end of our original guidance for 2016.

337. The above statement was materially false and/or misleading and/or omitted material facts necessary to make the statement not misleading. Specifically, the statements were materially false and/or misleading when made because they failed to disclose: (i) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming

and costly remediation and corrective activities; (ii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iii) that an FDA inspection of the Legacy Biomet North Campus was imminent; (iv) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus; and (v) that as a result of the foregoing, ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016. Additionally, the above statement was knowingly or recklessly materially false or misleading because Defendant Florin did not identify any of the foregoing issues as potential "headwinds" in response to the question.

338. During the September 12, 2016, Morgan Stanley conference, when asked about "the potential continued tailwinds into 2017 and 2018," Defendant Florin made the following statement: "I would think of the tailwinds continuing to be our step plan on synergies. So you'll see another installment of synergies in 2017 and 2018. ***Our top-line growth continuing to accelerate***. . . ."

339. The above statement was materially false and/or misleading and/or omitted material facts necessary to make the statement not misleading for the reasons set forth above in ¶337. Additionally, the above statement was knowingly and/or reckless false or misleading because touting the synergies of the Merger was misleading by not also disclosing the substantial remediation expenses for the North Campus that Defendant Dvorak had approved in July 2016 to address the "systemic issues," or the additional necessary remediation costs (upwards of $300 million) that were needed, all of which would substantially offset a significant amount of the highlighted synergies.

340. During the September 12, 2016 Wells Fargo conference Defendant Florin made

the following statement: "***We continue to feel very good about our $225 million this year and our path to $350 million.*** To the extent there are excess synergies, we first and foremost would look to reinvest that into top-line growth. Top-line growth in that mid-single digit range is a high priority for us, and that's where we'd to look first and foremost to reinvest any excess synergies."

341. The above statement was materially false and/or misleading and/or omitted material facts necessary to make the statement not misleading for the reasons set forth above in ¶337. Additionally, the above statement was knowingly and/or reckless false or misleading because touting the synergies of the Merger was misleading by not also disclosing the substantial remediation expenses for the North Campus that Defendant Dvorak had approved in July 2016 to address the "systemic issues" or the additional necessary remediation costs (upwards of $300 million) that were needed, all of which would substantially offset a significant amount of the highlighted synergies.

8. The October 31, 2016 Conference Call Statements

342. On October 31, 2016, ZBH held a public conference call with investors and analysts to discuss the Company's financial results announced that same day. Defendants Dvorak, Florin, and Marshall participated in the conference call.

343. During the October 31, 2016 conference call, Defendant Dvorak made the following statement:

> ***Variable commercial performances by our sales teams were in part caused by unanticipated supply constraints, related to our transitioning supply chain infrastructure.*** This resulted in shortfalls of needed implants and additional instrument sets, to fully exploit sales opportunities in key product categories.
>
> ***In response to this challenge, we've accelerated work to enhance certain aspects of our supply chain infrastructure as we harmonize and optimize our sourcing, manufacturing and quality management systems.*** Through these efforts, we expect to improve our demand fulfillment in the coming months.

> ***As a consequence of these supply constraints, we project fourth quarter sales results to be similar to those of the third quarter;*** however, as we look ahead, we remain confident in our ability to successfully reaccelerate our revenue growth in 2017. As I mentioned, demand for our expansive portfolio of differentiated and clinically proven musculoskeletal technologies, solutions and services has never been stronger.

344. The above statement was materially false and/or misleading and/or omitted material facts necessary to make the statement not misleading. The statement was materially false and/or misleading when made because it failed to disclose: (i) that the true cause of the supply shortages in Q3'16 and lowered Q4'16 organic revenue guidance was the disruption being caused by a disastrous ongoing FDA inspection of the North Campus; (ii) that there were "systemic issues" with the QS at the North Campus; (iii) that ZBH lacked the ability to meet demand for its products while remediating the issues at the North Campus; and (iv) that Defendant Dvorak and Florin had attempted to persuade Barney to concoct a story to cover up the reason for the sales shortfall and supply shortages in Q3'16, and that Barney, a senior executive of ZBH and key employee to ensuring the continued operations of the Company could recover from the rampant manufacturing/regulatory problems, had resigned in protest over being asked to participate in Defendant Dvorak and Florin's cover up.

345. During the October 31, 2016, conference call, Defendant Florin made the following statements:

> Third-quarter revenue was below our expectations, ***primarily due to execution issues within our large joints supply chain, which led to a degradation in order fulfillment rates late in the quarter***, as well as our performance in dental. As noted by David, customer demand was strong in the quarter, ***but certain aspects of our supply chain integration impacted our ability to effectively respond to shifting product mix, most notably within*** our knee ***and hip portfolios***.
>
> ***As a consequence, we underestimated demand for certain key cross-sell brands within our existing customer base, leading to a depletion of our safety stocks, and also affecting our ability to capitalize on new customer opportunities. We are working diligently to enhance our supply chain processes and execution***,

> particularly in the areas of demand forecasting, global inventory tracking, and asset deployment systems, while we replenish our safety stock levels.
>
> ***However, these issues have some carryover effect into the fourth quarter, which I will address shortly in the context of our updated Q4 guidance.***
>
> ***
>
> I'd like now to review our guidance. ***As we look to the fourth quarter, revenue growth is expected to be in a range of 1.6% to 2.6%*** . . .

346. Similarly, during the October 31, 2016, conference call Defendant Florin also stated:

> And our current supply chain not being fully integrated did hamper our ability to respond effectively to this shifting product mix. And while not anticipated, we understand the root causes. We understand the fixes that are necessary and we're highly confident in our ability to implement those changes. It will take several months to make those corrections.

347. The above statements in ¶¶345-346 were materially false and/or misleading and/or omitted material facts necessary to make the statement not misleading for the same reasons set forth above in ¶344. Additionally, the statements were knowingly or recklessly false or misleading because the primary problem was not that ZBH had "underestimated demand" but really that the Company was forced to "voluntarily" stop production/distribution out of its North Campus facility because of an ongoing FDA inspection and the existence of "systemic issues" with the QS at the North Campus that had not been remediated.

B. Additional Allegations Regarding The Officer Defendants' Scienter

348. As alleged herein, Defendant ZBH and the Officer Defendants acted with scienter since Defendant ZBH and the Officer Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public;

and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Officer Defendants, by virtue of their receipt of information reflecting the true facts regarding ZBH, their control over, and/or receipt and/or modification of ZBH's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning ZBH, participated in the fraudulent scheme alleged herein.

349. The Officer Defendants knew or recklessly disregarded the false and misleading nature of the information that they caused to be disseminated to the investing public. The ongoing fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company, including the Officer Defendants.

350. The following additional facts give rise to strong inference that ZBH and the Officer Defendants acted with scienter.

351. The fraud alleged herein relating to concealing of the true state of affairs with respect to the QS deficiencies at the North Campus, ZBH's inability to increase organic revenue growth to above market level, and the Company's inability to satisfy demand for its products (while remediating the issues at the North Campus), all involved ZBH's core operations, and knowledge of the fraud may therefore be imputed to the Officer Defendants. Specifically, the North Campus was one of the Company's primary and most important manufacturing facilities and the successful integration of the Legacy Zimmer and Legacy Biomet operations following the colossal $13 billion Merger was undoubtedly crucial to the Company's viability and success.

352. With respect to the North Campus, Defendant Florin acknowledged on multiple

occasions, including at a February 2017 Leerink Partners Global Healthcare Conference, that the North Campus was "one of our major production facilities." Defendant Dvorak noted on the April 27, 2017 1Q'17 earnings call that the products produced at the North Campus were a vital part of the Company's promised accelerated revenue growth in 2016 from cross selling opportunities: "some of these key brands that come out of that facility provide us with some of our best competitive opportunities, so they're a very important set of brands and strategically relevant to the acceleration of the top line."

353. Defendants Dvorak and Florin were substantially involved in the planning and monitoring of the integration of the Legacy Biomet and Legacy Zimmer operations. According to a Form 425 filed with the SEC by LVB Acquisition Group, Inc. on October 23, 2014, Defendants Dvorak and Florin were both members of the Integration Steering Committee ("ISC"), which was established in June 2014. The ISC was responsible for a "smooth and seamless integration planning effort" and was to meet weekly to review progress of the teams on integration planning. The ISC: (a) set priorities and strategic direction for the new company; (b) established the overall process for planning the integration; (c) established goals and identified opportunities that will create value and bring together the best of both companies; (d) worked closely with the Integration Management Office ("IMO") to evaluate the progress of integration planning and resolve any emerging issues that require ISC attention; (e) monitored integration planning teams' weekly updates and monthly submissions; and (f) conducted detailed reviews ("deep dives") of integration planning teams' plans to ensure that they were in line with the priorities established for the new company.

354. The Officer Defendants, as members of ZBH corporate management, had access to and reviewed reports and information about ZBH's sales, internal projections, inventory, and

corporate audit reports of the North Campus. According to a J.P. Morgan report issued on October 31, 2016, which recounted a conversation the J.P. Morgan analyst had with ZBH management about the 3Q'16 supply issues, ZBH management admitted that "management sees daily sales reports for the US businesses and gets updated weekly sales projections from every business around the globe." The report also indicated that management received monthly supply chain reports.

355. In the December 21, 2016 Letter, ZBH acknowledged/admitted that "corporate management" had had access to, and had learned of the "systemic" issues at the North Campus from the corporate audit reports of the North Campus issued on March 31, April 13, and June 7, 2016. The December 21, 2016 Letter admits that Defendant Dvorak knew of these issues because he personally approved certain funding to address the "systemic" issues at the North Campus in July 2016.

356. Additionally, as alleged at ¶94, FDA regulations make senior company management responsible for ensuring adherence to cGMP. Defendant Dvorak, as the CEO of the Company, was directly responsible for ensuring the products manufactured at the North Campus, were produced in accordance with cGMP. The Officer Defendants were aware of FDA policy with respect to cGMP and understood and appreciated the ramifications if ZBH failed to comply with FDA requirements, as indicated in the Company's annual report to shareholders filed with the SEC on February 29, 2016. Despite this responsibility and admittedly knowing of "systemic" issues that had not been remediated, Defendant Dvorak and the other Officer Defendants knowingly permitted or recklessly disregarded that ZBH was continuing to manufacture and distribute products that were manufactured, cleaned, sterile packed, and sterilized at the North Campus.

357. Furthermore, as indicated below at ¶365, corporate compliance and regulatory compliance, including product quality and safety, were considered in Defendant Dvorak's and Defendant Florin's performance evaluations.

358. The Officer Defendants were also well aware of the FDA regulations, including the industry requirements and timing of FDA inspections, by virtue of their extensive industry experience. Because, as alleged *supra* at Section VII.D.1, the FDA had conducted inspections at the North Campus in June 2014 resulting in an FDA 483, the Officer Defendants were well aware and reasonably expected that another biennial inspection would occur by June 30, 2016, or soon thereafter.

359. According to the Company's Proxy Statement filed with the SEC on March 21, 2016, the Company's Board of Directors, of which Defendant Dvorak was a member, was responsible for overseeing risk management and "the full Board considers specific risk topics, including risk-related issues pertaining to laws and regulations enforced by the U.S. Food and Drug Administration." Like the other members of ZBH's Board of Directors, Defendant Dvorak and the other Officer Defendants were highly skilled and experienced veterans of some of the medical device and healthcare industries' largest corporations, and they were familiar with FDA regulations, manufacturing requirements, and the timing and nature of FDA inspections, as well as the grave consequences that would result if the FDA discovered that ZBH was continuing to manufacture and distribute products from the North Campus without having adequately remediated known "systemic" issues with the QS.

360. By virtue of serving as a ZBH director, Defendant Dvorak also had access to and was provided with other types of critical information. For example, the March 21, 2016, Proxy Statement also indicated that "The Board is routinely informed of developments that could affect

our risk profile or other aspects of our business."

361. The Officer Defendants also had access to and received important information about regulatory risks from the Company's Audit Committee. The March 21, 2016 Proxy Statement indicates that the audit committee is "tasked with overseeing our compliance with legal and regulatory requirements, ***discussing our risk assessment and risk management processes with management*** and receiving information on material legal and regulatory affairs, including litigation."

362. In light of the Officer Defendants' complete dereliction of their duties by permitting the Company to continue distributing products from the North Campus in the face of known "systemic" issues, the Company's most recent Proxy statement filed with the SEC on March 30, 2017, indicates that "to provide an additional layer of oversight and review of these important matters," the Board of Directors has "decided to establish explicit Board committee responsibility for oversight of FDA regulatory compliance, including product quality and safety." Specifically, the Proxy states:

> We expect that the [Research, Innovation and Technology] committee will be ***re-named to incorporate the word "Quality"*** and that its charter will be amended to address its expanded scope of responsibilities, including the following:
>
> - providing assistance to the Board in its oversight of product quality and safety; and
> - overseeing risk management in the area of product quality and safety, ***including reviewing processes in place to monitor and control*** product quality and safety; periodically ***reviewing results of product quality and quality system assessments by the company*** and external regulators; and reviewing any significant product quality issues that may arise.

363. The Officer Defendants were also highly motivated to conceal the adverse facts about the North Campus (rather than take prompt remediation actions, which would have stopped ZBH's ability to reaccelerate revenue growth) and conceal adverse facts about the

problems with the integration of the Legacy Zimmer and Legacy Biomet operations, because of ZBH's executive compensation program, which included annual and long-term incentive programs, as well as, a Zimmer Biomet Cash Integration Incentive. These incentives were based on weighted performance metrics, including 35% constant currency revenue; 35% Adjusted operating profit; 10% Free Cash Flow; and 20% Adjusted EPS.

364. For example, Defendant Florin admitted that the Officer Defendants were highly motivated by ZBH compensation plans to achieve organic revenue growth. Before the Class Period, during a March 16, 2016, industry conference, Defendant Florin stated: "***The management team is very focused on driving organic growth and to the point that our incentives are weighted towards driving organic revenue growth.*** So we understand the import of that. We are focused on it and feel really bullish about our opportunity to drive that acceleration."

365. Specifically, under the programs, the revenue target must be achieved at 95% for a 50% payout; other metrics must be achieved at 90% for a 50% payout. Achievement below these thresholds would result in zero payout. The committee would also consider individual performance and consider goals pertaining to corporate strategy, corporate compliance and regulatory compliance, including product quality and safety, among other areas. Defendant Dvorak was rewarded $1,205,714 and Defendant Florin was rewarded $422,357 based on the Company's 2016 net earnings achievement, representing an 83.4% weighted payout.

366. In June 2015, the compensation committee adopted a three-year cash integration incentive plan upon the closing of the Merger "to promote the integration of [Legacy] Zimmer and [Legacy] Biomet, which is critical to our long-term value creation strategy and to achieving target synergies over the first three years post-closing." The 2016 performance measure was

Earnings before interest and taxes from integration cost synergies related to the Merger, net of revenue dis-synergies ("net EBIT synergies") in the amount of $249 million and the Company's actual performance was $252 million, resulting in 100% payouts for Defendant Dvorak and Defendant Florin in the amounts of $727,740 and $254,925 respectively.

367. ZBH also considered performance in awarding long-term equity-based awards and annual equity-based awards. The Company used iTSR, a function of operating profit growth and free cash flow yield, over a three-year period as the performance measure applicable to the PRSU component of the annual LTI grant. The annual equity-based awards in 2016 were an equal mix of stock options and PRSUs.

368. In 2016, Defendant Dvorak earned 76% of the target award earned under the PRSU component of the 2014 LTI grant resulting in $3,750,023 in stock awards, and $2,750,039 in option awards. Defendant Florin's 2016 compensation included $1,000,189 in stock awards and $999,982 in option awards. The stock awards consist of PRSUs at target and Defendant Florin's included a one-time grant of RSUs in 2015 in connection with the Merger and his commencement of employment.

369. At a May 3, 2017, Deutsche Bank Securities Health Care Conference, Defendant Florin acknowledged the focus of these incentives: "So, we're very focused on not just our adjusted earnings, but our GAAP earnings. In fact, our internal incentives include our adjusted – not our adjusted earnings, but our reported earnings, as well as our free cash flow yield. Those metrics drive a lot of our performance-based restricted stock vesting criteria. So we're very focused on all metrics."

370. These metrics were artificially inflated as a result of ZBH's failure to remediate known compliance issues at the North Campus. For example, the Company has estimated the

total remediation costs at $300 million, yet only $38 million of that amount was incurred in 2016 because ZBH failed to timely or adequately take necessary remediation steps until the FDA arrived in September 2016, thereby artificially inflating the performance metrics for 2016.

C. The Private Equity Defendants Sold ZBH Common Stock While In Possession Of Material Nonpublic Information In Violation Of The Exchange Act

371. Section 20A of the Exchange Act provides that "[a]ny person who violates any provision of this chapter or the rules or regulations thereunder by purchasing or selling a security while in possession of material nonpublic information shall be liable in an action . . . to any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased (where such violation is based on a sale of securities) or sold (where such violation is based on a purchase of securities) securities of the same class."

372. The Private Equity Defendants each committed underlying violations of Section 10(b) and Rule 10b-5 thereunder by selling ZBH common stock in the June 2016 Offering and/or the August 2016 Offering while in possession of material nonpublic information about the Company's North Campus (including information that there were "systemic issues" with the QS at the North Campus and that an FDA inspection of the North Campus was imminent), and, consequently, are liable to contemporaneous purchasers of ZBH stock under Section 20A of the Exchange Act. *See* 15 U.S.C § 78t-1(a).

373. Each of the Private Equity Defendants, through their designees to ZBH's Board of Directors and through direct communications from ZBH and the Officer Defendants, possessed material nonpublic information at the times they sold shares in the June 2016 Offering and/or the August 2016 Offering. In total, the Private Equity Defendants collectively sold 18,557,208 shares of ZBH common stock in both offerings for proceeds of approximately $2.25

billion.

374. Material nonpublic information known to the Private Equity Defendants at the time they sold their stock in the June 2016 Offering and August 2016 included, among others, that:

(i) there were "systemic issues" with the QS at the North Campus that would effectively require a total shutdown of the facility to fully remediate but that ZBH was instead continuing to manufacture, sterile pack and distribute products from the North Campus without meaningfully or promptly remediating the issues;

(ii) the North Campus was imminently due for a routine FDA inspection and that ZBH was already being carefully scrutinized by the FDA following a number of highly critical inspections, including a problematic inspection of Legacy Zimmer's primary West Campus facility;

(iii) that ZBH could not satisfy demand for its products while remediating the QS issues with the North Campus; and

(iv) that ZBH could not accelerate organic revenue growth to above market level in the second half of 2016 because of the remediation required to address the "systemic" QS problems at the North Campus.

375. Simply put, the Private Equity Defendants had directly or indirectly owned Legacy Biomet prior to the Merger and possessed nonpublic knowledge about ZBH's operations at the Legacy Biomet North Campus facility that they knew or recklessly disregarded would cause the Company's share price to fall when publicly disclosed, and used the June 2016 Offering and August 2016 Offering to unload all of their holdings at inflated prices before the nonpublic information was revealed. The Private Equity Defendants were able to sell all of their

stock in the June 2016 Offering and August 2016 Offering to the public at prices of $115.85 and 129.75 per share, respectively, as opposed to the $101.83 per share closing price on November 8, 2016, following the final corrective disclosures related to the material nonpublic information at issue here (*i.e.*, the November NCR Report disclosing, among others, supply issues and product holds related an FDA inspection of the North Campus).

1. The Private Equity Defendants Designated ZBH Board Members And Received Material Nonpublic Information From Their Designees

376. In connection with the Merger, the Private Equity Funds entered into a Stockholders Agreement that, *inter alia*, entitled the Private Equity Defendants to designate two members of ZBH's Board of Directors. Pursuant to the Stockholders Agreement, the Private Equity Funds exercised their power under the Stockholders Agreement and designated Defendants Michelson and Rhodes to the Board of Directors (the "Private Equity Designated Directors").[62]

377. The Private Equity Designated Directors had substantial ties to Defendant KKR Biomet and the TPG Defendants. Specifically: (i) Michelson was a member of KKR Management LLC, the general partner of KKR, since October 1, 2009, and was previously, a member of the limited liability company which served as the general partner of KKR; and (ii)

[62] The rights of the Private Equity Funds to designate directors pursuant to the Stockholders Agreement terminated on June 16, 2016, the closing date of the June 2016 Offering, due to the Private Equity Funds beneficially owning at that time less than 30% of the shares of ZBH common stock acquired by the Private Equity Funds as consideration in the Merger. As a result, the Stockholders Agreement required the Private Equity Funds to cause their designated directors, Michelson and Rhodes, to immediately resign from the Board of Directors unless otherwise consented to by a majority of the other directors. However, ZBH temporarily waived such obligation to allow the Board of Directors the opportunity to further discuss its future composition and, following such discussions, the other directors unanimously consented on July 15, 2016, to Michelson and Rhodes continuing to serve as directors of ZBH. Consequently, the Private Equity Defendants were not obligated to cause Michelson and Rhodes to resign from the Board of Directors.

Rhodes was a Partner at TPG, and had been a principal of TPG since 2005.

378. During the Class Period, the Private Equity Designated Directors served as members of at least two committees, including, ZBH's Corporate Governance Committee and Research, Innovation and Technology Committee.

379. The Private Equity Funds and the Private Equity Designated Directors already possessed a detailed knowledge of Legacy Biomet and its primary North Campus facility. The Private Equity Defendants had owned (approximately 97%) and controlled LVB (*i.e.*, Legacy Biomet) prior to the Merger, Michelson had been a director of LVB since 2007, and Rhodes a director of LVB since 2012.

380. Through the Private Equity Designated Directors (and through direct communications with the Company), the Private Equity Defendants were entitled to and did receive material nonpublic information, and, as discussed below, possessed such material nonpublic information about the disastrous regulatory conditions at the North Campus at the times they reaped billions of dollars in proceeds from selling their ZBH shares at artificially inflated prices to Plaintiffs and other unsuspecting Class members.

381. Section 1.6 of the Stockholders Agreement provided for "Information Rights." Specifically, that provision granted the Private Equity Designated Directors certain information and access rights, including, to information related to the management, operations and finances of ZBH and its subsidiaries, as and when provided to the non-management directors. Under the Stockholders Agreement, the Private Equity Designated Defendants were obligated to keep confidential certain ZBH information, subject to certain exceptions, including the ability to share

confidential information with the Private Equity Funds and its affiliates.[63]

382. Importantly, the Stockholders Agreement provided the Private Equity Designated Directors (and, as a result, the Private Equity Funds) with unfettered insight into all the material provided to the Board of Directors, including all materials provided to each committee of the Board of Directors, and the right to attend all committee meetings. Specifically, the Stockholders Agreement provided:

> . . . [T]he Company and its Subsidiaries will give notice of each meeting of any committee of the Board (at the same time such notice is provided to any committee member) to [Private Equity Designated Directors], ***provide all information provided to members of each such committee simultaneously to [Private Equity Designated Directors] and permit the [Private Equity Designated Directors] to attend all such committee meetings as an observer.***

383. During 2015, the Board of Directors held five meetings and committees of the Board held a total of twenty-four meetings. This included eleven meetings of the Audit Committee, six meetings of the Compensation and Management Development Committee, five meetings of the Corporate Governance Committee, and two meetings of the Research, Innovation and Technology Committee.

384. During 2016, the Board of Directors held nine meetings and committees of the Board of Directors held a total of twenty-five meetings. This included twelve meetings of the Audit Committee, six meetings of the Compensation and Management Development Committee, four meetings of the Corporate Governance Committee, and three meetings of the Research, Innovation and Technology Committee. Plaintiffs are informed and believe that one of ZBH's regular board meetings occurred on July 15, 2016, the date on which the Board of Directors

[63] The stockholders agreement contained a number of other provisions that applied during 2016 until the stockholders agreement automatically terminated on August 12, 2016, the closing date of the August 2016 Offering and the date on which the Private Equity Funds no longer owned ZBH common stock. This included the provision providing the ability to share confidential information with the Private Equity Defendants and their affiliates.

discussed and agreed to allow the Private Equity Designated Directors to remain as directors of the Company.

385. Additionally, by virtue of being one of the largest medical device manufacturers and operating in a highly regulated industry, the Company's compliance with FDA regulations was a core operation of the Company. Members of ZBH's Board of Directors were focused on and routinely provided extensive information and reports about ZBH's compliance with FDA regulations. For this reason, as noted in the Company's proxy materials in connection with the Company's 2016 Annual Meeting of Stockholders:

> ***The full Board considers specific risk topics, including risk-related issues pertaining to laws and regulations enforced by the U.S. Food and Drug Administration*** and foreign government regulators and risks associated with our strategic plan and our capital structure. ***In addition, the Board receives detailed regular reports from members of our executive operating committee and other personnel that include discussions of the risks and exposures involved with their respective areas of responsibility.*** Further, ***the Board is routinely informed of developments that could affect our risk profile*** or other aspects of our business.

386. Additionally, the Company's proxy materials also indicated that other committees of the Board of Directors also carefully monitored the Company's regulatory compliance. For example, the Audit Committee was tasked with "overseeing [the Company's] compliance with legal and regulatory matters and aspects of our risk management processes."

2. The Private Equity Funds Sold ZBH Common Stock While In Possession Of Material Nonpublic Information

387. By virtue of the information granted to the Private Equity Funds under the Stockholders Agreement, the Private Equity Funds had fulsome and detailed knowledge about ZBH's extensive problems with the FDA and QS regulations between November 2015 and the time of the June 2016 Offering and the August 2016 Offering.

388. FDA compliance and the Company's North and West Campuses were effectively

ZBH's core operations and were heavily focused on by the Board of Directors. Indeed, Compliance with FDA regulations was one of, if not the most important, risks to ZBH's operations, financial performance, and reputation.[64] Moreover, the Company's West and North Campuses, were the primary manufacturing facilities for Legacy Zimmer and Legacy Biomet during the Class Period.

389. Prior to the June 2016 Offering and the August 2016 Offering, the Private Equity Defendants knew, among others, that: (i) the FDA was carefully scrutinizing and identifying highly problematic QS issues at various ZBH facilities between November 2015 and early 2016; (ii) an FDA inspection of the North Campus was imminent and would occur around June 30, 2016 or shortly thereafter; (iii) corporate audits were conducted in early 2016 (partly in response to the problems with the West Campus design controls) and identified material issues that would require upwards of $300 million and over 1 year to remediate; (iv) that the prior issues with the Legacy Biomet North Campus raised in a June 2014 North Campus FDA 483 had not been remediated; and (v) that ZBH was continuing to manufacture, sterile pack, and distribute products from the North Campus despite the QS issues at the facility.

390. In early 2016, the Private Equity Defendants were made aware that ZBH was under heightened FDA scrutiny. As discussed in detail above, between November 2015 and the Spring of 2016, the Company was in the cross hairs of the FDA and it would be a complete failure of their corporate duties for the Board of Directors to have neither been aware nor to have monitored these issues. The November 2015 West Campus FDA Inspection and the resulting

[64] The Company's reputation and the perception that the devices are safe for use and manufactured and sterilized in accordance with FDA standards was vital to the Company's operations. As with all manufacturers and sellers of Class II and III medical devices, disclosures of FDA regulatory action or quality issues, can negatively impact a company's ability to sell its products.

November 2015 West Campus FDA 483 were highly problematic and presented a real and substantial risk that the FDA would issue a warning letter to the Company because repeated observations from prior inspections had not been remediated.[65] Additionally, in November 2015 the Legacy Zimmer Puerto Rico facility also had a problematic FDA inspection, which was a substantial issue for the Company because ZBH still had an open FDA warning letter from 2012 relating to a different Puerto Rico facility. Additionally, in January 2016, the FDA had conducted a highly critical inspection of the Legacy Zimmer facility in Canada that resulted in the issuance of a warning letter in late May 2016.

391. Also, given the Board of Director's combined experience with FDA regulations and the sophistication of its members, including the experience and sophistication of the Private Equity Designated Directors, it was well known to Private Equity Defendants that the North Campus was due for a routine inspection of the North Campus around June 2016 or soon thereafter. This was also known to them as the former owners of LVB (*i.e.*, Legacy Biomet) because the North Campus was the primary Legacy Biomet manufacturing facility and, as the owners, the Private Equity Defendants knew it was inspected in June 2014 and was up for its regular 2 year inspection around June 2016.

392. Additionally, because of the expected inspection, and, in part because of the substantial QS issues identified at the West Campus, ZBH's Board of Directors would have been hyper-focused on the internal corporate audits of the North Campus that ZBH corporate management had requested in early 2016 (including the design controls audit requested to

[65] Plaintiffs are informed and believe that the November 2015 West Campus FDA Inspection, along with the September 2016 North Campus Inspection are still ongoing and have not yet been closed. The FDA has denied Plaintiffs' requests for copies of the Establishment Inspection Reports from those inspections on the basis that the inspections are still open. As a result, it is presently possible that ZBH will still receive a warning letters relating to one or both inspections.

evaluate the applicability of the lessons learned from the Zimmer West Campus design control 483 observations) in anticipation of the upcoming North Campus inspection. As a result, at the various Board of Directors and committee meetings (and in materials prepared for those meetings), including at Audit Committee meetings (which occurred more frequently), detailed information about the findings of the corporate audit reports issued on March 31, April 13, and June 7, 2016, would have been provided to the Private Equity Defendants informing them of the disastrous conditions at the North Campus.

393. The Private Equity Defendants were fully aware of all this adverse information about ZBH's troubles with the FDA and the issues uncovered with the North Campus. There is no doubt that, at all relevant times, the Private Equity Defendants were fully utilizing their contractual rights under the Stockholders Agreement to access all of the confidential non-public information provided to the Board of Directors about ZBH's management, operations and finances. In late 2015 and leading up until the Class Period, the Private Equity Defendants had substantial investments in ZBH common stock, which they ultimately sold for approximately $2.25 billion. The Private Equity Defendants are among the most sophisticated investors in the world and their resources include expert financial and investment analysts and other investment professionals.[66] In connection with selling their entire holdings of ZBH common stock, the

[66] The individual private equity funds, which comprise the Private Equity Defendants, are managed by leading private equity investors, KKR and TPG, and the private equity arm of the investment bank Goldman Sachs. The strategic importance of Defendant KKR Biomet's investment to the overall KKR franchise underscores the incentives that the individual Private Equity Defendants had to maximize individual profits in advance of the release of materially adverse information. More specifically, KKR publicly lists 30% of its shares on the NYSE through an affiliate KKR & Co. L.P., which reported $73.8 billion assets under management and $52.2 billion fee paying assets under management in for FY16. Prior to the Merger, in fiscal year, [Legacy] Biomet was KKR & Co.'s third largest "significant aggregate portfolio company investment" representing of 2.3% of KKR & Co.'s portfolio investment. Subsequent to the Merger, in 3Q'15, ZBH was its fifth largest aggregate portfolio investment representing 0.9% of

Private Equity Defendants would have ensured that they obtained every piece of available information to which they were entitled under the Stockholders Agreement. Moreover, the Private Equity Defendants would have carefully and fully scrutinized the confidential non-public information provided to the Private Equity Designated Directors (which included all materials provided to directors in connection with all Board of Directors or committee meetings).

394. Adding to this, the Private Equity Defendants, as the prior owners of LVB (*i.e.*, Legacy Biomet), were aware of and appreciated the gravity of the "systemic issues" with the QS at the North Campus and appreciated that the remediation required would be costly, take a substantial amount of time, and worst of all, be highly disruptive to the distribution of products from the facility. Rather than spending/investing the funds to address prior FDA 483 observations from the June 2014 North Campus FDA Inspection, the Private Equity Defendants instead focused on cashing out of their Legacy Biomet investment in the form of a two-step process that would ultimately leave the North Campus QS issues as the future problems of ZBH shareholders. The two-steps involved first merging with Legacy Zimmer, in which the Private Equity Defendants received over $10 billion of cash as consideration, and then second, unloading all of their shares of ZBH stock (that they had received as consideration for the Merger) in public offerings.

395. Indeed, the December 21, 2016 Letter indicates that Legacy Biomet hid the issues with the North Campus from Legacy Zimmer in connection with the Merger:

> Until the Zimmer Biomet merger on June 24, 2015, North Campus had been operating independently and with indications that its quality system was in substantial compliance. Once the merger was completed, the new Zimmer Biomet corporate management team conducted audits, learned of issues through

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KKR & Co.'s portfolio. Accordingly, the auspicious timing of KKR's decision to liquidate its ZBH position locked in millions in additional profits for Defendant KKR Biomet and its investment manager.

the audits ….

396. Finally, by the time of the August 2016 Offering, Defendant KKR Biomet and the TPG Defendants, which sold the last of their ZBH common stock in the August 2016 Offering for nearly $1 billion, were well aware of the issues uncovered by the corporate audit reports in the Spring of 2016. As noted above, Plaintiffs are informed and believe that the Board of Directors held a regular meeting on or around July 15, 2016, and Plaintiffs are informed and believe that the materials provided to the Private Equity Designated Defendants (and, as a result, were provided to Defendant KKR Biomet and the TPG Defendants) provided details about the substantial problems with the North Campus, that an FDA inspection of the North Campus was imminent and could occur any day, and that it was impossible for the issues to be addressed prior to the FDA inspection. Indeed, the timing of the July 2016 meeting coincides with the observation in the December 21, 2016 Letter that Defendant Dvorak had approved limited remediation funding in July 2016. The fact that the CEO had to approve the funding evidences that it was of a sufficient magnitude that it would have also been brought to the attention of the Board of Directors.

397. Finally, the timing of the June 2016 Offering and August 2016 Offering provides powerful evidence that the Private Equity Defendants sold their stock in those offerings because of material nonpublic information alerting them to the fact that the North Campus was effectively a ticking time bomb, which would eventually explode when the FDA arrived for its routine inspection. For example, the Private Equity Funds were able to sell their entire holdings of ZBH common stock just in time before the situation blew up. The September 2016 North Campus Inspection occurred approximately one month after the closing of the August 2016 Offering, in which Defendant KKR Biomet and the TPG Defendants sold the last of the stock

that the Private Equity Defendants had received in the Merger. Additionally, the timing of the August 2016 Offering was perfectly timed in that it occurred near ZBH's highest trading price during the Class Period.

D. Additional Allegations Regarding Loss Causation

398. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class.

399. During the Class Period, Plaintiffs and the Class purchased ZBH's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed or materialized, causing investors' losses.

400. Artificial inflation in ZBH's stock price was removed when concealed risks materialized and/or the truth about the material misrepresentations and omissions was partially revealed to the public on October 31, 2016, and November 8, 2016. The combined disclosures made on those days revealed on a piecemeal basis the true nature and extent of the scheme to conceal, among others, the "systemic" issues with QS at the North Campus, that ZBH was unable to satisfy demand for its products while remediating these issues, that ZBH was unable to accelerate revenue growth to above market level in the second half of 2016, that an inspection of the North Campus was imminent, and the true reasons for the supply shortages in Q3'16 and Q4'16. As more particularly described above (*see* Section VII.B), these disclosures reduced the amount of inflation in the price of ZBH's publicly traded securities, causing economic injury to Plaintiffs and other members of the Class.

401. None of these disclosures was sufficient on its own to fully remove the inflation

from ZBH's stock price because each of them only partially revealed the conditions, risks and trends that had been concealed from investors. The corrective impact of the disclosures alleged herein was tempered by Defendant ZBH and the Officer Defendants' continued misstatements and omissions about ZBH's organic revenue growth, the true cause of the supply shortages, the "systemic issues" with the QS at the North Campus, and ZBH's ability to meet demand for its products (while remediating the QS issues at the North Campus). These misrepresentations and omissions inflated and maintained the prices of ZBH's publicly traded stock at levels that were artificially inflated, inducing members of the Class to continue purchasing ZBH stock even after the truth began to partially enter the market.

E. Presumption Of Reliance

402. The market for ZBH'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, ZBH's securities traded at artificially inflated prices during the Class Period. On October 10, 2016, the Company's stock price closed at a Class Period high of $132.74 per share. Plaintiffs and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of ZBH's securities and market information relating to ZBH, and have been damaged thereby.

403. During the Class Period, the artificial inflation of ZBH's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiffs and 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 ZBH's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of ZBH 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 disclosed, negatively affected the value of the Company's stock. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs and 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.

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

(a) ZBH 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, ZBH filed periodic public reports with the SEC and/or the NYSE;

(c) ZBH 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) ZBH 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.

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

artificially inflated prices and a presumption of reliance applies.

406. 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, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—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 Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

IX. VIOLATIONS OF THE SECURITIES ACT

407. Plaintiffs' claims under the Securities Act do not sound in fraud and Plaintiffs expressly disavows and disclaimss any allegations of fraud, scheme or intentional conduct as part of its claims under the Securities Act. Any allegations of fraud, fraudulent conduct, or motive are specifically disclaimed from the following allegations for the purposes of Plaintiffs' claims under the Securities Act, which do not have scienter, fraudulent intent or motive as required elements. To the extent that these allegations incorporate factual allegations elsewhere in this Complaint, those allegations are incorporated only to the extent that such allegations do not allege fraud, scienter, or intent of the Defendants to defraud Plaintiffs or members of the Class.

408. As alleged below, ZBH and other Defendants made a series of materially untrue statements and omissions of material facts in: (i) the June SPO Materials in connection with the Company's June 2016 Offering of 11,116,533 shares of ZBH common stock; and (ii) in the

August SPO Materials in connection with the August 2016 Offering of 7,440,675 shares of ZBH common stock.

409. Both the June 2016 Offering and August 2016 Offering were made pursuant to an automatic "shelf" registration statement filed with the SEC on Form S-3 on February 4, 2016. The Registration Statement was signed by the Director Defendants and Defendants Dvorak, Florin, and Collins. Both the June 2016 Offering and August 2016 Offering were underwritten by Goldman Sachs & Co. LLC and J.P. Morgan Securities LLC (the "Underwriters").[67]

410. The June SPO Materials incorporated by reference, among other documents: (i) ZBH's 2015 10-K; and (ii) ZBH's Q1'16 10-Q.

411. The August SPO Materials incorporated by reference, among other documents: (i) ZBH's 2015 10-K; (ii) ZBH's Q1'16 10-Q; and (iii) ZBH's Q2'16 10-Q.

412. The June SPO Materials and August SPO Materials were negligently prepared and, as a result, contained untrue statements of material facts and/or omitted to state facts necessary to make the statements made therein not misleading and neither the June SPO Materials nor the August SPO Materials were prepared in accordance with the rules and regulations governing their preparation.

413. The statements in and incorporated into the June SPO Materials and the August SPO Materials were materially misleading and omitted to state the following facts necessary to make the statements made therein not misleading: (i) that ZBH was unable to accelerate organic revenue growth to above market level in the second half of 2016; (ii) that there were "systemic issues" with the QS at the North Campus requiring highly disruptive, time consuming and costly

[67] Pursuant to underwriting agreements, in connection with the offerings, ZBH and the Private Equity Defendants agreed to indemnify the Underwriters for any liabilities in connection with any material misstatements or omissions in the offering materials.

remediation and corrective activities; (iii) that ZBH was not taking prompt and meaningful actions to remediate and correct the "systemic issues" at the North Campus; (iv) that an FDA inspection of the Legacy Biomet North Campus was imminent; and (v) that ZBH was unable to meet demand for its products while remediating the "systemic issues" with the QS at the North Campus

414. Additionally, the statements in and incorporated into the June SPO Materials and the August SPO Materials were materially misleading and omitted to state the following facts necessary to make the statements made therein not misleading: failed to warn investors that (i) that ZBH would be unable to satisfy demand for its products while remediating the QS deficiencies at the North Campus; and (ii) that ZBH would have to disrupt production and distribution of key products because ZBH was manufacturing, sterile packing, and distributing products from the North Campus despite knowing that "systemic issues" with the QS had not been adequately remediated and knowing that an FDA inspection of the facility was imminent.

415. Also, the failure to disclose the facts in ¶413 also rendered the June SPO Materials and August SPO Materials materially misleading because those facts were required to be stated therein pursuant to Reg S-K Item 303. Additionally, the June SPO Materials and the August SPO Offering omitted the following additional fact required to be stated therein under Reg. S-K Item 303: the Legacy Biomet North Campus required substantial remediation, which would take considerable time and money (exceeding one year and costing $300 million), which was particularly evident to ZBH in light of the significant time and funds that were being expended for the purported ongoing remediation activities for the Legacy Zimmer West Campus, as well as, by virtue of the spending that was authorized for the North Campus in July 2016 (ahead of the August 2016 Offering).

X. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND THE BESPEAKS CAUTION DOCTRINE

416. 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 ZBH who knew that the statement was false when made.

XI. CLASS ACTION ALLEGATIONS

417. Plaintiff brings 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 persons or entities that purchased or acquired ZBH's securities (including common stock and options) during the Class Period, including persons or entities that purchased or otherwise acquired ZBH common stock pursuant or traceable to the June 2016 Offering and/or the August 2016 Offering, and were damaged thereby (the "Class"). 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.

418. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, ZBH's common stock actively traded on the NYSE. 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 at least hundreds or thousands of members in the proposed Class. Millions of ZBH shares were traded publicly during the Class Period on the NYSE. As of October 28, 2016, ZBH had 200,299,566 shares of common stock outstanding. Record owners and other members of the Class may be identified from records maintained by ZBH 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.

419. 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.

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

421. 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 omitted and/or misrepresented material

facts;

(c) whether Defendants made false and/or misleading statements;

(d) whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and

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

422. 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.

XII. CLAIMS FOR RELIEF

COUNT I
Violation Of Section 10(b) Of The Exchange Act And Rule 10b-5 Promulgated Thereunder Against ZBH And The Officer Defendants

423. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

424. During the Class Period, Defendant ZBH and the Officer 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 other Class members, as alleged herein; and (ii) cause Plaintiffs and other members of the Class to purchase ZBH's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct,

Defendants, and each defendant, took the actions set forth herein.

425. Defendant ZBH and the Officer 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 ZBH's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. Defendants ZBH and the Officer Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

426. Defendant ZBH and the Officer 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 ZBH's financial well-being, operations and prospects, as specified herein.

427. Defendant ZBH and the Officer 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 ZBH'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 ZBH 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.

428. Each of the Officer Defendants' primary liability and controlling person liability arises from the following facts: (i) the Officer 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, 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; 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.

429. Defendant ZBH and the Officer 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 ZBH's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendant ZBH and the Officer Defendants' misstatements and omissions of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendant ZBH and the Officer 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.

430. 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 ZBH'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 Defendant ZBH and the Officer 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 Defendant ZBH and the Officer Defendants, but not disclosed in public statements by Defendant ZBH and the Officer Defendants during the Class Period, Plaintiffs and the other members of the Class acquired ZBH's securities during the Class Period at artificially high prices and were damaged thereby. The scienter of each of the Individual Defendants and of all other management-level employees of ZBH, including each member of the Executive Management Team, is imputable to ZBH. The knowledge of each of these individuals should therefore be imputed to ZBH for the purposes of assessing corporate scienter.

431. At the time of said misrepresentations and/or omissions, Plaintiffs and 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 ZBH was experiencing, which were not disclosed by Defendant ZBH and the Officer Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their ZBH 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.

432. By virtue of the foregoing, Defendant ZBH and the Officer Defendants violated

Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

433. As a direct and proximate result of Defendant ZBH and the Officer 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 Officer Defendants

434. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

435. Officer Defendants acted as controlling persons of ZBH 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 intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Officer 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. Officer 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.

436. In particular, Officer Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

437. As set forth above, ZBH and Officer Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Officer Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Officer 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.

COUNT III
Violation Of Section 20(A) Of The Exchange Act
Against The Private Equity Defendants
(Relating To The June 2016 Offering)

438. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

439. As set forth in the paragraphs above, the Private Equity Defendants each committed underlying violations of Section 10(b) and Rule 10b-5 thereunder by selling ZBH common stock in the June 2016 Offering while in possession of material nonpublic information about the Company's North Campus (including information that there were "systemic issues" with the QS at the North Campus and that an FDA inspection of the North Campus was imminent), and, consequently, are liable to contemporaneous purchasers of that stock under Section 20A of the Exchange Act. *See* 15 U.S.C § 78t-1(a).

440. Each of the Private Equity Defendants, through their designees to ZBH's Board of Directors and through direct communications from ZBH and the Officer Defendants, possessed material nonpublic information at the times they sold shares in the June 2016 Offering. In total, the Private Equity Defendants collectively sold 11,116,533 shares of ZBH common stock for net proceeds of $1,281,847,420.23.

441. Simply put, the Private Equity Defendants had directly or indirectly owned

Legacy Biomet prior to the Merger and possessed nonpublic knowledge about ZBH's operations at the Legacy Biomet North Campus facility that they knew or recklessly disregarded would cause the Company's share price to fall when publicly disclosed, and used the June 2016 Offering to unload significant portions of their holdings at inflated prices before the nonpublic information was revealed. The Private Equity Defendants were able to sell their stock in the June 2016 Offering to the public at a price of $115.85 per share, as opposed to the $101.83 per share closing price on November 8, 2016, following the final corrective disclosures related to the material nonpublic information at issue here (*i.e.*, the November NCR Report disclosing, among others, supply issues and product holds related to an FDA inspection of the North Campus).

442. Due to the Private Equity Defendants' conduct in selling ZBH common stock while in possession of material nonpublic information, which is a violation of Section 10(b) and Rule 10b-5 thereunder, the Private Equity Defendants are liable under Section 20A of the Exchange Act to all Class members who purchased ZBH's common stock at inflated prices contemporaneously with sales by the Private Equity Defendants, including, Plaintiff UFCW Local 1500, which purchased shares of ZBH common stock contemporaneously with the June 2016 Offering.

443. Moreover, upon information and belief, based on, among other things, the fact the Private Equity Defendants sold more than 11.1 million shares in the June 2016 Offering to the investing public, thousands of other Class Members also purchased shares contemporaneously with the Private Equity Defendants' Class Period sales.

444. Section 20A of the Exchange Act provides that "[a]ny person who violates any provision of this chapter or the rules or regulations thereunder by purchasing or selling a security while in possession of material nonpublic information shall be liable in an action . . . to any

person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased (where such violation is based on a sale of securities) or sold (where such violation is based on a purchase of securities) securities of the same class."

445. As set forth above, the Private Equity Defendants each committed underlying violations of Section 10(b) and Rule 10b-5 thereunder, by their acts and omissions as alleged in this Complaint. Specifically, the Private Equity Defendants violated Section 10(b) and Rule 10b-5 thereunder by selling ZBH common stock while in possession of material nonpublic information about the "systemic issues" with the QS at the North Campus and the imminent FDA inspection. Consequently, the Private Equity Defendants are liable pursuant to Section 20A of the Exchange Act to any Plaintiff or other Class member who purchased common stock contemporaneously with the Private Equity Defendants' sales of ZBH common stock in the June 2016 Offering.

COUNT IV
Violation Of Section 20(A) Of The Exchange Act
Against KKR Biomet And The TPG Defendants
(Relating To The August 2016 Offering)

446. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

447. As set forth in the paragraphs above, Defendant KKR Biomet and the TPG Defendants each committed underlying violations of Section 10(b) and Rule 10b-5 thereunder by selling ZBH common stock in the August 2016 Offering while in possession of material nonpublic information about the Company's North Campus (including information that there were "systemic issues" with the QS at the North Campus and that an FDA inspection of the North Campus was imminent) and, consequently, are liable to contemporaneous purchasers of that stock under Section 20A of the Exchange Act. *See* 15 U.S.C § 78t-1(a).

448. Each of Defendant KKR Biomet and the TPG Defendants, through their designees to ZBH's Board of Directors and through direct communications from ZBH and the Officer Defendants, possessed material nonpublic information at the times they sold shares in the August 2016 Offering. In total, Defendant KKR Biomet and the TPG Defendants collectively sold 7,440,675 shares of ZBH common stock for net proceeds of $959,847,075.

449. Simply put, Defendant KKR Biomet and the TPG Defendants had directly or indirectly owned Legacy Biomet prior to the Merger and possessed nonpublic knowledge about ZBH's operations at the Legacy Biomet North Campus facility that they knew or recklessly disregarded would cause the Company's share price to fall when publicly disclosed, and used the August 2016 Offering to unload significant portions of their holdings at inflated prices before the nonpublic information was revealed. Defendant KKR Biomet and the TPG Defendants were able to sell their stock in the August 2016 Offering to the public at a price of $129.75 per share, as opposed to the $101.83 per share closing price on November 8, 2016, following the final corrective disclosures related to the material nonpublic information at issue here (*i.e.*, the November NCR Report disclosing, among others, supply issues and product holds related to an FDA inspection of the North Campus).

450. Due to Defendant KKR Biomet and the TPG Defendants' conduct in selling ZBH common stock while in possession of material nonpublic information, which is a violation of Section 10(b) and Rule 10b-5 thereunder, the Defendant KKR Biomet and the TPG Defendants are liable under Section 20A of the Exchange Act to all Class members who purchased ZBH's common stock at inflated prices contemporaneously with sales by Defendant KKR Biomet and the TPG Defendants, including, Plaintiff UFCW Local 1500, which purchased shares of ZBH common stock contemporaneously with the August 2016 Offering.

451. Moreover, upon information and belief, based on, among other things, the fact the Private Equity Defendants sold more than 7.4 million shares in the August 2016 Offering to the investing public, hundreds or thousands of other Class Members also purchased shares contemporaneously with the Defendant KKR Biomet and the TPG Defendants' Class Period sales.

452. Section 20A of the Exchange Act provides that "[a]ny person who violates any provision of this chapter or the rules or regulations thereunder by purchasing or selling a security while in possession of material nonpublic information shall be liable in an action . . . to any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased (where such violation is based on a sale of securities) or sold (where such violation is based on a purchase of securities) securities of the same class."

453. As set forth above, the Defendant KKR Biomet and the TPG Defendants each committed underlying violations of Section 10(b) and Rule 10b-5 thereunder, by their acts and omissions as alleged in this Complaint. Specifically, Defendant KKR Biomet and the TPG Defendants violated Section 10(b) and Rule 10b-5 thereunder by selling ZBH common stock while in possession of material nonpublic information about the "systemic issues" with the QS at the North Campus and the imminent FDA inspection. Consequently, Defendant KKR Biomet and the TPG Defendants are liable pursuant to Section 20A of the Exchange Act to any Plaintiff or other Class member who purchased common stock contemporaneously with Defendant KKR Biomet and the TPG Defendants' sales of ZBH common stock in the August 2016 Offering.

COUNT V
Violation Of Section 11 Of The Securities Act
Against Defendants ZBH, Dvorak, Florin, And Collins,
And The Director Defendants
(Relating to the June 2016 Offering)

454. Plaintiffs repeat and reallege the allegations in ¶¶43-89, 92-137, 407-422, as if alleged fully in this Count.

455. This Count is brought by Plaintiffs pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of all members of the Class who purchased or otherwise acquired ZBH common stock pursuant or traceable to the June 2016 Offering, and who were damaged thereby.

456. This Count expressly excludes and disclaims any allegation of fraud or intentional or reckless conduct, as this Count is solely based on claims of strict liability and/or negligence under the Securities Act. For purposes of asserting this Count, Plaintiffs do not allege that Defendants acted with scienter or fraudulent intent, which are not elements of a Section 11 claim.

457. Liability under this Count is predicated on ZBH's filing the June 2016 SPO Materials, the Director Defendants', Dvorak's, Florin's, and Collin's signing of the Registration Statement for the June 2016 Offering, and ZBH's, the Director Defendants', Dvorak's, Florin's, and Collin's respective participation in the June 2016 Offering, which was conducted pursuant to the June 2016 SPO Materials. The June 2016 SPO Materials were false and misleading, contained untrue statements of material facts, omitted to state facts necessary to make the statements not misleading, and omitted to state material facts required to be stated therein.

458. Less than one year elapsed between the time that Plaintiffs discovered, or could reasonably have discovered, the facts upon which this Complaint is based and the initial

complaint in this action. Less than three years has elapsed since the time that the securities at issue in this Complaint were bona fide offered to the public.

459. By reason of the foregoing, the Defendants named in this Count are each jointly and severally liable for violations of Section 11 of the Securities Act to Plaintiffs and the other members of the Class pursuant to Section 11(e).

COUNT VI
Violation Of Section 12(a)(2) Of The Securities Act
Against ZBH And The Private Equity Defendants
(Relating To The June 2016 Offering)

460. Plaintiffs repeat and reallege the allegations contained in ¶¶43-89, 92-137, 407-422, 454-459, above as if fully set forth herein.

461. This Count is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77l, on behalf of all members of the Class who purchased or otherwise acquired ZBH securities in the June 2016 Offering and who were damaged thereby.

462. This Count expressly excludes and disclaims any allegation that could be construed as alleging fraud or intentional or reckless conduct, as this Count is solely based on claims of strict liability and/or negligence under the Securities Act. For purposes of asserting this Count, Plaintiffs do not allege that Defendant ZBH and the Private Equity Defendants acted with scienter or fraudulent intent, which are not elements of a Section 12(a)(2) claim.

463. The Private Equity Defendants and ZBH were statutory sellers of ZBH securities that were registered in the June 2016 Offering pursuant to the Registration Statement and sold by means of the June 2016 SPO Materials. By means of the June 2016 SPO Materials, the Private Equity Defendants and Defendant ZBH sold approximately 11,116,533 shares of common stock in the June 2016 Offering to members of the Class. The Private Equity Defendants and Defendants ZBH were at all relevant times motivated by their own financial interests. In sum, the

Private Equity Defendants and Defendant ZBH were sellers, offerors, and/or solicitors of sales of the securities that were sold in the June 2016 Offering by means of the materially false and misleading June 2016 SPO Materials.

464. Plaintiff UFCW 1500 purchased or acquired ZBH common stock in the June 2016 Offering and subsequently sustained an economic loss when it sold those shares.

465. The June 2016 SPO Materials contained untrue statements of material fact and omitted other facts necessary to make the statements not misleading, and failed to disclose material facts, as set forth herein.

466. Less than one year elapsed between the time that Plaintiffs discovered, or could reasonably have discovered, the facts upon which this Complaint is based and the initial complaint in this action. Less than three years has elapsed since the time that the securities at issue in this Complaint were bona fide offered to the public.

467. By reason of the foregoing, the Private Equity Defendants and Defendant ZBH are liable for violations of Section 12(a)(2) of the Securities Act to Plaintiffs and the other members of the Class who purchased securities in or traceable to the Offerings, and who were damaged thereby.

COUNT VII
Violation Of Section 15 Of The Securities Act
Against Defendants Dvorak, Florin, And Collins, And The Director Defendants
(Relating To The June 2016 Offering)

468. Plaintiffs repeat and reallege the allegations contained in ¶¶43-89, 92-137, 407-422, 454-467, above as if fully set forth herein.

469. This Count is brought pursuant to Section 15 of the Securities Act, 15 U.S.C. § 77o, against the Director Defendants and Defendants Dvorak, Florin, and Collins.

470. At all relevant times, the Director Defendants and Defendants Dvorak, Florin,

and Collins were controlling persons of ZBH within the meaning of Section 15 of the Securities Act. As set forth herein, because of their positions at ZBH and/or because of their positions on ZBH Board, the Director Defendants and Defendants Dvorak, Florin, and Collins had the requisite power to directly or indirectly control or influence the decision-making of the Company and the conduct of ZBH's business, including the wrongful conduct complained of herein.

471. In their capacities as senior corporate officers of the Company, and as more fully described above, Defendants Dvorak, Florin, and Collins had direct involvement in the day-today operations of the Company, and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities law violations as alleged herein. They were also directly involved in providing false information and certifying and/or approving the false and/or misleading statements disseminated by ZBH during the Class Period. As a result of the foregoing, Defendants Dvorak, Florin, and Collins, as a group and individually, were controlling persons of ZBH within the meaning Section 15 of the Exchange Act.

472. Defendants Dvorak, Florin, and Collins also each signed the Registration Statement in connection with the June 2016 Offering, the June 2016 SPO Materials were disseminated to the investing public, and the Registration Statement became effective. Thus, these defendants controlled the contents and dissemination of the June 2016 SPO Materials.

473. Similarly, the Director Defendants and Defendant Dvorak served as Directors on ZBH's board of directors at the time the June 2016 Offering was conducted and at the time that the Registration Statement was signed. As directors of a publicly owned company, these defendants had a duty to disseminate accurate and truthful information with respect to ZBH's financial condition and results of operations. These Director Defendants and Defendant Dvorak each signed the Registration Statement in connection with the June 2016 Offering, the June 2016

SPO Materials were disseminated to the investing public, and the Registration Statement became effective. Thus, these defendants controlled the contents and dissemination of the June 2016 SPO Materials.

474. This claim does not sound in fraud. For purposes of asserting this claim under the Securities Act, Plaintiffs do not allege that any defendant acted with scienter or fraudulent intent, which are not elements of a Section 15 claim.

475. By reason of the aforementioned conduct, each of the defendants named in this Count is liable under Section 15 of the Securities Act to Plaintiffs and the other members of the Class with claims pursuant to Sections 11 or 12(a)(2) of the Securities Act, as set forth above. As a direct and proximate result of the conduct of these Defendants, Plaintiffs and members of the Class suffered damages in connection with their purchase or acquisition of securities pursuant and/or traceable to the June 2016 Offering.

COUNT VIII
Violation Of Section 11 Of The Securities Act
Against Defendants ZBH, Dvorak, Florin, And Collins, And
The Director Defendants
(Relating to the August 2016 Offering)

476. Plaintiffs repeat and reallege the allegations in ¶¶43-89, 92-137, 407-422, as if alleged fully in this Count.

477. This Count is brought by Plaintiffs pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of all members of the Class who purchased or otherwise acquired securities sold pursuant or traceable to the August 2016 Offering, and who were damaged thereby.

478. This Count expressly excludes and disclaims any allegation of fraud or intentional or reckless conduct, as this Count is solely based on claims of strict liability and/or negligence

under the Securities Act. For purposes of asserting this Count, Plaintiffs do not allege that Defendants ZBH, Dvorak, Florin, and Collins, and the Director Defendants, acted with scienter or fraudulent intent, which are not elements of a Section 11 claim.

479. Liability under this Count is predicated on ZBH's filing the August 2016 SPO Materials, the Director Defendants', Dvorak's, Florin's, and Collin's signing of the Registration Statement for the Offering, and ZBH's, the Director Defendants', Dvorak's, Florin's, and Collin's respective participation in the Offering, which was conducted pursuant to the August 2016 SPO Materials. The August 2016 SPO Materials were false and misleading, contained untrue statements of material facts, omitted to state facts necessary to make the statements not misleading, and omitted to state material facts required to be stated therein.

480. Less than one year elapsed between the time that Plaintiffs discovered, or could reasonably have discovered, the facts upon which this Complaint is based and the initial complaint in this action. Less than three years has elapsed since the time that the securities at issue in this Complaint were bona fide offered to the public.

481. By reason of the foregoing, the defendants named in this Count are each jointly and severally liable for violations of Section 11 of the Securities Act to Plaintiffs and the other members of the Class pursuant to Section 11(e).

COUNT IX
Violation Of Section 12(a)(2) Of The Securities Act
Against ZBH, Defendant KKR Biomet, The TPG Defendants
(Relating To The August 2016 Offering)

482. Plaintiffs repeat and reallege the allegations contained in ¶¶43-89, 92-137, 407-422, 476-481, above as if fully set forth herein.

483. This Count is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77l, on behalf of all members of the Class who purchased or otherwise acquired ZBH

securities in the August 2016 Offering and who were damaged thereby.

484. This Count expressly excludes and disclaims any allegation of fraud or intentional or reckless conduct, as this Count is solely based on claims of strict liability and/or negligence under the Securities Act. For purposes of asserting this Count, Plaintiffs do not allege that Defendants acted with scienter or fraudulent intent, which are not elements of a Section 12(a)(2) claim.

485. Defendant KKR Biomet, the TPG Defendants, and Defendant ZBH were statutory sellers of ZBH securities that were registered in the August 2016 Offering pursuant to the Registration Statement and sold by means of the August 2016 SPO Materials. By means of the August 2016 SPO Materials, Defendant KKR Biomet, the TPG Defendants, and Defendant ZBH sold approximately 7,440,675 shares of ZBH common stock in the August 2016 Offering to members of the Class. Defendant KKR Biomet, the TPG Defendants, and Defendant ZBH were at all relevant times motivated by their own financial interests. In sum, Defendant KKR Biomet, the TPG Defendants, and Defendant ZBH were sellers, offerors, and/or solicitors of sales of the securities that were sold in the August 2016 Offering by means of the materially false and misleading August 2016 SPO Materials.

486. Plaintiff UFCW 1500 purchased or acquired ZBH common stock in the August 2016 Offering and subsequently sustained an economic loss when it sold the shares.

487. The August 2016 SPO Materials contained untrue statements of material fact and omitted other facts necessary to make the statements not misleading, and failed to disclose material facts, as set forth herein.

488. Less than one year elapsed between the time that Plaintiffs discovered, or could reasonably have discovered, the facts upon which this Complaint is based and the initial

complaint in this action. Less than three years has elapsed since the time that the securities at issue in this Complaint were bona fide offered to the public.

489. By reason of the foregoing, Defendants KKR Biomet, the TPG Defendants, and Defendant ZBH are liable for violations of Section 12(a)(2) of the Securities Act to Plaintiffs and the other members of the Class who purchased securities in or traceable to the Offerings, and who were damaged thereby.

COUNT X
Violation Of Section 15 Of The Securities Act
Against Defendants Dvorak, Florin, And Collins,
And The Director Defendants
(Relating To The August 2016 Offering)

490. Plaintiffs repeat and reallege the allegations contained in ¶¶43-89, 92-137, 407-422, 476-489, above as if fully set forth herein.

491. This Count is brought pursuant to Section 15 of the Securities Act, 15 U.S.C. § 77o, against the Director Defendants and Defendants Dvorak, Florin, and Collins.

492. At all relevant times, the Director Defendants and Defendants Dvorak, Florin, and Collins were controlling persons of ZBH within the meaning of Section 15 of the Securities Act. As set forth herein, because of their positions at ZBH and/or because of their positions on ZBH Board, the Director Defendants and Defendants Dvorak, Florin, and Collins had the requisite power to directly or indirectly control or influence the decision-making of the Company and the conduct of ZBH's business, including the wrongful conduct complained of herein.

493. In their capacities as senior corporate officers of the Company, and as more fully described above, Defendants Dvorak, Florin, and Collins had direct involvement in the day-today operations of the Company, and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities law violations as alleged

herein. They were also directly involved in providing false information and certifying and/or approving the false and/or misleading statements disseminated by ZBH during the Class Period. As a result of the foregoing, Defendants Dvorak, Florin, and Collins, as a group and individually, were controlling persons of ZBH within the meaning Section 15 of the Exchange Act.

494. Defendants Dvorak, Florin, and Collins also each signed the Registration Statement in connection with the August 2016 Offering, the August 2016 SPO Materials were disseminated to the investing public, and the Registration Statement became effective. Thus, these defendants controlled the contents and dissemination of the August 2016 SPO Materials.

495. Similarly, the Director Defendants and Defendant Dvorak served as Directors on ZBH's board of directors at the time the August 2016 Offering was conducted and at the time that the Registration Statement was signed. As directors of a publicly owned company, these defendants had a duty to disseminate accurate and truthful information with respect to ZBH's financial condition and results of operations. These Director Defendants and Defendant Dvorak each signed the Registration Statement in connection with the August 2016 Offering, the August 2016 SPO Materials were disseminated to the investing public, and the Registration Statement became effective. Thus, these defendants controlled the contents and dissemination of the August 2016 SPO Materials.

496. This claim does not sound in fraud. For purposes of asserting this claim under the Securities Act, Plaintiffs do not allege that any defendant acted with scienter or fraudulent intent, which are not elements of a Section 15 claim.

497. By reason of the aforementioned conduct, each of the defendants named in this Count is liable under Section 15 of the Securities Act to Plaintiffs and the other members of the Class with claims pursuant to Section 11 of the Securities Act, as set forth above. As a direct and

proximate result of the conduct of these defendants, Plaintiffs and members of the Class suffered damages in connection with their purchase or acquisition of securities pursuant and/or traceable to the August 2016 Offering.

XIII. 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;

(d) as to the claims set forth under the Securities Act, awarding rescission or a recessionary measure of damages; and

(e) such other and further relief as the Court may deem just and proper.

XIV. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: March 21, 2019

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PROOF OF SERVICE

I, the undersigned say:

I am not a party to the above case and am over eighteen years old.

On March 21, 2019, I served true and correct copies of the foregoing document, by posting the document electronically to the ECF website of the United States District Court for the Northern District of Indiana, for receipt electronically by the parties listed on the Court's Service List.

I affirm under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on March 21, 2019.

s/ Robert V. Prongay
Robert V. Prongay

Mailing Information for a Case 3:16-cv-00815-PPS-MGG Shah et al v. Zimmer Biomet Holdings, Inc. et al

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- (No manual recipients)