

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA

|   |   |                                |
|---|---|--------------------------------|
| PLUMBERS AND PIPEFITTERS LOCAL                  | : | No.                            |
| UNION 719 PENSION FUND, Individually            | : |                                |
| and On Behalf of All Others Similarly Situated, | : | <u>CLASS ACTION</u>            |
|   | : |                                |
| Plaintiff,                                      | : | COMPLAINT FOR VIOLATION OF THE |
|   | : | FEDERAL SECURITIES LAWS        |
| vs.   | : |                                |
|   | : |                                |
| ZIMMER HOLDINGS, INC., DAVID C.                 | : |                                |
| DVORAK and JAMES T. CRINES,                     | : |                                |
|   | : |                                |
| Defendants.                                     | : |                                |
|   | : | <u>DEMAND FOR JURY TRIAL</u>   |

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## **INTRODUCTION**

1. This is a securities fraud class action on behalf of persons who purchased the common stock of Zimmer Holdings, Inc. (“Zimmer” or the “Company”) between January 29, 2008 and July 22, 2008 (the “Class Period”), against Zimmer and its top officers, for violations of the federal securities laws arising out of defendants’ dissemination of false and misleading statements concerning the Company’s results and operations.

## **SUMMARY OF THE ACTION**

2. Zimmer designs, develops, manufactures and markets reconstructive orthopedic implants, including joint, dental and spinal implants, trauma products and related orthopedic surgical products. The Company’s related orthopedic surgical products include surgical supplies and instruments designed to aid in orthopedic surgical procedures. Zimmer also has a limited array of sports medicine products. The Company’s primary customers include musculoskeletal surgeons, neurosurgeons, oral surgeons, dentists, hospitals, distributors, healthcare dealers and, in their capacity as agents, healthcare purchasing organizations or buying groups. These customers range from large multi-national enterprises to independent surgeons.

3. During the Class Period, defendants materially misrepresented the Company and its products. Specifically, defendants failed to disclose material flaws in the quality systems at Zimmer’s Dover, Ohio facility, which manufactured Zimmer Orthopaedic Surgical Products (“OSP”). In addition, defendants failed to disclose that patients receiving the Company’s Durom Acetabular Component (“Durom Cup”), used in total hip replacement procedures, disproportionately experienced cup loosening requiring additional corrective surgery after implantation.

4. As a result of defendants’ materially false and misleading statements, Zimmer’s common stock traded at artificially inflated prices during the Class Period. When the true condition

of the Company, its facilities, and its products began to come to light, the price of Zimmer stock declined as artificial inflation came out of the stock price.

### **JURISDICTION AND VENUE**

5. The claims asserted herein arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (“1934 Act”), 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R. §240.10b-5, promulgated thereunder. Jurisdiction is conferred by §27 of the 1934 Act, 15 U.S.C. §78aa.

6. Venue is proper here pursuant to §27 of the 1934 Act. Acts and transactions giving rise to the violations of law complained of occurred here.

### **THE PARTIES**

7. Plaintiff Plumbers and Pipefitters Local Union 719 Pension Fund purchased Zimmer common stock as detailed in the attached Certification and was damaged thereby.

8. Defendant Zimmer is headquartered in Warsaw, Indiana. During the Class Period, Zimmer had over 200 million shares of common stock outstanding, which shares traded in an efficient market on the New York Stock Exchange under the symbol ZMH.

9. Defendant David C. Dvorak (“Dvorak”) was President and Chief Executive Officer (“CEO”) of the Company during the relevant period.

10. Defendant James T. Crines (“Crines”) was Executive Vice President, Finance and Chief Financial Officer (“CFO”) of the Company during the relevant period.

11. Each of the Individual Defendants listed in ¶¶9-10, by reason of their stock ownership and positions with and relations to Zimmer as officers and/or managers, were controlling persons of Zimmer. Zimmer in turn controlled each of the Individual Defendants. Defendant Zimmer and each of the Individual Defendants are liable under §20(a) of the 1934 Act.

## BACKGROUND

12. In March of 2005, Zimmer received subpoenas from the U.S. Department of Justice (“DOJ”) through the U.S. Attorney’s Office in Newark, New Jersey, seeking information pertaining to consulting contracts, professional service agreements and other agreements by which remuneration is provided to orthopedic surgeons. Eighteen months later, on September 27, 2007, Zimmer announced that it had entered into a deferred prosecution agreement with the DOJ regarding allegedly improper agreements between the Company and orthopedic surgeons. Pursuant to that agreement, the Company paid a civil settlement amount of \$169.5 million, and agreed to be subject to oversight by a federal monitor appointed by the DOJ for 18 months.

13. One month later, on October 24, 2007, defendants announced lower-than-expected growth for the Company going forward. As a result, the Company’s stock price plummeted from \$79.37 to \$67.39 in one day, a 15% decline.

## FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

14. On January 29, 2008, Zimmer issued a press release announcing the Company’s financial results for the fourth quarter and full year 2007. Later that day, defendants held a conference call with financial analysts who covered Zimmer. During that call, defendants stated:

**David Dvorak – *Zimmer Holdings, Inc.* – *President, CEO***

\* \* \*

Turning to our 2008 outlook. We developed our 2008 guidance taking into account our assessment of the market and the opportunities and risks that could impact our performance. I’ll now take you through our expectations for our sales and earnings. First, looking at the market for our core reconstructive product categories and geographies, we enter 2008 with positive momentum and underlying market demand for orthopedic devices. When all Company reports are in for 2007, we expect the results will indicate that the global reconstructive market grew in the range of 8 to 10%. We continue to believe this reflects mid single digit growth and procedures with the balance due to mix and flat to modest price improvements. We anticipate similar market dynamics in 2008 and slightly higher market growth rates for spine, trauma, dental, and extremities consistent with recent trends. Our outlook

calls for top line growth for the year of 10 to 11% net sales on a reported basis and adjusted earnings per share of \$4.20 to \$4.25. Sales will be driven by new product introductions and further market penetration by key products launched in 2007, as well as the positive effect of a weaker U.S. dollar abroad. We attribute approximately 2 points of sales growth in our range to the impact of foreign currency exchange rates.

\* \* \*

**Jim Crines – *Zimmer Holdings, Inc. – EVP-Fin., CFO***

\* \* \*

We are changing our approach by only issuing full year guidance. We want to guide the Street as we run the business which is with the longer term perspective and accountability for annual performance. For 2008, we will provide some more detailed guidance with regard to our spending plans and also share with you our thinking on margins and expense ratios. This should give you more information than you have had in the past to help with your models. We hope for now this will strike the right balance between your need for detail and our desire to stay focused on our longer term goals and objectives.

As David mentioned, after reviewing market dynamics and our relative opportunities and risk we expect to deliver 10 to 11% top line sales growth in 2008 and adjusted earnings per share in a range of \$4.20 to \$4.25.

\* \* \*

**Bob Hopkins – *Lehman Brothers – Analyst***

Okay, and then finally just to be clear on the philosophy around guidance, I think you were pretty clear on this but these are not aspirational goals, these are things that you expect to meet or exceed; is that correct?

**David Dvorak – *Zimmer Holdings, Inc. – President, CEO***

That is correct.

\* \* \*

**Matt Miksik – *Morgan Stanley – Analyst***

Okay, and then just one last question, just in the past couple of quarters, I think it's fair to say that it sounds and looks like you've learned some lessons in terms of forecasting and providing guidance and perhaps managing the business as well. I just wanted to ask if there's anything that you see yourself doing differently over the next, as you talk about your quarter and your guidance today or going forward, based on what you've learned say in the last nine months?

**David Dvorak – Zimmer Holdings, Inc. – President, CEO**

Well, Matt, we obviously went through an extremely methodical process to put our 2008 plan together. We described that process broadly to people that we've met with and really all of that hard work puts us in a great position and provides us with nice momentum coming out of the fourth quarter, so we're anxious to execute on these plans and optimistic that the we're going to have a good year in 2008.

\* \* \*

**Joanne Wuensch – BMO Capital Markets – Analyst**

Okay and this question has been sort of asked a couple of different ways but I want to really get my arms around it which is that in the second quarter, the Company met expectations and then guided lower and in the third quarter they met expectations and guided lower and now in the fourth quarter you beat expectations and guided in line with the Street. If you had to say what happened between the last conference call and this conference call, could you just put a couple of items that the may give you some increased confidence in the way of the financial guidance is being provided? Thank you.

**Jim Crines – Zimmer Holdings, Inc. – EVP-Fin., CFO**

Sure, as David explains, we've had the opportunity to go through a very detailed review of our business unit and corporate operating plans, we're very pleased frankly with the performance in the fourth quarter relative to our earlier expectations. We see our supply chain and our sales and distribution networks responding to the increase that we're seeing in demand across the quarter. That together with the process that we went through gives us the confidence that we have going into 2008 that we will meet or exceed the financial targets that we've set for ourselves.

\* \* \*

**Tao Levy – Deutsche Bank – Analyst**

All right, and you mentioned you talked about investing in compliance and systems. Do you currently have any issues with the FDA, any warning letters, that usually takes a few months for those to be posted, that they may have been issued or 483'd?

**David Dvorak – Zimmer Holdings, Inc. – President, CEO**

We don't have any warning letters at this point.

\* \* \*

**Bill Plovanic – Canaccord Adams – Analyst**

Great, thank you, just a few questions, clarification questions for me here. First of all just in terms of the double digit earnings growth '09 off of '08, is that off of the 4.20 to 4.25 guidance?

**David Dvorak – Zimmer Holdings, Inc. – President, CEO**

That's correct.

\* \* \*

**Michael Matson – Wachovia Capital Markets – Analyst**

Thanks for taking my question. I haven't heard a lot of questions about your acquisition strategy so I thought I would revisit that. I just wanted to see looking out at 2008 if you're still targeting the sort of 100 million \$400 million range that you've talked about in the past?

**David Dvorak – Zimmer Holdings, Inc. – President, CEO**

You shouldn't start that as a reference point, I think going forward, Michael. I think with respect to our merger and acquisition strategy, we again think that we have a great portfolio of businesses and one of the reasons that we like the mix of businesses that we have now is many of the acquisitions that we do such as in ORTHOsoft, we feel we can leverage that to the advantage of all those different business units. So that's going to be beneficial to hips, knees, to spine, and we'll take it to other business units over time as well. Our priorities going forward will continue to be in a category of fill-in acquisitions, for spine, dental, we like that space as we've talked about on this call, and we would like to expand critical mass within the dental marketplace and of course, biologics we believe that these solutions will be the wave of the future and so we continue to be interested in exploring opportunities there. It's not limited to those three categories but those are principal categories that organize our proactive efforts at this point in time.

Our criteria really hasn't changed from our past discussions, strategic fit is of the utmost importance to us. We have an organization that I think has done enough, especially through the Centerpulse integration to understand how much work these transactions take and so we want to make sure that through all of those efforts in spending the capital that we're going to get a good return for our shareholders and so we're very financially disciplined in the approach that we take to these acquisitions.

15. As a result of these statements, Zimmer's stock price shot from \$68.08 to \$77.03 in one day, a 13% increase, as the stock became artificially inflated.

16. On January 30, 2008, Zimmer presented at the Wachovia Healthcare Conference. Specifically, defendant Crines stated:

[S]ummarizing our guidance for 2008, we guided to top line of 10% to 11% reported growth. That does include about 200 basis points from currency, so it would translate into 8% to 9% constant currency growth and adjusted earnings per share of \$4.20 to \$4.25. That reflects about a 4% to 5% growth in adjusted earnings per share over 2007 and includes significant obviously incremental expenses associated with the infrastructure and operating initiatives, as well as monitor and related compliance expenses.

\* \* \*

Within our core franchise, we would expect to be able to achieve at least low double-digit growth in earnings going into '09 and have the opportunity to leverage some of these investments beyond 2009.

17. On March 18, 2008, Zimmer presented at the Cowen and Company Health Care Conference. Specifically, defendant Crines stated:

We also, as we look at our hip portfolio, recognize and would acknowledge that we have some challenges and opportunities. . . . So there are some things that we need to do in terms of providing training to orthopedic surgeons and some things that we can do, as well, from a development perspective, to address some design differences with respect to our device and how it matches up with competitive devices. That's something that will take a bit longer. But certainly, the training is something that we can begin to address already in 2008.

\* \* \*

We have, as we talked about on our fourth quarter call three, major priorities for 2008, the first of which is to meet or exceed our financial commitments for this year.

18. On April 3, 2008, Zimmer issued a press release which stated:

Zimmer Holdings, Inc. announced today that it has taken a number of actions to improve quality systems at its Dover, Ohio facility, which manufactures Zimmer Orthopaedic Surgical Products (OSP).

The Company recently conducted a review of quality systems at the Dover, Ohio OSP facility and initiated voluntary product recalls of certain OSP products manufactured at the Dover facility that the Company has determined do not meet internal quality standards. In addition, the Company has voluntarily and temporarily suspended production and sales of certain OSP products manufactured at the Dover facility. The suspension will permit the Company to focus the OSP organization on the needed improvements to manufacturing and conduct enhanced quality training for employees.

The Company has notified the U.S. Food and Drug Administration (FDA), distributors and end-users of the recalls. These recalls do not affect the Company's core hip and knee implants business.

The OSP division produces a variety of patient care items used to support orthopaedic surgery, including disposables used in blood management, surgical wound site debridement and cement accessories. In 2007, Zimmer reported revenues from its OSP and Other product category of \$234 million, less than half of which were generated by products affected by the recalls and suspension. These actions are expected to adversely impact 2008 OSP revenues by \$70 to \$80 million. Additional detail on the expected impact will be provided during the Company's first quarter investor conference call on April 24, 2008.

19. On April 24, 2008, Zimmer issued a press release announcing the Company's financial results for the first quarter of 2008. Later that day, defendants held a conference call with financial analysts who covered Zimmer. During that call, defendants stated:

**David Dvorak – *Zimmer Holdings, Inc. – President, CEO***

\* \* \*

We previously explained that we developed our guidance taking into account our assessment of the market and the ongoing opportunities and risks that could cause and impact our performance. Our outlook called for top line growth for the year of 10 to 11% net sales on a reported basis. As we indicated in our fourth quarter call, sales will be driven by new product introductions and further market penetration by key products launched in 2007 and this year, as well as the positive effect of a weaker U.S. dollar a broad. Our guidance for top line growth remains in the 10 to 11% range on a reported basis. The previously announced impact on OSP revenues is expected to be offset by the positive effect of a weaker dollar. In addition, as the year began, we projected earnings per share between \$4.20- and \$4.25 based on those expectations. We've maintained that guidance today, after taking into account the negative financial impact we'll experience as a result of lost sales, inventory losses, and remediation costs in our OSP business. We have also now factored in the anticipated positive financial impact of a number of other planned actions that that Jim will describe in your detail which are expected to offer the negative impact of the OSP situation.

On our fourth quarter earnings call, Jim and I previewed a number of significant infrastructure initiatives that will position us to respond to the growing medical needs of an aging population. Chief among these are the investments we're making to ensure that we maintain state-of-the-art quality systems and processes in all of our business operations globally. Our ongoing commitment to quality will be unyielding as we continuously improve our quality systems. To that end, our infrastructure investment plans for 2008 are in part directed at opportunities to enhance quality systems across our entire manufacturing network and to ensure the

quality systems and practices in all divisions meet or exceed our standards as well as those of agencies that regulate us. As a result of this endeavor, in the first quarter we initiated a comprehensive remediation effort at our OSP division in Dover, Ohio, including voluntary product recalls of certain OSP products, voluntary and temporary suspension of manufacturing and sales of certain products, facilities equipment and procedural upgrades, enhanced quality training for OSP employees, and appointment of a new Divisional President. While we're clearly disappointed by the OSP situation, we believe the actions we've taken demonstrate the seriousness with which we take quality systems matters and we're keeping the FDA informed of all of our actions.

\* \* \*

**Jim Crines – Zimmer Holdings, Inc. – CFO**

\* \* \*

Finally, orthopaedic surgical products and other sales grew 0.8% constant currency in the quarter. Patient care product sales declined 15.6% as a result of the OSP actions, while bone cement and accessory sales now reported in this category increased 23.4% over the first quarter 2007. The OSP and other category was up 3.2% in the Americas, 0.5% in Asia Pacific and declined 9.1% in Europe compared with prior year period.

\* \* \*

Now, I'd like to provide an update on guidance for 2008. As reported in our press release on April 3, OSP related actions are expected to adversely impact 2008 OSP revenues by 70 million to \$80 million. These actions are expected to negatively impact 2008 adjusted earnings per share by \$0.18 to \$0.20 including \$0.07 related to inventory charges, idle plant costs, and other nonrecurring expenses. Approximately \$0.03 of the full year effect is reflected in our first quarter results. We expect this impact to be offset by reductions in planned operating expenses, share repurchases, and other actions.

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**Kristen Stewart – Credit Suisse – Analyst**

It sounds like OSP was something that maybe took you a little bit by surprise. Have you gone through and reviewed the quality systems at your other facilities? Are you comfortable there? Do you have any FDA warning letters that you perceive or any 483 observations? I guess what level of comfort do you have that your quality systems elsewhere are what you might expect?

**Jim Crines – Zimmer Holdings, Inc. – CFO**

Yes, the manufacturing in our other facilities isn't affected by the OSP announcement and the quality of our products from those facilities isn't in question

in our minds. We have a very proactive effort to continuously improve our quality systems and those over the course of the last year or so have included in depth audits conducted by a third party and it's the same firm that we brought into OSP and are getting their help in scoping out any redesigns that are necessary as part of those remediation efforts. So our implant facilities, our major facilities have been reviewed by that same firm and we're comfortable with our quality systems at those facilities.

20. As a result of these disclosures, Zimmer's stock price declined from \$75.95 to \$72.87, a 4% drop in one day, as artificial inflation came out of the stock price. The stock remained artificially inflated, however, because the full truth had not yet been disclosed.

21. On April 25, 2008, analyst Philip Legendy of Thomas Weisel Partners issued a report on Zimmer which stated:

**Ortho Surgical Products recall impact substantial:** On Thursday's earnings call, the company provided additional details of the OSP recall originally announced in April. Management expects adjusted EPS to be negatively impacted by \$0.18 to \$0.20 for the full year, with \$0.03 reflected in the first quarter's results. The impact is much higher than our previous estimate of \$0.10-\$0.12.

22. On April 25, 2008, analyst Ben Andrew of William Blair & Company issued a report on Zimmer which stated:

The Orthopedic Surgical Products (OSP) division, which is involved in the voluntary product recall, is expected to have modest impact of around \$75 million on Zimmer's top line in 2008. But the impact on earnings is likely much higher, at \$0.18 to \$0.20, than our expectation of around \$0.05, due to lost operating income, related inventory charges, idle plant costs, and other nonrecurring expenses. We expect the company to offset a large part of this lost earnings through cost reductions, share repurchases, and other initiatives, but view the quality of those EPS gains as low.

23. On May 6, 2008, defendants made a presentation at the Deutsche Bank Securities Inc. Health Care Conference. At that conference, defendant Crines stated::

We have talked in the past about a segment – subsegment of the hip portfolio growing at a faster rate than the overall hip portfolio, that subsegment being the alternate bearing offerings that address the needs of a younger patient, where there's an expectation with, for example, the metal-on-metal offerings, that surgeons will be able to achieve better longevity with those devices. In our particular case, we have this Durom cup, which goes with our Metasul large diameter heads. That is our metal-on-metal offering here in the U.S.

\* \* \*

I will tell you that this device, this construct, has been in the market here in the U.S. since the second half of 2006. There are many surgeons that have had very good clinical results with this device. It's been in the European market for over three and a half years. There's independent registry data – as an example, the Swedish registry that's tracking over 200 patients and out three and a half years is reporting 99.5% survivorship with this device. . . .

I will also tell you that we did receive . . . indications in the European market in the early part of 2007 with a couple of surgeons in France. We were able to trace their experiences to issues with the technique that they were using. This is a cup that once it's seated up into the acetabulum cannot be repositioned. And we have had situations where – this particular situation in France where a couple of surgeons had experienced early failures as a result of the technique that they were using where they were repositioning the cup after it had been seated up into the acetabulum. So we were able to address that particular issue with surgical technique training.

That's an issue I can tell you that we paid a lot of attention to here in the U.S. as this product has been launched into the U.S. There's a lot of information that's provided to our sales reps, training that's provided to our sales reps, so they're able to convey to any surgeons that are using this device the importance of following the technique.

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**Tao Levy – Deutsche Bank Securities – Analyst, Moderator**

But as far as Zimmer is concerned, I mean, in terms of the product properly manufactured, working well with the proper technique, data out of Europe and out of Australian registries, no reason to pull this thing off the market. It's still a very good product.

**Jim Crines – Zimmer Holdings, Inc. – CFO**

We have no plans at this stage to recall this product.

**Tao Levy – Deutsche Bank Securities – Analyst, Moderator**

Okay. Any questions from the audience? So I'll move on. OSP, it's another topic of conversation. Obviously last week there was some commentary among investors of the theoretical possibility that that facility would get a warning letter. So maybe you could walk us through the timeline of events, and does – obviously a warning letter can happen at any manufacturing facility, by definition, but where you stand regarding those thoughts.

**Jim Crines – Zimmer Holdings, Inc. – CFO**

Sure. I had at an earlier conference responded to questions concerning whether or not that's a possibility, and as you point out that's always a possibility following an inspection. There was an inspection at this facility in the first quarter. There were observations that were made as a result of that inspection. So, again, is there a possibility that that could lead to a warning letter? Yes. That possibility does exist. I want to be very careful to stay away from speculating as to what the FDA will do. The FDA has their own processes, I'm sure, that they go through. And I have no way of knowing, or no insight as to whether or not they would go forward in this particular case and issue a warning letter. At this point we do not have a warning letter.

**Tao Levy – Deutsche Bank Securities – Analyst, Moderator**

But it's fair to assume, so they went in, I think it was January time frame, did their inspection, since you recalled products, that you probably got some 483s after they left. Again, I'm assuming that. My understanding of how a warning letter develops is there's some back and forth over time. FDA poses some issues that they've found. Zimmer tries to address them or indicate how they're going to address them. And then FDA comes back saying whether they're comfortable with that or not, and if not then maybe you get a warning letter down the road.

**Jim Crines – Zimmer Holdings, Inc. – CFO**

Well, I'll just walk -- I'll walk through the timeline of events at the Dover facility. There was an inspection, as I said, in the first quarter. There were observations made. The Company, following that inspection and the observations that were made, made a decision internally to pull together a team and send a team into that facility to do our own more in-depth review. The FDA inspection, I will tell you, is really focused on quality systems. Our more in-depth review covered not just the quality systems but all manufacturing processes, really doing a deep dive on the operation. And we did that, again, coming out of the observations that were made by the FDA inspector, which caused us some concern.

That ultimately led to some additional product recalls and the decision, then, ultimately, to voluntarily suspend production of certain – sales and production of certain products there. We have, you can assume, both responded to the FDA in terms of what our action plans are concerning the observations that they've made, and then have also provided information to the FDA concerning the additional product recalls, the issues that led us to make those decisions and what our plans – what our broader plans are with respect to addressing all of the issues at that facility, not just the issues that the FDA identified as part of their inspections, but other issues, as well, that we identified as part of our internal review.

**Tao Levy – Deutsche Bank Securities – Analyst, Moderator**

You had mentioned that FDA initially went in there to look at quality.

**Jim Crines – Zimmer Holdings, Inc. – CFO**

That particular inspection happened to be focused on quality systems. It was a routine inspection, to my understanding. They – as a matter of routine, the FDA is in all of these facilities periodically.

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**Unidentified Audience Member**

Do you think you could help us with the Durom issue? I mean, looking at past product issues at other companies, how are these things usually handled over time? How do they play out? What happens in terms of products, in terms of surgeon training, in terms of your liability for medical costs for these revision surgeries, if any, etc.? How does that work?

**Jim Crines – Zimmer Holdings, Inc. – CFO**

You know, this Company has a long history, as the industry does, in dealing with failures. They do happen. They happen in the normal course. They are typically multifactorial. It could be an issue with surgical technique. It could be an issue with a patient going off and doing things that they're told not to do after getting a total hip or total knee replacement. As we get information about failures submitted to the Company, we have an obligation to report those to the FDA on a medical device report, an MDR report, so those all get submitted to the FDA. The surgeons also have an obligation to submit those to the FDA, so as they experience failures within some segment of their patient population they would be submitting. So there's a fair amount of information in that FDA database – gives you some sense of what the historical sort of failure rate is for these devices. You know, we talk about 98 to 99% survivorship, which is somewhat unprecedented among medical devices, but that does tell you that there's at least a 2% failure rate.

In terms of how we deal with what arises in the form of product liability claims associated with those failures, we get them. We have people internally who manage those product liability claims. I will tell you we're self-insured for those claims. And at any point in time we are managing a portfolio of product liability claims and either settling out of those claims with cash payments to individuals to cover their cost of their revisions and maybe some payment for pain and suffering. And that is very common and has been, and I imagine very common across the industry.

24. On June 26, 2008, analyst Raj Denhoy of Thomas Weisel Partners issued a report on

Zimmer which stated:

In 1Q08, ZMH announced the recall of several products within their OSP (orthopedic surgical products) segment, reducing 2008 sales by ~\$70-\$80mn and removing ~\$0.20 from EPS. The recall of roughly ½ of ZMH's \$230mn OSP product portfolio was precipitated by a spot of silicone lubrication appearing on the pouch of its PulsaVac product, creating sterility concerns.

Following the issue with the spotting, the company and the FDA conducted inspections of its Dover facility. The FDA issued several 483 letters and ZMH proactively brought down several manufacturing lines and recalled products on several ancillary product lines. The recalls were voluntary and Zimmer will bring the lines back up as it validates them – further FDA sign off isn't needed.

25. On July 22, 2008, Zimmer issued a press release announcing the Company's financial results for the second quarter of 2008 stating:

#### Durom Acetabular Component

Zimmer is temporarily suspending marketing and distribution of the Durom® Acetabular Component (Durom Cup) in the U.S. on a voluntary basis, while the Company updates labeling to provide more detailed surgical technique instructions to surgeons and implements its surgical training program in the U.S. The Durom Cup will continue to be marketed without interruption outside the U.S.

While many surgeons have had success implanting the Durom Cup since it was launched in the U.S. in 2006, a subset have reported cup loosening and revisions of the acetabular component used in total hip replacement procedures. These results contrast with product experience in Europe, where post-marketing data continue to show excellent clinical outcomes since the product launched in 2003. Following a comprehensive review of clinical experience and product conformance to specifications in the U.S. and Europe, Zimmer has found no evidence of a defect in the materials, manufacture, or design of the implant. The Company has identified that surgeons who regularly achieve the desired outcome with the Durom Cup consistently execute crucial technique steps and place the cup in a specific manner. Following its review, Zimmer has determined that revised surgical technique instructions and a surgical training program are required to more consistently achieve desired clinical results in the U.S. The Company has shared its review and conclusions with the U.S. Food and Drug Administration and will continue to update the Agency.

While the Company believes the likelihood of currently implanted patients requiring revision is low, Zimmer has sent a letter to U.S. surgeons advising them to stop implanting the Durom Cup, until the updated labeling is issued providing more detailed surgical technique instructions and they receive training. Additional information is being made available at [www.zimmer.com](http://www.zimmer.com).

## Guidance

The Company is revising its guidance and expects full-year 2008 sales growth to be in a range of 8.5% to 9.0% over the prior year, which reflects constant currency growth of 4.5% to 5.0%. This compares with prior guidance of 10% to 11% reported and 6% to 7% constant currency growth over prior year. The adjustment to sales guidance includes a projected loss of \$20 to \$30 million in hip product sales pertaining to the Durom Cup in the U.S., weakness in U.S. Dental revenues and slower than anticipated uptake on certain new products. Adjusted diluted earnings per share for the full year are expected to be in a range of \$4.05 to \$4.10, as compared to prior guidance of \$4.20 to \$4.25. Revised earnings guidance gives effect to the reduction in sales from prior guidance as well as an increase in operating expenses associated with the global implementation of the Company's enhanced compliance program. Further details regarding the revised guidance will be discussed during tomorrow's investor conference call.

26. As a result of these disclosures, Zimmer's stock price declined from \$70.88 to \$66.01, a 7% drop in one day, as artificial inflation came out of the stock price.

27. On July 23, 2008, defendants held a conference call with financial analysts who followed Zimmer. On that call, defendants stated:

As we communicated last night, we have completed an extensive investigation into the performance of the Durom Cup here in the United States, following reports of cup loosening and revisions of acetabular component in some patients who have undergone total hip replacement.

While many US surgeons have had success with the Durom Cup since its launch, a subset have experienced elevated revision rates. This observation clearly contrasts ongoing positive clinical experience in Europe, where the product has been available since 2003.

We launched a rigorous investigation, which included a thorough review of manufacturing processes, design specifications, production documentation and clinical experience in the US and Europe. Based on the results of that investigation we will temporarily suspend marketing and distribution of the Durom Cup in the US.

We will update labeling to provide more detailed surgical technique instructions to surgeons and prepare to implement a comprehensive surgical technique training program for the US.

We have reviewed our investigation and conclusions with the US Food and Drug Administration, and are actively communicating with surgeons now through multiple channels to explain this field action and identify and address their related needs.

We're also communicating with customers around the world to clarify that the Durom Cup will continue to be marketed and distributed outside the United States without interruption.

Our primary objective in taking prompt action based on the results of our Durom investigation is to ensure better clinical outcomes for patients. We believe that the likelihood of currently implanted patients requiring revisions is low.

But we want to make sure that we are clear with our US surgeons that they should stop implanting the Durom Cup until we issue the updated labeling that provides more detailed guidance on surgical technique, and until they receive training.

We also, of course, want to make sure we support surgeons in every way we can as we implement these actions. With this goal in mind, we will provide clinical management guidelines to assist surgeons in the ongoing evaluation of patients currently implanted with the Durom Cup. Within the next several weeks we will issue a further communication to US surgeons that provides them with updated labeling, including more detailed surgical technique instructions.

We also are working with experts in Europe and the United States to develop a robust surgical skills training curriculum. Following initiation of the new training program, the Durom Cup will be made available to US surgeons again as they complete training.

We're confident that these measures are the prudent and responsible course of action. And we are committed to conducting them in a manner that demonstrates our deep commitment to patients and our customers.

\* \* \*

We made good progress during the quarter on our quality systems upgrades. With respect to our orthopedic surgical products operation in Dover, Ohio, our remediation plans continue as scheduled. And we expect to have most, if not all, of OSP products back in production by the end of this year, many in the next two or three months.

\* \* \*

During the quarter Jim, Cheryl and I, as well as many other members of our senior management team, personally met with over 100 surgeons. We explained the chronology of events of the past year or so, where we are today, and how we believe our surgeon relationships will carry forward. While this process certainly has not been easy, and we have addressed many tough and fair questions, I will tell you that it is great to be reengaged with our surgeon community.

\* \* \*

I will now turn to our updated guidance for the full year 2008. Jim will provide more details momentarily. Due to the developments in the second quarter, including Durom, we are revising our expectations for 2008 fully full year sales growth to 4.5% to 5% constant currency.

We're also lowering our adjusted earnings guidance for the full year to be between \$4.05 and \$4.10 per fully diluted share.

\* \* \*

Sales of \$1,080 million for the quarter represent an increase of 11.2% reported and 5.5% constant currency. These results, among other things, reflect the benefit of one additional selling day in the quarter compared to same period in the prior year, strong underlying unit growth in knees in all three of our operating segments, and lower OSP, Durom and dental product sales.

\* \* \*

In the US Durom Cup sales volume was off 26% from our first quarter in response to reports of loosening and revisions. Durom Cup sales units outside the US grew by over 10% in the second quarter compared to same period prior year. These results, absent Durom-related losses, reflect steady growth across our primary hip portfolio, including porous primary stems and our Trilogy and TM Acetabular Cups.

\* \* \*

The OSP and other category was down 15.6% in the Americas, declined 26.8% in Europe, and was down 17.3% in Asia-Pacific compared with the prior year period.

\* \* \*

Now I would like to provide an update on guidance for 2008. We expect to deliver topline sales growth in 2008 of 8.5% to 9% compared to the original 10% to 11% range. And adjusted earnings per share in the range of \$4.05 to \$4.10.

Our sales guidance anticipates approximately 4 points of growth to come from foreign currency, and therefore assumes a constant currency growth rate of 4.5% to 5%. The adjustment to our sales guidance includes a projected loss of \$20 million to \$30 million in hip products sales, pertaining principally to Durom Cup in the US, weakness in US Dental revenues, and slower than anticipated uptake on certain new products, partly due to delays in offering training programs in support of the new products introductions.

\* \* \*

**Tao Levy – Deutsche Bank – Analyst**

I was wondering maybe if you could spend a few minutes going through – you did mention as we move into 2009 some of the headwinds you are facing in '08 start to disappear. I was wondering if you could quantify the three main areas and the impact that you're seeing this year, and what percentage of that could disappear in '09?

I would love it if you could hit Durom, OSP and the compliance monitors.

**Jim Crines – Zimmer Holdings, Inc. – EVP Finance, CFO**

This is Jim. First of all, with respect to – I guess will start with OSP. As David indicated and I indicated in my comments, we're on schedule with our remediation efforts. Expect to be back in production of those patient care products between now and the end of the year. And have the opportunity to go back into the market as those products come back online.

Going into 2009 we would look to get back as much of that \$70 million to \$80 million as we lost as we possibly can. We wouldn't expect to get all back. But we will certainly be back in the market with those products and pursuing opportunities to regain share in that segment.

\* \* \*

**Bruce Nudell – UBS – Analyst**

I have two questions actually. The first just pertains to Durom itself. In your background you mentioned 1.1% failure rate for people who knew what they were doing and around 6% for groups that really weren't following the protocol exactly.

What is the aggregate – what is the anticipated aggregate revision rate, early revision rate with the product, given the disparities in training? And how much reputational damage could do that cause, given the 13,000 implants that have taken place to date?

**David Dvorak – Zimmer Holdings, Inc. – President, CEO**

I'm going to let Cheryl respond to that question.

**Cheryl Blanchard – Zimmer Holdings, Inc. – Chief Scientific Officer**

I think the best way to answer that question is, first of all, to understand that what our analysis tells us to date is that the likelihood of currently implanted patients requiring revision is going to be low.

I will tell you that in our detailed analysis of the clinical aspects of those investigations, you did see in the backgrounder piece that in the group that had

success with the device that they had about a 1.1% revision rate, while the other groups were at 5.7%.

It is very difficult for us to project out where we think those numbers are going to go eventually. What I can tell you is that we were able to discern there were some specific elements of surgical technique and cup placement that are the items that really make the difference in terms of those clinical outcomes.

I think it is difficult to comment on the last part of your question, which is reputational damage. I think that will frankly be determined by the actions that we have taken today and our level of being proactive as we move forward, trying to work with surgeons to help them get through this difficult situation with their patients.

We absolutely recognize that for those patients that are involved that there will be some items that we will need to help them with, and we're going to be proactive about that.

\* \* \*

**Michael Jungling – Merrill Lynch – Analyst**

\* \* \*

Secondly on Durom, the \$20 million to \$30 million worth of sales, can you indicate how much that is in terms of annual sales? I think it is pretty much the entire amount.

\* \* \*

**Jim Crines – Zimmer Holdings, Inc. – EVP Finance, CFO**

This is Jim. With regard to Durom, as we indicated in earlier comments, it represents about 5% to 10% of our hip revenues in the US. It happens to be the case as well outside the US.

If you look at how, and we look at how that product was growing coming into the year, coming out of the first quarter before reports of loosening and revisions, we were trending clearly to the high end of that range. And the \$20 million to \$30 million, again principally associated with Durom, does get you to two-thirds to the full amount.

But as I indicated, with regard to the hip franchise there's also the impact that some disruption that training is having on the new products that we reintroduced in the hip portfolio, namely the M/L taper with Kinectiv and the Fitmore and the EPOCH devices, that we're focused on in the second half of year as well.

\* \* \*

**Ben Andrew – *William Blair – Analyst***

I just wanted to follow up with a couple of quick things. Is there any plan to accumulate clinical data related to Durom in the United States? You talked about the need for clinical evidence, maybe with a registry or a broader study?

**Cheryl Blanchard – *Zimmer Holdings, Inc. – Chief Scientific Officer***

What I can tell you is with respect to the ongoing experience and the experience that we will move forward with post training, that we will be continuing to very closely monitor the clinical experience with this device.

28. On July 23, 2008, analyst Ben Andrew of William Blair & Company issued a report on Zimmer which stated:

Zimmer announced it is suspending the marketing and distribution of Durom in the United States, which has been the major concern for investors in the past couple months.

**DEFENDANTS' CLASS PERIOD STATEMENTS  
WERE MATERIALLY FALSE AND MISLEADING**

29. Defendants' Class Period statements were materially false and misleading for failing to disclose that a) the quality systems at Zimmer's Dover, Ohio facility, which manufactured Zimmer OSP were seriously flawed, and b) that many patients receiving the Durom Cup in total hip replacement procedures disproportionately experienced cup loosening that required additional corrective surgery after implantation.

**DEFENDANTS' SCIENTER**

30. Defendants are Zimmer, its President and CEO, as well as its CFO. Each of the Individual Defendants, by virtue of their high-level positions with Zimmer, directly participated in the management of Zimmer, were directly involved in the day-to-day operations of Zimmer at the highest levels, and were privy to confidential proprietary information concerning Zimmer and its business, operations, products, growth, financial statements and financial condition, and were aware of or deliberately disregarded that the false and misleading statements were being made by and regarding the Company. Because of their managerial positions with Zimmer, each Individual

Defendant had access to the adverse undisclosed information about Zimmer's business, financial condition, and prospects and knew (or deliberately disregarded) that the adverse facts alleged herein rendered the positive representations made during the Class Period materially false and misleading.

### **LOSS CAUSATION/ECONOMIC LOSS**

31. During the Class Period, as detailed herein, defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated Zimmer's stock price and operated as a fraud or deceit on Class Period purchasers of Zimmer stock by misrepresenting the Company's business success and future business prospects. Later, however, when defendants' prior misrepresentations and fraudulent misconduct were disclosed and became apparent to the market, Zimmer's stock price fell precipitously as some of the prior artificial inflation came out of Zimmer stock. As a result of their purchases of Zimmer stock during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

### **CLASS ACTION ALLEGATIONS**

32. This is a class action on behalf of purchasers of Zimmer common stock between January 29, 2008 and July 23, 2008, excluding defendants (the "Class"). Excluded from the Class are officers and directors of the Company, as well as their families and the families of the defendants. Class members are so numerous that joinder of them is impracticable.

33. Common questions of law and fact predominate and include whether defendants: (i) violated the 1934 Act; (ii) omitted and/or misrepresented material facts; (iii) knew or recklessly disregarded that their statements were false; and (iv) artificially inflated the price of Zimmer common stock and the extent of and appropriate measure of damages.

34. Plaintiff's claims are typical of those of the Class. Prosecution of individual actions would create a risk of inconsistent adjudications. Plaintiff will adequately protect the interests of the

Class. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

## **COUNT I**

### **For Violations of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

35. Plaintiff incorporates by reference ¶¶1-34 herein.
36. Defendants violated §10(b) and Rule 10b-5 by:
- (a) Employing devices, schemes and artifices to defraud;
  - (b) Making untrue statements of material facts and omitting to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and
  - (c) Engaging in acts, practices and a course of business that operated as a fraud or deceit upon the Class in connection with their purchases of Zimmer common stock.
37. Class members were damaged as they paid artificially inflated prices for Zimmer common stock in reliance on the integrity of the market.

## **COUNT II**

### **For Violations of §20(a) of the 1934 Act Against All Defendants**

38. Plaintiff incorporates by reference ¶¶1-37 herein.
39. Each of the Individual Defendants acted as a controlling person of the Company within the meaning of §20(a) of the 1934 Act, 15 U.S.C. §78t(a), as alleged herein. By virtue of their stock ownership, and high-level positions, and participation in and/or awareness of the Company's operations, each Individual Defendant 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 that plaintiff contends are false and misleading.

Each Individual Defendant was provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by plaintiff 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.

40. Each Individual Defendant had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, was presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same. Zimmer controlled the Individual Defendants and all of Zimmer's employees.

41. By reason of such wrongful conduct, Zimmer and the Individual Defendants are liable pursuant to §20(a) of the 1934 Act. As a direct and proximate result of the wrongful conduct, plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's stock during the Class Period.

#### **PRAYER FOR RELIEF**

WHEREFORE, plaintiff, on behalf of itself and the Class, prays for judgment as follows:

A. Declaring this action to be a class action properly maintained pursuant to Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding plaintiff and other members of the Class damages together with interest thereon;

C. Awarding plaintiff and other members of the Class costs and expenses of this litigation, including reasonable attorneys' fees, accountants' fees and experts' fees and other costs and disbursements; and

D. Awarding plaintiff and other members of the Class such equitable/injunctive or other and further relief as may be just and proper under the circumstances.

**JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: August 5, 2008

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SCOTT D. GILCHRIST (16720-53)

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