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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

BRADLEY COOPER, Individually and On Behalf of All Others Similarly Situated, Plaintiffs, v. THORATEC CORPORATION, GERHARD F. BURBACH, TAYLOR C. HARRIS, and ROXANNE OULMAN, Defendants.	Case No. 4:14-cv-00360-CW CLASS ACTION **AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** DEMAND FOR JURY TRIAL

Lead Plaintiff Bradley Cooper ("Plaintiff"), individually and on behalf of all others similarly situated, by his undersigned attorneys, for the Amended Complaint against Defendants Thoratec Corporation ("Thoratec" or the "Company"), Gerhard F. Burbach ("Burbach"), Taylor C. Harris ("Harris"), David V. Smith ("Smith"), and Roxanne Oulma ("Oulma"),[1] allege the following based upon personal knowledge as to Plaintiff and his own acts, and upon information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiffs' attorneys, which includes, among other things, interviews with former Thoratec employees, a review of the Company's public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Thoratec, analysts' reports and advisories about the Company, and information readily publicly available. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities class action on behalf of all persons or entities that purchased or otherwise acquired the common stock of Thoratec Corporation ("Thoratec" or the "Company") between April 29, 2010 and November 27, 2013, both dates inclusive (the "Class Period"), against Thoratec and certain of its officers and/or directors for violations of the Securities Exchange Act of 1934.

2. Thoratec is medical device company that researches, develops, manufactures, and markets devices for circulatory support and vascular graft applications. One of the Company's primary products is a Ventricular Assist System ("VAS"), the HeartMate II Left Ventricular Assist Device ("HeartMate II" or the "Device"). A ventricular assist device is a mechanical pump that is used to support heart function and blood flow in people who have weakened hearts.

[1] Burbach, Harris, Smith, and Oulma are referred to collectively as the "Individual Defendants." Thoratec and the Individual Defendants are referred to collectively as the "Defendants."

3. Prior to 2009, Thoratec was the sole manufacturer of ventricular assist systems. In 2009, competition entered the market from Heart Ware International, Inc., and its Heart Ware Ventricular Assist Systems ("Heart Ware"). In response to the new competition, during the Class Period, Thoratec marketed the HeartMate II as achieving lower thrombosis rates than Heart Ware, even though Thoratec was aware that thrombosis rates associated with the use of HeartMate II were increasing, which caused increased morbidity and mortality in patients receiving the HeartMate II.

4. Indeed, during the Class Period, data showed that the HeartMate II had significant serious safety issues, causing serious adverse events ("SAE's"), including serious injuries and deaths. Sixty-nine (69) patients receiving the HeartMate II died during the Class Period due to thrombosis associated with the use of the device. Thoratec and the Individual Defendants, however, knowingly, or at a minimum, recklessly, failed to disclose the increase in morbidity and mortality, much less any concerns about the device's safety.

5. Instead, during the Class Period, Defendants routinely misrepresented to the public that the HeartMate II was safe, and that it was experiencing a small number of SAE's. The statements about the small number of SAE's, however, were based on old data obtained from the device's pre-approval clinical trials. The current data, to the contrary, evidenced that the HeartMate II was experiencing increased rates of thrombosis, including deaths. When Defendants were asked specifically about the increased rates of thrombosis during the Class Period, they misrepresented the new clinical data, and instead of disclosing the truth, opted to mislead investors by touting low thrombosis rates associated with the pre-approval clinical trials.

6. Thoratec and the Individual Defendants were aware of the increased rates of thrombosis, and the increase in morbidity and mortalities, because such information was communicated to them by (1) the Company's own internal monitoring of SAE's, as well as (2) clinicians who treated or monitored patients receiving the HeartMate II.

7. Former employees who worked at Thoratec during the Class Period have acknowledged that the Company's senior management was notified as part of the Company's complaint process of any ongoing problems with the device. One Confidential Witness ("CW") specifically stated that Thoratec was marketing the HeartMate II as safer than its only competitor, Heart Ware, and claiming lower thrombosis rates, when, in fact, the Company was aware that thrombosis rates were rising at alarming rates causing serious morbidity and mortality. Further, Defendants received warnings from the United States Food and Drug Administration ("FDA") regarding (1) safety issues with HeartMate II, and (2) violation of regulations concerning the reporting of adverse events.

8. Rather than disclose this material information about the increase in thrombosis rates and increase in morbidity and mortality, Defendants concealed it from the public during the Class Period, opting instead to tell the public that the device was safe and experienced low rates of thrombosis. Specifically, Thoratec and Defendants touted the safety of the device despite their knowledge of increased rates of pump thrombosis,[2] increased safety issues with the bend relief, and increased safety issues with the device's battery, which all caused increased morbidity and mortality. As a result of the foregoing, the Company's positive statements about the HeartMate II were materially false and misleading at all relevant times.

9. Throughout the Class Period, analysts covering Thoratec echoed Defendants' false and misleading statements and omissions while emphasizing the increase in HeartMate II sales. For example, on April 4, 2012, the FDA issued a class 1 recall of the HeartMate II, due to the lack of safety of the detachment of the bend relief, which caused SAE's(and have been associated with pump

[2] Pump Thrombosis is defined as "a thrombus found on the blood-contacting surfaces of the HeartMate II, its inflow cannula, or its outflow conduit at pump replacement, urgent transplantation, or autopsy." *See* Randall C. Starling, M.D., *et al.*, *Unexpected Abrupt Increase in Left Ventricular Assist Device Thrombosis*, New Eng. J. Med. Nov. 27, 2013. Thrombosis is defined by the Merriam-Webster Dictionary as "a serious condition caused when a blood clot blocks the flow of blood in a blood vessel."

thrombosis), requiring the Company to report them to the FDA. On that same day, analyst Christopher Pasquale of JP Morgan, advised investors:

> The incidence of outflow graft problems reported to date has been very low….Thoratec believes that the problem can be effectively avoided by carefully following the implant instructions…. Impact on results should be negligible. We do not expect this field action to result in any disruption of Thoratec's implant volume.

10. The house of cards began to tumble after the market closed on November 27, 2013, when The New England Journal of Medicine released a study entitled, "Unexpected Abrupt Increase in Left Ventricular Assist Device Thrombosis" concluding that the "rate of pump thrombosis related to the use of the HeartMate II has been increasing at our centers and is associated with substantial morbidity and mortality."

11. The New England Journal of Medicine study determined that the occurrence of pump thrombosis associated with the HeartMate II jumped from the 2% which was reported with the pre-approval trials to 8.4% by January 2013, and was not expected to return to the previously reported pre-approval trial level.

12. On this news, Thoratec shares declined $2.75 per share or 6.5%, to close at $39.37 per share on November 29, 2013.

13. In interviews shortly after the New England Journal of Medicine study was reported, Defendant Burbach admitted that there was an increase in rates of thrombosis during the Class Period, and that Thoratec's own data confirmed as much, noting that "there's a slight increase beginning in 2010 and then ranging through 2011 and 2012."[3]

14. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant damages.

[3] Piper Jaffray Health Care Conference, Management Discussion Section, December 2, 2013.

15. The Individual Defendants, on the other hand, realized substantial profits during the Class Period. While issuing false statements and omitting to disclose material information to investors about the device's safety, the Individual Defendants netted approximately $23.3 million from sales of Thoratec stock during the Class Period. Most egregiously, Defendant Burbach had only previously sold 41,286 shares of stock for a profit of around $1.1 million in the three plus years prior to the class period. During the three years of the Class Period, however, Burbach sold more than 10 times the amount of shares he sold prior to the Class Period, selling 541,173 shares and reaping a profit of approximately $21.4 million.

JURISDICTION AND VENUE

16. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule l0b-5 promulgated thereunder by the SEC, 17 C.F.R § 240.10b-5.

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

18. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). Thoratec maintains its principal place of business in this District and many of the acts and practices complained of occurred in substantial part herein.

19. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

20. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Thoratec securities at artificially inflated prices during the Class Period and was damaged thereby.

21. Defendant Thoratec is a California corporation with its principal place of business at 6035 Stoneridge Drive, Pleasanton, CA 94588. Thoratec's common stock trades on the NASDAQ Global Market ("NASDAQ") under the ticker symbol "THOR."

22. Defendant Gerhard F. Burbach ("Burbach") was, at all relevant times, the Company's President and Chief Executive Officer ("CEO").

23. Defendant Taylor C. Harris ("Harris") has been the Company's Chief Financial Officer ("CFO") and Vice President since October 11, 2012.

24. Defendant Roxanne Oulman ("Oulman") was the Company's Vice President of Finance and served as the Company's interim Chief Financial Officer between June 2011 and October 2012.

25. Defendant David V. Smith ("Smith") was the Company's Executive Vice President and Chief Financial Officer between December 2006 and July 2011.

26. The Defendants referenced above in ¶¶ 22-25 are referred to herein as the "Individual Defendants."

SUBSTANTIVE ALLEGATIONS

Background

27. Thoratec states that it is a world leader in mechanical support with a product portfolio to treat the full range of clinical needs for advanced heart failure patients. The Company develops, manufactures and markets proprietary medical devices used for mechanical circulatory support ("MCS") for the treatment of heart failure ("HF") patients. For chronic circulatory support for HF patients, the Company's primary product line is HeartMate II.

28. HeartMate II is an implantable, electrically powered, continuous flow, left ventricular assist device consisting of a rotary blood pump designed to provide intermediate and long-term MCS. HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients.

29. When the HeartMate II was created, the device represented a new design for Ventricular Assist Devices. Instead of the standard pulsatile pump that simulates the action of the heart, the device used a continuous flow pump that constantly moved blood with a single moving part, a spinning rotor. The new design allowed the device to be slimmed down compared to Thoratec's previous version, the HeartMate XVE.

30. In November 2003, the pilot trial for the HeartMate II began and consisted of 46 study patients at 15 centers.

31. On February 18, 2005, the Food and Drug Administration ("FDA") approved the HeartMate II pivotal clinical Trial. The HeartMate II pivotal clinical Trial included the evaluation of HeartMate II for two indications: Bridge-to-Transplantation ("BTT") and Destination Therapy ("DT"), for HF patients who are not eligible for heart transplantation.

32. In November 2005, Thoratec completed the required conformity assessment procedure and design dossier reviews to be given authority from the Notified Body to affix the CE Mark to the HeartMate II for marketing in Europe. The regulatory application for European approval was based on data from the first 20 patients implanted in the company's Phase I U.S. trial and in a European study.

33. In December 2006, Thoratec completed the submission of a Pre-Market Approval (PMA) seeking approval for a BTT indication.

34. On April 21, 2008, HeartMate II received FDA approval for BTT. The FDA also published a summary of safety and effectiveness data for the HeartMate II. The data demonstrated that as of September 14, 2007 the HeartMate II had a 2% rate of thrombosis for all patients.

35. In April 2009, Thoratec filed a PMA Supplement to provide data on adjunctive cohorts totaling an additional 409 patients, including those who had originally been supported by a HeartMate XVE who elected to receive a HeartMate II based on the need for device replacement.

36. On January 20, 2010, Thoratec received FDA approval for DT.

The Market for the HeartMate II

37. As of April 2008, about 5 million Americans suffered from heart failure, and those awaiting transplants spent $3 billion a year on devices to pump blood.

38. When the HeartMate II was approved for BTT use in 2008 Defendant Burbach announced that, "The HeartMate II is the first continuous flow device to receive FDA approval for this intended use in the U.S., representing a milestone in the treatment of advanced-stage heart failure patients and for the clinicians who treat them."

HeartMate II was marketed as safe and effective

39. In an April 21, 2008 press release, Thoratec described the benefit of the HeartMate II as being "easier to implant than prior devices, and with only one moving part, the HeartMate II is designed to provide exceptional reliability and improved patient quality of life. The device is designed to have a much longer functional life than the previous generation of devices and to operate more simply and quietly."

40. The Thoratec website describes the HeartMate II as:

> The HeartMate II is Thoratec's first-line intermediate-to-chronic left ventricular assist device. Designed to dramatically improve survival and quality of life, the HeartMate II was developed with the goal of providing several years of circulatory support for a broad range of advanced heart failure patients. Its small size and quiet operation make the HeartMate II suitable for a wider range of patients, including women and those of smaller stature. With product attributes specifically developed to minimize the risk of complications, **the HeartMate II is exceptionally durable, dependable, and thomboresistant**. (emphasis added).

41. Defendants further market the "HeatMate II Pocket Controller" as "the only lightweight, pocket-sized LVAD controller that safely and smartly enables an active lifestyle for HeartMate II Patients." They further emphasize that the "[backup battery provides at least 15 minutes of full power for peace of mind in an emergency situation," and the "[d]esign features make it easy to tech and

intuitive to learn how to live with the HeartMate II." The tagline for the "HeartMate II Pocket Controller" is "The Safe, Smart Face of the HeartMate II System."[4]

Pressure from HeartWare

42. Thoratec was the sole manufacture of Ventricular Assist Systems ("VAS") until 2009. Up until this point, the only competing device to the HeartMate II was Thoratec's own HeartMate XVE, which was an older and larger version of the HeartMate II.

43. In 2009, the HeartWare Ventricular Assist System, created by HeartWare International, Inc., received CE Marking in the European Union, for marketing and sale of the device in Europe. This created new competition to Thoratec's stranglehold on the Ventricular Assist System market.

44. In early 2009, HeartWare began its United States Clinical Trial to evaluate the safety and efficacy if the HeartWare VAS. On December, 28 2010, HeartWare filed its PMA with the FDA for the HeartWare VAS.

45. On April 5, 2012, Analysts Spencer Nam and Mary Nielson of ThinkEquity LLC noted the growing concern of competition by stating, "THOR is facing a strong competition. As we have indicated above, THOR is facing a challenging competitor that may take market share in BTT market once the device (HVAD) is approved. Strong clinical outcomes combined with an aggressive expansion plan by HTWR could put pressure on THOR's growth over time."

46. On November 20, 2012, the HeartWare VAS was approved by the FDA for BTT therapy.

47. Prior to and throughout the Class Period, there was a growing comparison and competition between the HeartMate II and the HeartWare VAS. Defendants proclaimed that the HeartMate II was safer than the HeartWare VAS.

[4] http://www.thoratec.com/medical-professionals/vad-product-information/pocket-controller.aspx

48. On December 4, 2012, The Advisory Board Company, a global health care research, technology, and consulting firm, published in article related to HeartWare's approval which stated:

> It is estimated that about half a million Americans have advanced heart failure (HF). The new HeartWare HVAD device will tap into this large and growing patient population. Roughly 2,000 patients worldwide have already been implanted with HVAD, and its commercial approval in the U.S. will change a landscape previously dominated by Thoratec.

Confidential Witnesses

49. Confidential Witness 1("CW 1") was a market development Manager with Thoratec from August 2010 through June 2012. CW1's primary job responsibility was to sell Thoratec devices, including HeartMate II to cardiologists through in-person sales and marketing. CW1 stated that she was instructed to tout the benefits of HeartMate II to doctors on the fact that the HeartMate II was safer than a comparable device made by a competitor, HeartWare, "because HeartWare caused more bleeding."

50. CW1 stated that although HeartMate II was advertised as safer than its competitor, HeartWare, due to lower rates of bleeding in patients. Despite the large amounts adverse event reports, CW1 stated that, Thoratec would circulate reports around the office about young people who had prolonged their lives due to HeartMate II, to counteract the adverse event data.

Thoratec Had Safety Issues From The Beginning

51. On October 24, 2008, Thoratec issued a worldwide medical device correction for the HeartMate II. The FDA stated that, "[o]ver time, wear and fatigue of the percutaneous lead connecting the HeartMate II LVAS blood pump with the System Controller may result in damage that could interrupt pump function, require reoperation to replace the pump and potentially result in serious injury or death." Thoratec voluntarily issued the device correction notice after confirming 27 reports where wear and fatigue to the percutaneous lead necessitated pump replacement. Thoratec's Stock dropped $1.11 or 4.24% on this date and continued to fall another $3.36 or 13.42% on the next trading day.

52. During the development of the device and through the Class Period there were a myriad of safety issues associated with the device. Both the bend relief and the battery pack have caused numerous safety issues and have led to Defendants issuing recalls relating to the bend relief and the battery pack. Further, it has been reported that the safety issues reported with the bend relief are associated with increased thrombosis, which Defendants had been claiming were lower rates than their competitor. However, Defendants never disclosed these issues to investors throughout the Class Period. Rather, Defendants continued to tout the device's safety and advantages over HeartWare.

53. The bend relief is part of the sealed implant kit that according to Thoratec "reduces overall procedure time, costs and variability associated with pre-clotting while maintaining the flexible inflow conduit design." The bend relief slides over the outflow graft of the HeartMate II to prevent the graft from kinking. In early 2011, Thoratec designed a new version of the bend relief so that it could be detached after initial attachment to allow for re-examination of the graft. The new version was designed to make it easier for surgeons to take air out of the graft.

54. Confidential Witness 2 ("CW 2") was a Manufacturing Engineer at Thoratec from October 2007 to February 2011. CW2 was mainly responsible for maintenance of equipment used to manufacture parts at Thoratec. CW2 had serious concerns about the safety of the HeartMate II, due to design flaws. CW2 specifically noted that in 2010 there were concerns with the safety of the bend relief. CW2 voiced his concerns to many individuals and engineers in the company from 2008 through 2010. However, these safety concerns were ignored and the product was manufactured without making changes to the design flaws in order to save money. Specifically, CW 2 brought concerns to CW's boss, Peter Obico ("Obico"), and Obico's boss, Caryn Aulenback, Senior Manager of Manufacturing New Production Introduction.

55. CW 2 noted that there was a culture at Thoratec to cut corners for economic purposes. CW 2 stated that the main reason he quit his job was over these expressed safety concerns that were

ignored. CW 2 learned about adverse events during meetings with the engineers in 2010 about products coming through the production line. He also heard about adverse events because they would interrupt the production line.

56. Confidential Witness 3 ("CW 3") was a technical writer for Thoratec working on literature for the HeartMate II. CW3 stated that in November 2010, she started hearing about a great deal of adverse event data from the secretary to Thoratec's Vice President of Marketing. CW 3 stated that the information was presented to her as something that was a concern to the Vice-President of Marketing.

57. Confidential Witness 4 ("CW 4") was a Supply Chain Manager at Thoratec from September 2008 through early 2012. CW 4 worked on the supply chain for the HeartMate II.

58. CW 4 stated that in 2010 there were safety concerns over faulty cables in the HeartMate II. CW 4 stated that Thoratec's top management was notified immediately about the faulty cable problem with the HeartMate II. Specifically, Thoratec's Vice President of Operations, Patrick Schmitz, was responsible for reporting problems to Defendant Burbach and senior management. CW 4 stated that the concern over the faulty cables was "spread throughout the company, from quality control to engineering though upper management." CW 4 further stated that if there were adverse events associated with the cables, that a "discrepancy report" would have been generated in order to identify and address the problems.

59. Confidential Witness 5 ("CW 5") was an employee and consultant for Thoratec from 1999 to 2012. CW 5 most recently worked as a consultant for the HeartMate II from 2010 to 2012 to fix issues with the devices battery charger device.

60. CW 5 stated that said he reported to a senior mechanical engineer, who in turn reported to senior management, which assigned the fixes to the battery charger. As a result of the chain of command, senior management, including the CEO and CFO, were aware of all problems related to

HeartMate II. CW 5 further stated that Thoratec had a detailed record-keeping system for making changes to HeartMate II, and that getting approval for changes was a difficult process that involved many signatures.

61. CW 6 was a research and development engineer under contract with Thoratec from June 2010 through November 2010. CW 6 reported to Rob Evans, Thoratec's director of research and development during that time frame. CW 6 was hired as a contractor for Thoratec with the specific purpose of investigating a cable on the HeartMate II which had a number of device failures.

62. CW 6 stated that device failures were reports through data that came in from the field. Thoratec tracked the date associated with the device's failures from adverse event reports and other data provided from doctors and clinicians using the devices in the field.

63. CW 7 was the Director of Supply Chain Management at Thoratec from September 2006 to May 2010. CW 7 noted that Thoratec had a "customer driven complaint" department that was tasked with gathering and reporting feedback on HeartMate II. The vice-president who headed the complaints department reported the customer feedback to senior management on a monthly and quarterly basis. CW 7 stated that there was "definitely high visibility" looking at the trend level of complaints. CW 7 stated that Thoratec's senior management was notified during the complaint process of any ongoing problems with the device. CW 7 stated that "Based on the strength of the process, I think upper management was aware of any adverse effects related to the device." CW 7 was present when information was presented to senior management.

FDA Inspections

64. Throughout the Class Period, the FDA conducted several inspections of Thoratec's manufacturing facilities to determine whether the Company complied with all FDA requirements. The findings were conclusive that throughout the Class Period, Defendants failed to report SAE's to the FDA as required pursuant to Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), and Thoratec failed or

refused to furnish material information respecting the device that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and Title 21, Code of Federal Regulations (CFR), Part 803 - Medical Device Reporting.

65. Prior to the Class Period, on October 13, 2009, the FDA issued the Company an inspection report for inspections conducted during the period September 29, 2009 through October 13, 2009. The inspection report found, amongst other violations:

1. Clinical investigators participated in a study prior to the sponsor obtaining a complete financial disclosures.

2. For an investigational study, proper monitoring was not ensured.

66. On September 7, 2011, during the Class Period, the FDA issued the Company an inspection report for inspections conducted during the period August 22, 2011 through September 7, 2011 at Thoratec's Pleasanton, California Facility. The inspection report found amongst other violations:

1. Thoratec did not perform a thorough investigation for a complaint which involved a patient death.

2. Thoratec failed to submit a Medical Device Report ("MDR") 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.

3. Thoratec failed to submit a MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would likely have caused or contributed to a death or serious injury

67. Four months subsequent to the FDA's issuance of an inspection report on September 7, 2011, the FDA issued a warning letter to Thoratec, on January 3, 2012, addressed to Defendant Burbach informing the Company of a number of violations related to the safety of the HeartMate II. Specifically, Thoratec failed to report to the FDA that the HeartMate II may have caused several

adverse events and that the HeartMate II malfunctioned. The warning letter detailed the following violations, in a non-all-inclusive list of violations:

> 1. Failure to report to the FDA no later than 90 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that it markets may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1).
>
> 2. Failure to report to the FDA no later than 90 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that it markets has malfunctioned and that this device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR Part 803.50(a)(2).
>
> 3. Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and test, that the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 CFR 820.75(a).
>
> 4. Failure to establish and adequately maintain schedules for the adjustment, cleaning, and other maintenance of equipment, as required by 21 CFR 820.70(g)(1).
>
> 5. Failure to adequately review, evaluate and investigate any complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications, unless such investigation has already been performed for a similar complaint and another investigation is not necessary, as required by 21 CFR 820.198(c).

68. The violations continued. On May 18, 2012 the FDA issued an inspection report for an inspection performed on April 25, 2012 through May 18, 2012. The inspection report found amongst other violations:

> 1. Thoratec failed to ensure the Sealed Outf1ow Bend Relief Clip which is part of the HeartMate II Left Ventricular Assist System (LVAS) conforms to defined user needs and intended uses.
>
> 2. Thoratec's design input document … lacks input requirements to ensure that the physicians could connect the sealed Outflow Bend Relief to the graft, ensure that the connection was made, and ensure that the Sealed Outflow Bend Relief stays connected after implantation.
>
> 3. Thoratec failed to report events to the FDA as medical device complaint procedure.

Safety Recalls

69. On April 4, 2012, the FDA issued a class 1 recall of the HeartMate II, due to the lack of safety of the detachment of the bend relief, which caused SAE's (and have been associated with pump thrombosis), requiring the Company to report them to the FDA.

70. On January 17, 2013, The Journal of Heart and Lung Transplantation published a Columbia University study that confirmed that bend relief disconnection was common and resulted in SAE's. The Company failed to disclose the full extent of these the safety issues, which caused serious adverse reactions, including injuries and deaths, despite the fact that the SAEs were mounting throughout the Class Period.

71. Even continuing after the Class Period ended, the Defendants were still dealing with safety issues, causing a Voluntary Correction Notification on March 14, 2014, based on reports of serious injuries and deaths associated with the process of changing from a primary system controller to a backup in patients using pocket system controller. Ultimately, this caused the FDA to issue a Class 1 recall of the HeartMate II.

Serious Adverse Events

72. Starting with December 2009 (prior to the beginning of the Class Period, continuing through April 2014), there were approximately 3,500 SAE's reported to Thoratec, including, 767 reported deaths.

73. The reported adverse events included: death, bleeding, perioperative or late, cardiac arrhythmia, local infection, respiratory failure, device malfunction, sepsis, right heart failure, driveline or pocket infection, renal failure, stroke, neurologic dysfunction, psychiatric episode, thromboembolic event (peripheral), hemolysis, hepatic dysfunction, device thrombosis, and myocardial infarction.

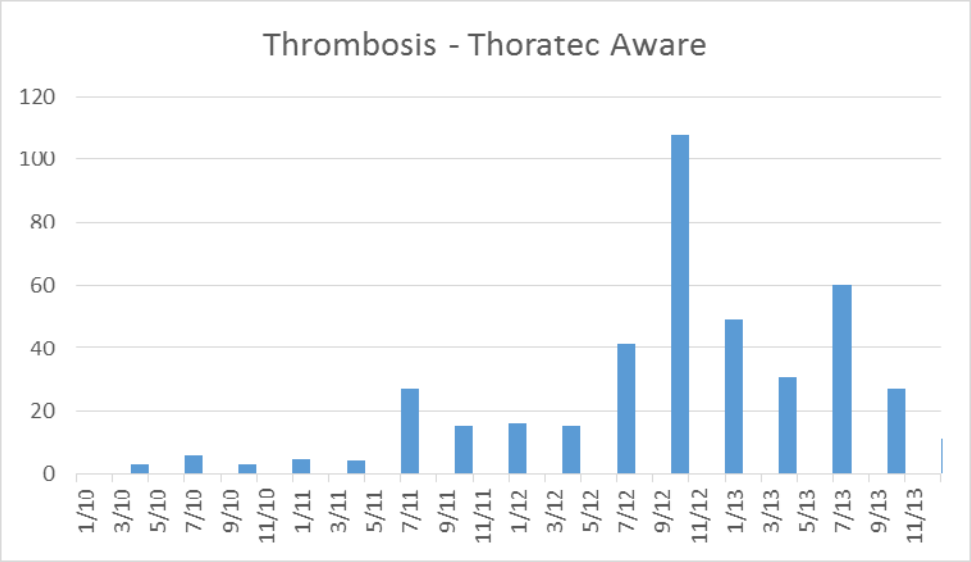
74. The number of adverse events reported to Thoratec increased dramatically throughout the Class Period. However, the most alarming increase in adverse events was the amount of reported events of thrombosis.

75. In early 2011, reported events of thrombosis began to increase dramatically and have not returned to the levels of thrombosis that had occurred in the pre-approval pivotal trials.

76. The FDA's Manufacturer and User Facility Device Experience ("MAUDE") database demonstrates that during the Class Period SAE's involving thrombosis were increasing and being reported to Defendants. The amount of adverse events involving thrombosis that were reported to Defendants during the Class Period, were as follows:

Yearly Periods	Newly Reported Events	Total Events
2010	12	12
2011	51	63
2012	180	243
2013	167	459

77. Below is a graph that demonstrates the dramatic increase of reported events of thrombosis from prior to the Class Period through the end of the Class Period:



Insider Trading

78. The Individual Defendants realized substantial profits during the Class Period. While issuing false statements and omitting to disclose material information to investors about the device's

safety and efficacy, the Individual Defendants netted approximately $23.3 million from sales of Thoratec stock during the Class Period. Individual Defendants' inside trading is shown below:

Filer	Trans. Date	Shares	Dollar Price	Mkt Value	Net During Class Period
Burbach, Gerhard F.	6/3/2010	100,000	$44.29	4,437,364	
Burbach, Gerhard F.	1/18/2011	4,838	$26.88	130,045	
Burbach, Gerhard F.	2/14/2011	5,187	$27.15	140,827	
Burbach, Gerhard F.	2/15/2011	61	$27.71	1,690	
Burbach, Gerhard F.	2/25/2011	3,933	$27.87	109,613	
Burbach, Gerhard F.	2/28/2011	4,668	$27.88	130,144	
Burbach, Gerhard F.	3/3/2011	5,917	$28.93	171,179	
Burbach, Gerhard F.	5/19/2011	30,000	$35.05	1,051,431	
Burbach, Gerhard F.	10/28/2011	2,896	$38.00	110,050	
Burbach, Gerhard F.	2/27/2012	8,640	$35.53	306,979	
Burbach, Gerhard F.	3/1/2012	1,002	$34.52	241,709	
Burbach, Gerhard F.	3/5/2012	5,917	$33.94	200,823	
Burbach, Gerhard F.	5/3/2012	44,623	$34.23	1,527,369	
Burbach, Gerhard F.	7/2/2012	3,822	$34.02	130,033	
Burbach, Gerhard F.	7/3/2012	3,400	$34.00	115,601	
Burbach, Gerhard F.	7/17/2012	37,500	$36.00	1,350,086	
Burbach, Gerhard F.	11/2/2012	900	$38.02	34,218	
Burbach, Gerhard F.	11/23/2012	5,000	$38.01	190,050	
Burbach, Gerhard F.	11/26/2012	6,600	$38.15	251,805	
Burbach, Gerhard F.	2/25/2013	4,422	$35.57	157,291	
Burbach, Gerhard F.	3/1/2013	7,828	$35.29	276,250	
Burbach, Gerhard F.	3/4/2013	6,613	$35.28	233,307	
Burbach, Gerhard F.	3/11/2013	7,406	$35.79	265,061	
Burbach, Gerhard F.	10/10/2013	40,000	$38.05	1,526,573	
Burbach, Gerhard F.	10/14/2013	400	$39.05	15,620	
Burbach, Gerhard F.	10/16/2013	8,870	$39.00	345,967	
Burbach, Gerhard F.	10/17/2013	730	$39.00	28,470	
Burbach, Gerhard F.	10/25/2013	10,213	$40.00	408,520	
Burbach, Gerhard F.	10/28/2013	4,787	$40.07	191,831	
Burbach, Gerhard F.	10/31/2013	55,000	$41.46	2,327,068	
Burbach, Gerhard F.	11/11/2013	80,000	$41.25	3,299,624	
Burbach, Gerhard F.	11/12/2013	20,000	$42.01	840,208	
Burbach, Gerhard F.	11/14/2013	20,000	$43.00	860,044	21,406,850
Smith, David	6/3/2010	30,000	$44.29	1,331,209	
Smith, David	12/29/2010	3,112	$28.60	89,003	
Smith, David	2/25/2011	1,289	$27.87	35,924	
Smith, David	2/28/2011	1,518	$27.88	42,322	

Smith, David	3/3/2011	1,370	$28.93	39,634	
Smith, David	3/15/2011	1,556	$27.17	42,277	1,580,369
Oulman, Roxanne	2/27/2012	1,355	$35.53	48,143	
Oulman, Roxanne	3/1/2012	841	$34.52	29,031	
Oulman, Roxanne	3/5/2012	470	$33.94	15,952	
Oulman, Roxanne	6/15/2012	934	$31.90	29,795	
Oulman, Roxanne	9/6/2012	3,300	$35.07	115,722	238,643
Harris, Taylor C.	3/1/2013	735	$35.29	25,938	
Harris, Taylor C.	3/11/2013	561	$35.79	20,078	
Harris, Taylor C.	3/15/2013	924	$35.71	32,996	
Harris, Taylor C.	6/17/2013	653	$32.06	20,935	
Harris, Taylor C.	10/15/2013	640	$0.00	0	99,947
	TOTAL	590,431		23,325,809	

79. Defendants' insider trading coincided with the increasing thrombosis rates during the Class Period. As the Class Period went on, and Defendants gained more knowledge of the increased thrombosis rates, they continued to dump shares at alarming rates. As shown below, Defendant Burbach had only previously sold 41,286 shares of stock for a profit of around $1.1 million in the three plus years prior to the class period. During the three years of the Class Period, Burbach sold more than 10 times the amount of shares he sold prior to the Class Period, selling 541,173 shares and reaping a profit of approximately $21.4 million.

Year	**Shares**	**Mkt. Value**
2007	3,888	$81,415
2008	7,815	$130,931
2009	14,412	$383,949
2010 pre-class period	18,671	$541,719
2010 post-class period	100,000	$4,437,364
2011	57,500	$1,844,979
2012	117,404	$4,348,673
2013	266,269	$10,775,834

80. Similarly, Defendant Smith, who previously had only sold 15,580 shares of Thoratec stock for a profit of approximately $430,000 in the three plus years prior to the Class Period, sold 38,845 shares of stock in less than one year of the Class Period for a profited of approximately $1.5 million.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING CLASS PERIOD STATEMENTS

81. On the first day of the Class Period, April 29, 2010, the Company issued a press release reporting financial results for the first quarter ended April 3, 2010. Specifically, the Company reported net income of $12.4 million, or $0.21 diluted EPS and sales of $121.6 million, as compared to net income of $5.6 million, or $0.10 diluted EPS and sales of $89.5 million for the same period a year ago.

82. In the press release, Defendant Burbach stated the following in relevant part:

> Thoratec had an excellent start to 2010 as we initiated the commercial launch of our HeartMate II LVAS (Left Ventricular Assist System) for Destination Therapy (DT) following the receipt of FDA approval of our PreMarket Application (PMA) Supplement in January
>
> Our DT launch initiatives have enabled us to achieve rapid traction in the market. Our financial performance in the quarter reflects not only the benefit of initial DT commercial activity in the U.S., but also continued adoption of the HeartMate II in Europe and our new HeartMate external peripherals introduced last fall.
>
> ***
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> "In addition, we continue to see the benefits of our clinical training and educational programs **as evidenced by the positive patient outcomes** portrayed in a number of recent journal articles and presentations at leading medical meetings." (emphasis added).

83. That same day, Defendant Burbach held a Q1 2010 Earnings Call. Defendant Burbach reiterated the success of the HeartMate II and touted the safety of the device, in pertinent part, as follows:

> The good news is that focus is now beyond what historically have been the primary focus areas: survival, stroke, device thrombosis. And we're now looking to improve upon things that have been kind of second order priorities. So we certainly believe there

> is opportunity to continue to work on that and improve on that, looking at a variety of opportunities including anticoagulation, antiplatelet management regimens.

84. The statements referenced in ¶¶ 81-83 above were materially false and/or misleading because they misrepresented and failed to disclose that Defendants were already aware of several SAE's caused by the HeartMate II. Contrary to Burbach's statements that there was "evidence[]" of "positive patient outcomes" reported in journal articles, the mounting evidence showed *negative* outcomes. These adverse events, including thrombosis, continued to be frequently reported to Thoratec but not disclosed to investors.

85. The market reacted extremely positively to Defendants' statements. On April 29, 2010, the price of the stock increased from 35.55 on April 28, 2010 to 36.29 on April 29, 2010. The following day, on April 30, 2010 the stock reached $44.76.

86. On May 5, 2010 Thoratec filed its Quarterly Report with the SEC on Form 10-Q for the quarter ended April 3, 2010. The Form 10-Q for the first quarter ended April 3, 2010 was signed by Defendants Burbach and Smith, and reiterated the financial results issued in the April 29, 2010 press release. In addition, the Form 10-Q contained certifications pursuant to Sarbanes Oxley ("SOX") signed by Defendants Burbach and Smith, stating:

> In connection with the Quarterly Report on Form 10-Q for the fiscal quarter ended April 3, 2010 of Thoratec Corporation (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gerhard F. Burbach, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:
>
> 1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
>
> 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

87. The 10-Q stated, in relevant part:

> The HeartMate II is designed to improve survival and quality of life and to provide five to ten years of circulatory support for a broad range of advanced HF patients.

***

> During the third quarter of 2009 we launched our new HeartMate external peripherals (GoGear), including new batteries, charger and power module, which are designed to provide an enhanced quality of life for HeartMate patients by providing them more freedom and mobility and the ability to more easily resume many aspects of a normal lifestyle.

88. On July 29, 2010, the Company issued a press release reporting financial results for the second quarter ended July 3, 2010. Specifically, the Company reported net income of $17.5 million, or $0.29 diluted EPS and sales of $95.1 million, as compared to net income of $2.9 million, or $0.05 diluted EPS and sales of $69.2 million for the same period a year ago.

89. In the press release, Defendant Burbach stated the following in relevant part:

> As has been the case over the past several quarters, our financial performance was driven by continued adoption of the HeartMate® II LVAS (Left Ventricular Assist System) for Bridge-to-Transplantation (BTT) and Destination Therapy (DT) in both North America and international markets. This reflects the value of our market development and clinical support programs, which are facilitating both adoption and continued positive patient outcomes with the device.

***

> In addition, 159 centers worldwide are now using our new HeartMate peripherals, **which are providing important quality of life improvements to patients** as well as incremental revenue growth. (emphasis added)

***

> As we continue to deliver solid financial results, we are also executing on our strategy to achieve longer-term growth," Burbach said. "We are making significant progress in the development of our HeartMate II platform enhancements that are designed to improve the HeartMate II patient experience and further strengthen our competitive leadership in the market. We are also strengthening our efforts to drive awareness of the therapy among referring clinicians and patients as well as to support our hospital customers as they treat and manage increasing numbers of patients.

90. That same day, Defendant Burbach held a Q2 2010 Earnings Call and specifically responded to questions regarding increasing thrombosis, in pertinent part, as follows:

> I think that it's generally being viewed as a patient management issue. The benefit of the HeartMate II dramatically outweighs the bleeding issue, kind of given the alternative for these patients, which is very short life expectancy, very poor quality of life. And certainly, the positive with the HeartMate II relative to that is when they do run into

> bleeding issues, **it's been a very forgiving pump in terms of thrombosis issues**. So their ability to dial back anticoagulation, antiplatelet has been very good in terms of giving them a fair bit of flexibility in terms of how they deal with those issues. (emphasis added)

91. The statements referenced in ¶¶ 85-90 above were materially false and/or misleading because Defendants knew that they could not execute a long-term growth strategy because of the increase in SAE's including thrombosis, causing serious injuries and death. Indeed, the increase in the rate of thrombosis, including deaths, evidenced that the "pump" was not forgiving in terms of thrombosis issues. They also knew, as CW 1 stated, that HeartMate was indeed, not providing any improvement in the patient's quality of life. Further, Defendants failed to inform the investing public of the increasing rate of thrombosis.

92. On August 10, 2010, the Company filed a quarterly report with the SEC on a Form 10-Q for the second quarter ended July 3, 2012, which was signed, by Defendants Burbach and Smith. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Burbach and Smith identical to the certifications referenced in ¶ 86.

93. The 10-Q stated in relevant part::

> The HeartMate II is designed to improve survival and quality of life and to provide five to ten years of circulatory support for a broad range of advanced HF patients.
>
> During the third quarter of 2009 we launched our new HeartMate external peripherals (Go Gear), including new batteries, charger and power module, which are designed to provide an enhanced quality of life for HeartMate patients by providing them more freedom and mobility and the ability to more easily resume many aspects of a normal lifestyle.

94. On October 28, 2010, Defendant Burbach held a Q3 2010 Earnings Call and stated, in pertinent part, as follows:

> And as I think you were just pointing out, a positive in terms of HeartMate II has been the forgiving nature of the pump in terms of the ability to dial down anticoagulation, antiplatelet utilization to address those patients where there are bleeding issues. And also, it's very much a secondary issue versus those more significant issues that have

> really plagued other pumps historically, such as thrombus formation driving the need to replace the pump, stroke, those kinds of more catastrophic events.

95. The statements referenced in ¶¶ 92-94 above were materially false and/or misleading because Defendants knew that the HeartMate II did not address patients' bleeding issues. Rather, the opposite occurred - the device caused thrombosis, causing serious injuries and death. By this time, thrombosis rates had been increasing as well as other safety issues with the device, which was concealed by Defendants. Defendants failed to inform the investing public of the increasing rate of thrombosis.

96. On October 28, 2010, the Company issued a press release reporting financial results for the third quarter ended October 2, 2010. Specifically, the Company reported net income of $15.5 million, or $0.26 diluted EPS and sales of $91 million, as compared to net income of $11.8 million, or $0.20 diluted EPS and sales of $65.1 million for the same period a year ago.

97. In the press release, Defendant Burbach stated the following in relevant part:

> Our top line performance was driven by the continued worldwide adoption of the HeartMate II® LVAS (Left Ventricular Assist System) for Bridge-to-Transplantation (BTT) and Destination Therapy (DT). At the same time, we continued to achieve solid operating leverage as reflected by our earnings performance.
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> Burbach noted that the FDA has approved a label change for the HeartMate II incorporating the data from the company's BTT post-approval study that showed survival of 90 percent at six months and 85 percent at one year. "The outcomes from this study also reflected continued improvements in several important adverse event categories among HeartMate II patients, including zero device replacements and lower reported rates of bleeding, stroke and right heart failure," he commented.
>
> In addition, we continue to see the release of favorable HeartMate II data in key scientific meetings and publications and are looking forward to a number of important HeartMate II data presentations at next month's Scientific Sessions of the American Heart Association meeting—including outcomes from DT Continued Access Protocol patients, updated cost effectiveness analysis and outcomes for New York Heart Association Class IIIB patients.

98. On November 4, 2010, the Company filed a quarterly report with the SEC on a Form 10-Q for the third quarter ended October 2, 2012 which was signed by Defendants Burbach and Smith. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Burbach and Smith identical to the certifications referenced in ¶ 86.

99. The 10-Q represented the following in relevant part:

> The HeartMate II is designed to improve survival and quality of life and to provide five to ten years of circulatory support for a broad range of advanced HF patients.
>
> ***
>
> During the third quarter of 2009 we launched our new HeartMate external peripherals (Go Gear), including new batteries, charger and power module, which are designed to provide an enhanced quality of life for HeartMate patients by providing them more freedom and mobility and the ability to more easily resume many aspects of a normal lifestyle.

100. On January 1, 2011 Defendant Burbach spoke at the J.P. Morgan Healthcare Conference. Defendant Burbach stated the following in relevant part:

> And collectively what we're seeing here is optimized blood flow, very low thrombosis risk, low anti-coagulation needs and a very high level of durability. So really the key elements of what clinicians are looking for a system like this to provide.

101. The statements referenced in ¶¶ 96-100 above were materially false and/or misleading because Defendants knew that in fact, HeartMate II did not reflect improvement in SAEs, nor in a patient's quality of life, since they had been receiving reports of increased rates of thrombosis, directly contrary to Defendant Burbach's statement that there were "lower reported rates of bleeding, stroke and right heart failure[.]" Defendants failed to inform the investing public of the increasing rate of thrombosis.

102. On January 27, 2011, after the market closed the Company issued a press release reporting financial results for the fourth quarter and year ended January 1, 2011. For the quarter, the Company reported net income of $12.62 million, or $0.21 diluted earnings per share ("EPS") and sales of $97.6 million, as compared to net income of $8.07 million, or $0.14 diluted EPS and sales of $81

million for the same period a year ago. For the year, the Company reported net income of $53.17 million, or $.89 diluted EPS and sales of $383 million, as compared to net income of $28.6 million, or $0.49 diluted EPS and sales of $280 million for the same period a year ago.

103. In the press release, Defendant Burbach stated the following in relevant part:

> This past year was marked by many successes, including FDA approval and launch of the HeartMate II® LVAS (Left Ventricular Assist System) for the Destination Therapy (DT) indication, continued improvements in clinical data in both the Bridge-to-Transplantation (BTT) and DT patient populations, and an impressive financial performance. We have also implemented a broad range of initiatives designed to further develop the market and advance our leadership position.
>
> ***
>
> The company indicated that it ended 2010 with 254 HeartMate II centers globally, an increase of 43 centers during the year, with 211 centers worldwide now utilizing its new HeartMate peripherals, which are providing important quality of life benefits to patients and generating incremental revenue growth. In addition, there are now 90 centers with CMS (Centers for Medicare and Medicaid Services) certification for reimbursement for DT.
>
> As we begin 2011, we have a solid foundation upon which to build our business, and with our market development initiatives to drive referrals from cardiologists, facilitate center expansion, increase our international presence and realize continued improvements in patient outcomes, we are optimistic about our ability to achieve significant long-term growth.

104. On February 23, 2011, the Company filed an annual report with the SEC on a Form 10-K for the year ended January 1, 2011 which was signed by, among others, Defendants Burbach and Smith. In addition, the Form 10-K contained certifications pursuant to SOX signed by Defendants Burbach and Smith identical to the certifications referenced in ¶ 86.

105. The 10-K represented the following in relevant part:

> The HeartMate II is designed to improve survival and quality of life and to provide five to ten years of circulatory support for a broad range of advanced HF patients
>
> ***
>
> During the third quarter of 2009 we launched our new HeartMate external peripherals (Go Gear), including new batteries, charger and power module, which are designed to provide an enhanced quality of life for HeartMate patients by providing them more

> freedom and mobility and the ability to more easily resume many aspects of a normal lifestyle.

106. On March 7, 2011, Defendant Smith, spoke at the Raymond James Institutional Investors Conference. At the conference Defendant Smith stated the following in relevant part:

> The same thing as well goes for textured surfaces; you get a neointimal layer that is created with the textured surfaces that more mimics a vessel, which lowers the risk of thrombosis as well… So I am going to take and just stop and talk a bit about pump thrombosis. We've shown and you can see here that **we've generated extremely low rates of pump thrombosis** and that's something that we measured very thoroughly in our trials both in the Bridge trial and in the DT trial. (emphasis added)

107. On March 16, 2011 Defendant Smith spoke again at the Barclays Capital Global Healthcare Conference. At the conference Defendant Smith stated the following in relevant part:

> I want to stop for a second and talk about pump thrombosis. There's been a lot of buzz about that recently and just talk about **how we've demonstrated a significantly low – extremely low rates of pump thrombosis** and the fact that we do track this in our clinical trials. It was tracked in both our Bridge Trial and our Destination Therapy Trial with a pretty broad definition. And that definition really was, any clinical manifestation of thrombus, be it from device replacement due to thrombus, any use of a thrombolytic agent like a tPA, any symptoms of impaired pump performance whether that required some sort of intervention or not. And in addition to that, we took on ex-plant we examine all pumps and if we see any significant level of thrombus, whether it led to any intervention or clinical manifestation or not and we accounted that as well. So, you can see over here on the charts extremely low thrombosis, 0.02 in the DT Trial between 0.02 and 0.03 in the Bridge Trial. But importantly, when you look at the DT Trial, the device replacement rate's 0.009, just significantly low rates of thrombosis, and that's all due to the design of the HeartMate II. (emphasis added)

108. The statements referenced in ¶¶ 102-108 above were materially false and/or misleading because quite the opposite was occurring-Defendants had been receiving **increasing** reports of thrombosis rates—not "extremely low rates of pump thrombosis" as Defendants proclaimed above. Defendants knew this information was important to investors but failed to disclose that the rates of thrombosis in their clinical trials were a lot lower than the reports they had been receiving at this time.

109. In April 2011, the International Society of Heart and Lung Transplantation ("ISHLT") held their annual meeting. At that meeting there was a growing concern about an increase in

thrombosis rates. Dr. Stuart Russell from Johns Hopkins University presented data that demonstrated an increase in adverse events associated with the HeartMate II. Specifically Dr. Russell noted an increase in thrombosis rates.

110. On May 3, 2011, the Company issued a press release reporting financial results for the first quarter ended April 2, 2011. Specifically, the Company reported net income of $16.5 million, or $0.27 diluted EPS and sales of $99.5 million, as compared to net income of $13.4 million, or $0.23 diluted EPS and sales of $99.3 million for the same period a year ago.

111. In the press release, Defendant Burbach stated the following in relevant part:

> "Thoratec had a solid first quarter, highlighted by 13% sequential VAD unit growth in North America. We believe this performance reflects favorably on our market and center development activities and shows continued momentum in the DT market.
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> ***
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> "There have been a number of important clinical education and market development events over the past four months, including our Thoratec Mechanical Circulatory Support Users' Conference and our largest summit for community cardiologists to date. In addition, there have been a number of data presentations at recent professional meetings that have continued to demonstrate the unrivaled clinical performance of the HeartMate II. **Despite the challenging patient populations and broad base of centers in which HeartMate II has been studied, it has generated impressive survival outcomes and the lowest reported rates of catastrophic adverse events, including pump thrombosis and stroke**." (emphasis added)
>
> "We also realized some important milestones with our product pipeline during the first quarter, including the full commercial launch of our sealed inflow and outflow grafts for the HeartMate II. Feedback so far has been excellent, with clinicians commenting favorably on the grafts' ease of implant and potential to reduce peri-operative bleeding," Burbach added.

112. That same day, Defendant Burbach held a Q1 2011 Earnings Call and stated, in pertinent part, as follows:

> There have been a few important professional meetings since our last call, most notably the Society of Thoracic Surgeons, or STS, and the International Society of Heart and Lung Transplantation, or ISHLT. The data presented at these meetings continue to demonstrate unrivaled clinical performance for HeartMate II, with excellent survival outcomes and the lowest reported rates of catastrophic adverse events, including pump thrombosis and stroke, despite the challenging patient populations and broad base of

centers in which HeartMate II has been studied. AT STS, Dr. Ranjit John from the University of Minnesota presented data of 1,496 HeartMate II Bridge-to-Transplantation patients treated commercially since April 2008 at over 80 centers. Of note, 61% of these patients were classified as INTERMACS profile one or two. The data showed 85% survival at one year, a 2% annual rate of device replacement and an 8% combined annual rate of ischemic and hemorrhagic stroke, impressive outcomes that confirm the results of our post-approval study in an even larger set of patients and centers. At ISHLT, Dr. Stuart Russell from Johns Hopkins presented comprehensive data from the HeartMate II BTT and DT clinical trials representing 701 post-discharge patients and over 1,000 years of patient support. On the topic of adverse events, the presentation showed a 3% annual rate of pump thrombosis and an 8% annual rate of stroke. Perhaps more importantly, the presentation identified risk factors for these events. For example, female patients and patients with infections were shown to have a significantly higher risk of both thrombosis and stroke, and older patients were shown to have a significantly elevated bleeding risk. The presentation's conclusion was that clinicians should consider tailoring anticoagulation profiles specific to certain patients in order to minimize the risk of these catastrophic adverse events. This finding aligns well with one of the core strengths of HeartMate II, which has proven to be a very forgiving device, allowing for flexibility in patient management, particularly with respect to anticoagulation and anti-platelet therapy over the full course of patient support.

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<**Q - Spencer Nam**>: Great. Appreciate that. And then the second question is there was a lot of discussions around the pump thrombosis during ISHLT. And given that the stroke rate as well as the survival rate between different products, the HeartMate II and competitor product seem to be fairly similar. We're curious how issues like pump thrombosis and related pump exchanges could really impact adoption and we're curious what you guys are telling the physicians about that. How are you positioning HeartMate II with respect to some of the new data points that were revealed at the ISHLT, and what other feedback that you are getting from physicians?

<**A - Gerhard F. Burbach**>: So, one, your characterization is accurate in terms of survival rates being similar, although I would point out that HeartMate II is realizing that in a sicker patient population, so it's important never to forget which INTERMACS categories these patients are coming from because they're still quite dramatically different with HeartMate II treating a sicker group of patients. But you mentioned stroke being similar. That's not the case. The HeartMate II stroke rate, both in the DT CAP, as well as the post-approval study is at 0.08 combined. The data that was presented on the HVAD at ISHLT, that combined stroke rate was 0.15, so it was roughly double. So we view that as a very significant difference between the two products. And certainly the pump thrombosis rate and the pump replacement rate is another dramatic difference in terms of the datasets and the performance of the pumps that's been demonstrated to date. So we're clearly very focused on making sure the clinicians understand those datasets, and expect that to be an important differentiator as we go forward. In terms of response, it's still very early in the process, so we'll know a lot more here over the course of the next couple of months.

113. The statements referenced in ¶¶ 109-112 above were materially false and/or misleading because Defendants continued to tout the safety of the device, specifically the low rates of thrombosis. Clearly, analysts and experts in the field were concerned with thrombosis rates and instead of disclosing the increasing SAEs related to thrombosis, Defendants touted that their device was much better than their only competitor based on lower incidences of thrombosis. Specifically, Defendant Burbach chose to speak about the new data being reported at the ISHLT conference, but failed to inform the public about increasing rates of thrombosis. Further, Burbach downplayed that HeartWare was a significant competitive device.

114. On May 3, 2011, the Company filed a quarterly report with the SEC on a Form 10-Q for the first quarter ended April 2, 2011, which was signed, by Defendants Burbach and Smith. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Burbach and Smith identical to the certifications referenced in ¶ 86.

115. The 10-Q represented the following in relevant part:

> The HeartMate II is designed to improve survival and quality of life and to provide five to ten years of circulatory support for a broad range of advanced HF patients.
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> ***
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> During the third quarter of 2009 we launched our new HeartMate external peripherals (GoGear), including new batteries, charger and power module, which are designed to provide an enhanced quality of life for HeartMate patients by providing them more freedom and mobility and the ability to more easily resume many aspects of a normal lifestyle.

116. On May 11, 2011, Defendant Smith spoke at the Bank of America Merrill Lynch Health Care Conference. Defendant Smith stated, in pertinent part, as follows:

> **I want to stop for a second and talk a bit about pump thrombosis. This has had a significant amount of buzz and discussion over the last several months. And, for us, we have a very broad definition of pump thrombosis and this is the – we have demonstrated extremely low rates here.** And, the definitions are pretty broad here for us in terms of any clinical manifestation of pump thrombosis including device replacement due to thrombosis, utilization of [ph] thrombo lytications (5:53) like tPA, and any symptoms of impaired pump performance, whether it has actually led to actual

> intervention or not. Add on top of that, at the [ph] point of X plan (6:02), we look at every pump, and if there is a significant thrombus, we capture that as an event whether it has been clinically manifested or not. And you can see that we have very low rates here, between 0.02 and 0.03, with the Bridge and the DT trials. And importantly, the devise replacement numbers are 0.009. This is the best that you have in the sector; and we're very pleased that – how well the pump is performing in this regard. (emphasis added).

117. On June 9, 2011 Defendant Burbach spoke at the Goldman Sachs Global Healthcare Conference. Defendant Burbach stated, in pertinent part, as follows:

> INTERMACS is another kind of rating criteria that's used for patients in this space. INTERMACS I and II are the sickest populations of patients, over 60% of the patients in the HeartMate II experience are those sickest population of patients in contrast to a little over 30% in the HeartWare clinical trial experience. So, substantively sicker patient populations, but showing similar survival outcomes. **And to date some significantly lower rates of some of the key adverse events that really are catastrophic, like thrombosis and stroke.** So that's number one is making sure that there is a thorough understanding of that clinical data and the clinical benefits that the HeartMate II has. The range of experience, the range of clinical data, kind of how well proven it is. (emphasis added).

118. On June 22, 2011, Defendant Burbach spoke at the Wells Fargo Securities Healthcare Conference. Defendant Burbach stated, in pertinent part, as follows:

> **As I mentioned earlier, lowest reported rates of critical adverse events like thrombus, stroke, device replacement, really the things that are most dramatic, most negative in terms of the impact to the patient.** If you look at those rates as reported, based on the clinical trials, HeartMate II had the lowest rates of those adverse events…Okay. Sure. The ISHLT data, we talked about it at the AHA when there was the initial HeartWare data, and we had a session, and one of the analysts asked, well, what are the advantages of HeartMate II? We actually talked at the time about the design of the pump, based on the design the expectation for lower thrombus rates, these issues that then appeared in the data at the ISHLT. And so, I think in terms of the reaction [ph] of the clinical community (19:25) to that certainly I think there is concern about the pump performance based on that data. We are in a clinical trial here in the United States, so these are clinicians that are used to dealing with issues during a clinical trial. So certainly they are going – our expectation is that they'll continue to push forward, enroll patients in the trial, some centers more aggressively, some maybe little more conservatively based on what they saw in the data. But I certainly expect that they will modify the protocol based on those hypotheses, continue to enroll patients and see what the outcomes look like as they continue forward. **And there is certainly a range of reactions from some physicians that I think believe the hypotheses and kind of have a little more aggressive approach, and then there is certainly many that I think have a higher level of concern, and are watching this very closely; may moderate their activity in the trial. We'll have to see what that looks like as those numbers**

> **come forward.** In terms of those changes, we won't know until there is a significant population of patients who've been implanted under that revised protocol, and with the new pump, and then there is a significant time period of follow-up. **At the AHA that, it wasn't as apparent, which was an earlier period of follow-up. It wasn't until we got out to 12 months of follow-up that that data really became apparent. So I think it's really a significant time period before we'll know definitively, hey, has this made a significant difference or not? And so to the data of this morning, I don't think really you can put much credence behind that data.** There's a number of questions there; one it's a kind of a slice in time of a patient group. That's really not a kind of scientifically valid approach. You really – all of our analysis is kind of from beginning of patient to kind of the end of follow-up period. There's all kinds of confounding factors if you just pick a slice in time. So I think that's a major issue. It's post-discharge only. It's device replacement only, not including TPA, or it sounds like there may be surgical issues that weren't included in those numbers. Private data is not all adjudicated yet, this is only as of a few days ago, it's hard to imagine that all the data could be in and adjudicated at this point. So I think you have to wait until there is kind of a substantive, credible, data set before you can really make any conclusions. (emphasis added).

119. The statements referenced in ¶¶ 114-118 above were materially false and/or misleading because Defendants continued to tout the safety of the device, specifically the low rates of thrombosis despite their knowledge that thrombosis rates were on the rise, and causing serious morbidity and mortality. The Defendants were downplaying the issue, undermining the real truth, by playing games with their rate numbers and how they achieved their "low" thrombosis rates. In reality, they were playing games with patients' lives and investor's money. Defendants knew that there was an increase in pump thrombosis caused by HeartMate II, but omitted to disclose the new data's increased rates. By this time, 14 SAE's directly related to thrombosis had been reported to Defendants.

120. On August 3, 2011, the Company issued a press release reporting financial results for the second quarter ended July 2, 2011. Specifically, the Company reported net income of $21.8 million, or $0.36 diluted EPS and sales of $111.2 million, as compared to net income of $17.5 million, or $0.29 diluted EPS and sales of $195.1 million for the same period a year ago.

121. In the press release, Defendant Burbach stated the following in relevant part:

> We were particularly pleased with HeartMate II unit growth of 21 percent in the U.S. and 20 percent internationally, demonstrating healthy underlying market trends and HeartMate II's strong competitive position. This growth is being fueled by the

> compelling long-term patient outcomes achieved with the device, as well as the impact of our programs to facilitate referral activity, support capacity expansion at existing centers, and foster VAD programs at new centers.

122. On August 3, 2011, Defendant Burbach held a Q2 2011 Earnings Call. Defendant Burbach stated, in pertinent part, as follows:

> **Complementing the programs I've outlined over the past few minutes is the continued dissemination of data demonstrating HeartMate II's excellent survival rates and lowest published rates of pump thrombosis and stroke over extended durations of support, despite the challenging patient populations and broad base of centers in which the device has been studied.** (emphasis added).
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> Well, so I don't know what HeartWare's enrollment in their trial is. So we – I speculated earlier that we might have seen some share gain in those trial centers because we did see a very strong growth in hose centers in Q2. So our speculation is that some of that is driven by market growth, but some of it could very well be share gain as some of those centers maybe have some concerns around thrombosis in that pump. So there may be a net positive there for HeartMate II. But again I'd emphasize that that's in the context of a belief that the substantial majority of the growth in the quarter was based on market growth.

123. This statement was false and misleading because Burbach knew that HeartMate II did not have the lowest pump thrombosis rate, despite what was published or not published. Burbach and Thoratec had received internal reports of increasing thrombosis rates, causing morbidity and mortality, which was not disclosed to the public. Defendants failed to inform the investing public of the increasing rate of thrombosis.

124. On August 4, 2011, the Company filed a quarterly report with the SEC on a Form 10-Q for the second quarter ended July 2, 2011 which was signed by Defendants Burbach and Oulman. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Burbach and Oulman identical to the certifications referenced in ¶ 86.

125. The 10-Q represented the following in relevant part:

> The HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients. Significantly smaller than previous ventricular assist devices and

> with only one moving part, the HeartMate II is simpler and designed to operate more quietly than pulsatile devices.
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> During the third quarter of 2009, we launched our new HeartMate external peripherals (GoGear), including new batteries, charger and power module, which are designed to provide an enhanced quality of life for HeartMate patients by providing them more freedom and mobility and the ability to more easily resume many aspects of a normal lifestyle.

126. On September 13, 2011 Defendant Burbach spoke at the Rodman & Renshaw Global Investment Conference. Defendant Burbach stated, in pertinent part, as follows:

> And then, finally, huge advance with HeartMate II versus previous generations of these devices in terms of bringing down adverse event rates. Historically, that was really the Achilles heel of previous generations of this therapy. You can see here some of the most significant adverse event issues that other devices have battled with. **Pump thrombosis, you can see very low rates 0.02% to 0.03% rate of pump thrombosis and device replacement associated with pump thrombosis.** (emphasis added).

127. On September 14, 2011, Defendant Burbach spoke at the Morgan Stanley Global Healthcare Conference. Defendant Burbach stated, in pertinent part, as follows:

> And it is well understood and recognized by the clinical community at this point that HeartMate II has demonstrated very strong performance in terms of low rates of thrombogenicity, tremendous flexibility in terms of the antiplatelet, anticoagulation regimen. So it gives the physicians a lot of flexibility in how they manage those patients. The most significant competitive device to date is the HeartWare HVAD device. At the most recent larger conference at ISHLT there was data presented that had substantially higher rates of thrombus. They are working to try to address that; time will tell what happens with those rates, to the kind of latter part of your question. But even if those rates come down, our view is it will occur because of a need to raise some of those antiplatelet, anticoagulation regimens to higher levels than are required with the HeartMate II and requires a kind of more rigorous, kind of tightly controlled process of patient management than – versus the more flexible paradigm with the HeartMate II. So even if those rates come down, our view is that that'll remain a significant competitive advantage for the HeartMate II
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> **That's really been one of the highlights with the HeartMate II, is a very low thrombus rate in the clinical trial environment. That's been well documented and published. There was a presentation of the broad commercial experience, which showed continued very low thrombus rate in the range of 2% to 3% with the HeartMate II in that environment. So that was a very positive demonstration of continued success with the HeartMate II.** (emphasis added).

128. On September 22, 2011, Defendant Harris spoke at the Lizard Capital Markets Circulatory Assist Device Conference. Defendant Harris stated, in pertinent part, as follows:

> And then importantly, on the adverse event front; HeartMate II has been very consistent in terms of generating low rates, particularly on the catastrophic adverse event front. These are some of the events we showed here that are the most difficult to manage as a clinician and as a patient, would be the most catastrophic. So, events such as pump thrombosis were across both the Bridge and the DT populations from an array of public – populations, from an array of published articles. **The rate of pump thrombosis has been about 2% to 3% per patient-year. When you look at a subset of pump thrombosis, those that led to device replacements, that rate has been slightly lower, at 1% to 2%.** And then on the stroke front, on a combined ischemic and hemorrhagic stroke basis, the rate in BTT, as well as the DT CAP, for example, has been in that 8% per patient-year range. So, we've been pleased with the consistently strong performance, in terms of low adverse event rates from HeartMate II. (emphasis added).

129. The statements referenced in ¶¶ 120-128 above were materially false and/or misleading because Defendants continued to tout the safety of the device, specifically the low rates of thrombosis. However, this information was contradicted by the adverse event reports that the Defendants were receiving. Defendants failed to inform the public that there was an increase in pump thrombosis related to the HeartMate II. Specifically, Defendant Burbach chose to undermine new data and concern over increased rates of pump thrombosis, despite Defendants' own knowledge that there was increase in reported events of thrombosis. Further, Defendants continued to tout the advantages of HeartMate II over HeartWare specifically based on lower thrombosis rates, when they knew that these SAEs were increasing, causing serious concern, resulting in injuries and death.

130. On November 3, 2011, the Company issued a press release reporting financial results for the third quarter ended October 1, 2011. Specifically, the Company reported net income of $19 million, or $0.31 diluted EPS and sales of $102.6 million, as compared to net income of $15.5 million, or $0.26 diluted EPS and sales of $91 million for the same period a year ago.

131. In the press release, Defendant Burbach stated the following in relevant part:

> "Thoratec had a solid third quarter, generating double-digit growth in pump unit sales year-over-year in both the U.S. and international markets. We continue to benefit from increased adoption of mechanical circulatory support, as well as the market leadership position of the HeartMate II® LVAS (Left Ventricular Assist System)," said Gary F. Burbach, president and chief executive officer of Thoratec.
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> "Our continued growth is being facilitated by our market development and clinical education programs. **In addition, the ongoing flow of data is demonstrating compelling long-term outcomes in HeartMate II patients**, including data published recently in leading peer-reviewed journals," he said.
>
> One of the recent data publications, which appeared in the October edition of The Annals of Thoracic Surgery, compared outcomes from nearly 1,500 commercial bridge-to-transplantation (BTT) HeartMate II patients with those of nearly 500 patients who participated in the HeartMate II BTT clinical trial. The findings included Kaplan-Meier survival of 89 percent at six months and 85 percent at one year for commercial patients. In addition, commercial patients experienced declines in most adverse events versus patients in the trial, with catastrophic events such as device replacement and stroke occurring in just one percent and six percent of patients, respectively. "This dataset demonstrates excellent and improving outcomes for HeartMate II patients in a real-world setting among a broad range of implanting centers," Burbach noted." (emphasis added)

132. On November 7, 2011, the Company filed a quarterly report with the SEC on a Form 10-Q for the third quarter ended October 1, 2011 which was signed by Defendants Burbach and Harris. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Burbach and Oulman identical to the certifications referenced in ¶ 86.

133. The 10-Q represented the following in relevant:

> The HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients.
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> During the third quarter of 2009, we launched our new HeartMate external peripherals (GoGear), including new batteries, charger and power module, which are designed to provide an enhanced quality of life for HeartMate patients by providing them more freedom and mobility and the ability to more easily resume many aspects of a normal lifestyle.

134. On November 9, 2011 Defendant Burbach spoke at the Credit Suisse Group Health Care Conference. Defendant Burbach stated, in pertinent part, as follows:

> And then, finally, in terms of the most significant adverse events, very low and consistently low adverse event rates as published and presented in a variety of peer-reviewed publications. You can see here pump thrombosis, device replacement, stroke, right heart failure. **You can see very low, very consistent rate.** (emphasis added).

135. The statements referenced in ¶¶ 130-134 above were materially false and/or misleading because Defendants continued to tout the safety of the device, specifically the low rates of thrombosis. However, this information was contradicted by the adverse event reports that the Defendants were receiving. Defendants failed to inform the public that there was an increase in pump thrombosis related to the HeartMate II. Specifically, Defendant Burbach chose to undermine new data and concern over increased rates of pump thrombosis, despite Defendants' own knowledge that there was increase in reported events of thrombosis. Further, Defendants continued to tout the advantages of HeartMate II over HeartWare specifically based on lower thrombosis rates, when they knew that these SAEs were increasing, causing serious concern, resulting in injuries and death. By this time however, there were approximately 77 incidents of thrombosis reported to Thoratec during the Class Period, causing 14 deaths.

136. On December 13, 2011, Defendant Harris spoke at the Oppenheimer & Co. Inc. Healthcare Conference. Defendant Harris stated, in pertinent part, as follows:

> So to some degree, that full set of data will inform the message, but we obviously, feel good about the data we have on HeartMate II. And particularly, the thromboembolic risk profile, which we think is low. The relative flexibility of managing patients on HeartMate II, in terms of the aspirin, coumadin. The broader anti-coagulation strategies. We have had positive feedback from the clinical community on that.

137. On January 3, 2012, the FDA issued a warning letter to Thoratec, informing Defendants of a number of violations related to the safety of the HeartMate II. These violations were the result of an August 2011 through September 2011 inspection. Thoratec never addressed the issues from the inspection. Specifically, Thoratec failed to report to the FDA that the HeartMate II may have caused

several adverse events and that the HeartMate II malfunctioned. The warning letter detailed the following violations:

> 1. Failure to report to the FDA no later than 90 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that it markets may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1).
>
> 2. Failure to report to the FDA no later than 90 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that it markets has malfunctioned and that this device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR Part 803.50(a)(2).
>
> 3. Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and test, that the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 CFR 820.75(a).
>
> 4. Failure to establish and adequately maintain schedules for the adjustment, cleaning, and other maintenance of equipment, as required by 21 CFR 820.70(g)(1).
>
> 5. Failure to adequately review, evaluate and investigate any complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications, unless such investigation has already been performed for a similar complaint and another investigation is not necessary, as required by 21 CFR 820.198(c).

138. On January 9, 2012 Defendant Burbach spoke at the JPMorgan Healthcare Conference. Defendant Burbach stated, in pertinent part, as follows:

> What's driving that are the tremendous outcomes that we're seeing, fantastic survival, both for bridge-to-transplant as well as destination therapy, tremendous improvements in quality of life, and then the lowest published rates of adverse events of any device, commercial, clinical trial in terms of key – really the most significant key adverse events, thrombosis, stroke, device replacement. And then very importantly, a very flexible, favorable patient management profile, so an easy pump for physicians to manage, especially with challenging patients, patients that have more significant bleeding issues, thrombosis issues, which is another very attractive feature of the pump. And that's really driven by the core design. There's a number of aspects of the HeartMate II that we believe are really unique. You can see them. I won't touch on all these in detail, but the flexible inflow conduit that allows it to adjust as the heart remodels over time, textured surfaces that allow for endothelial formation, and a really forgiving blood flow path in terms of anticoagulation requirements, potential for thrombosis, the bearings, and that whole inner aspect of the pump, which is unique and proprietary and which is really core to these tremendous results that we've seen, and an open flow path,

> wide gaps through the flow, which again is core to those fantastic outcomes. So optimized blood flow, **low thrombosis risk**, low anticoagulation needs, and then strong durability, which is clearly critical when we're talking about supporting patients over a multiple-year time horizon. (emphasis added)

139. The statements referenced in ¶¶ 136-138 above were materially false and/or misleading because Defendants continued to tout the safety of the device, and specifically the low rates of thrombosis. However, this information that Defendants were reporting to the public was contradicted by the adverse event reports that the Defendants were receiving. Defendants failed to inform the public that there was an increase in pump thrombosis related to the HeartMate II. Specifically, Defendant Burbach chose to undermine new data and concern over increased rates of pump thrombosis, despite Defendants' own knowledge that there was increase in reported events of thrombosis. Further, Defendants continued to tout the advantages of HeartMate II over HeartWare specifically based on lower thrombosis rates, when they knew that these SAEs were increasing, causing serious concern, resulting in injuries and death.

140. On February 8, 2012, after the market closed the Company issued a press release reporting financial results for the fourth quarter and year ended December 31, 2011. For the quarter, the Company reported net income of $15.3 million, or $0.25 diluted earnings per share ("EPS") and sales of $109.4 million, as compared to net income of $10.5 million, or $0.17 diluted EPS and sales of $97.6 million for the same period a year ago. For the year, the Company reported net income of $71.53 million, or $1.19 diluted EPS and sales of $422.7 million, as compared to net income of $53.2 million, or $0.89 diluted EPS and sales of $383 million for the same period a year ago.

141. In the press release, Defendant Burbach stated the following in relevant part, "Thoratec had another excellent year in 2011, driven by strong adoption of HeartMate II® for the Destination Therapy indication."

142. On that same day, Defendant Burbach held a Q4 2011 Earnings Call. Defendant Burbach stated, in pertinent part, as follows:

> First, it's important to put it into the context. **There's obviously been a lot of literature on the HeartMate II's performance cross both the trial and commercial experience showing HeartMate II thrombus rates in the low single digits per patient year. That's been a real positive aspect of the performance of the device.** I think kind of a very important point is that as we look across the broad base of utilization, across our full range of centers, those rates haven't – haven't changed from what we've seen in that literature. **One thing that's certainly notable, could be a contributor here, is that the absolute number of patients is obviously increased dramatically.** There are now more than 4,000 ongoing HeartMate II patients; just a few years ago, that was only a thousand. So, obviously, kind of from an absolute number of incidents, even with the same event rate, the number of incidents is going to go up pretty substantially. We do know – and we talked before about a wide variability across centers in the rates of all adverse events, not just thrombus but you name it: infection, et cetera. There is a high rate of variability. So all of that I think's a very important backdrop. **We have certainly heard, as was noted in some of the analyst notes from certain centers, that they believe they are seeing a higher rate of thrombus.** We are working diligently with those centers to understand the dynamics that are going on, and that's really, you know, I talked earlier in the call about last year, we had 60 of these site-specific improvement initiatives, so that's not a new aspect of what we do. That's a fundamental part of what we do to continue to improve the outcomes with HeartMate II across the full range of clinical outcomes, which also obviously impacts our economic outcomes. And – so in working with those centers, we have noted – a couple of things we have observed is frequent instances where there were issues with INR management or patients with high risk factors such as infection, but what we haven't found at this point are any aspects of the HeartMate II system which we believe would create higher-levels of thrombus, so that's kind of in a nutshell kind of what we've learned at this point. (emphasis added).

143. Defendants, knowing that analysts and investors were specifically concerned about rising thrombosis rates, failed to disclose the truth about their concerns and the fact that thrombosis was causing increased morbidity and mortality in patients. Rather, they continued to tout the safety of the device undermining the fact that there was an increase in pump thrombosis related to the HeartMate II. Defendants failed to inform the investing public of the increasing rate of thrombosis. By this time however, there were approximately 90 incidents of thrombosis reported to Thoratec during the class period.

144. On February 16, 2012, Defendant Harris spoke at the Leerink Swann Global Healthcare Conference. At the conference Defendant Harris answered questions, and stated, in pertinent part, as follows:

> **<Q - Danielle Antalffy>**: Okay, great. And we don't have a ton of time left, but I did want to touch on the recent thrombosis concern with Thoratec – I'm sorry, with the HeartMate II. What are you guys seeing on that front? Is it actually an issue, or is this just a little bit over blown?
>
> **<A - Taylor Harris>**: Well, so the most important point to make is that, when we look at national level data spanning the full spectrum of centers, **the rates of thrombosis that we're seeing right now are very consistence with the clinical trial, which was low single-digits.** So from that perspective, the story is, we've got a very good low single-digit rate of thrombosis. There are individual centers that from time-to-time will experience the levels of any adverse event above the national average. So it's pretty wide variability across the spectrum of centers. And that's where I think the Thoratec clinical support team actually plays a huge role and a role that we think provides us with a competitive advantage in that we got so much experience dealing with clinical issues, we can mobilize very quickly, identify themes, trends and really work with centers to promote overall improvement and outcome. And that's what we're seeing with HeartMate II. (emphasis added).

145. The statements referenced in ¶¶ 140-145 above were materially false and/or misleading because. Defendants continued to tout the safety of the device, specifically the low rates of thrombosis. However, this information was contradicted by the adverse event reports that the Defendants were receiving. Defendants failed to inform the public that there was an increase in pump thrombosis related to the HeartMate II. Specifically, Defendant Burbach chose to undermine new data and concern over increased rates of pump thrombosis, despite Defendants' own knowledge that there was increase in reported events of thrombosis.

146. On February 21, 2012, the Company filed an annual report with the SEC on a Form 10-K for the year ended December 31, 2011, which was signed by, among others, Defendants Burbach and Oulman. In addition, the Form 10-K contained certifications pursuant to SOX signed by Defendants Burbach and Oulman identical to the certifications referenced in ¶ 86.

147. The 10-K represented the following in relevant part concerning HeartMate II:

> The HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients. Significantly smaller than the HeartMate XVE and with only one moving part, the HeartMate II is simpler and designed to operate more quietly than pulsatile devices.
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> During the third quarter of 2009, we launched our new HeartMate external peripherals (GoGear), including new batteries, charger and power module, which are designed to provide an enhanced quality of life for HeartMate patients by providing them more freedom and mobility and the ability to more easily resume many aspects of a normal lifestyle.

148. On February 23, 2012 Thoratec initiated a voluntary worldwide medical device correction notification of the HeartMate II based on reports of disconnected bend reliefs. The disconnected bend reliefs were resulting in pump thrombosis and other SAE's.

149. On March 14, 2012 Defendant Harris spoke at the Barclays Capital Global Healthcare Conference. At the conference Defendant Harris answered questions, and materially mislead investors regarding the January 3, 2012 warning letter from the FDA, in pertinent part, as follows:

> **Matthew Charles Taylor**
> Great. One area we should probably talk about is you received a warning letter in October. It seems like most of the issues in it were very procedural and fairly benign. But, is there any update that you can give us there?
>
> **Taylor Harris**
> Yeah. So actually we were pleased that last week we received a letter from the FDA, which indicated that our responses to the warning letter were – appeared satisfactory to the FDA. That's certainly subject down the road to audit and inspection, but for now that we were certainly pleased with that response, those issues have been resolved. And specifically the one issue that the warning letter raised was our preventative plan for late MDR filing. So that's what we were focused on. We have implemented a plan and policies in that arena. We obviously described that to the FDA and their indication to us was that it appears satisfactory.
>
> **Matthew Charles Taylor**
> And so, you continue to expect no material impact?
>
> **Taylor Harris**
> Correct. Yeah, we didn't anticipate any material impact at the time we received it and certainly now that we have this news from the FDA that feeling is confirmed.

150. These statements were materially false and misleading because in fact, the FDA was not satisfied with their responses. Just 5 months later, the FDA found violations with respect to inspections they made in April and May of 2012. Specifically, they found on May 18, 2012 that:

> 1. Thoratec failed to ensure the Sealed Ou1f1ow Bend Relief Clip which is part of the HeartMate II Left Ventricular Assist System (LVAS) conforms to defined user needs and intended uses.
>
> 2. Thoratec's design input document … lacks input requirements to ensure that the physicians could connect the sealed Outflow Bend Relief to the graft, ensure that the connection was made, and ensure that the Sealed Outflow Bend Relief stays connected after implantation.
>
> 3. Thoratec failed to report events to the FDA as medical device complaint procedure.

151. On April 4, 2012, U.S. regulators ordered a recall for the company's HeartMate II heart pumps for a potentially deadly defect. In a regulatory posting by the FDA, it was stated that the recall "was initiated after Thoratec found that a component of the implanted device, which pumps blood for heart failure patients, may sometimes be improperly attached to the HeartMate II."

152. On this same day, the Company issued a statement attempting to alleviate market concerns, claiming "There is no physical recall of the product. The action involved communicating to our hospitals new information on how to correctly attach the outflow bend relief to the sealed outflow graft so it doesn't become inadvertently disconnected." On the news, shares of THOR fell $1.52 or almost 4.5% to close at $32.83 on volume of 5,441,400 shares.

153. Analysts took note of the Company's statement alleviating the market concerns. On April 4, 2012, analyst Larry Biegelsen of Wells fargo, issued a report entitled "THOR FDA Posting On HMII Recall Was Not New Information" commenting on potential safety issues by stating, "We are told that the field safety notice issued by THOR was deemed a Class I recall by FDA in March and that the posting today did not include any new information or new classification. We think the bend relief graft issue is not related to a design problem with the HMII but rather to the mechanics of connecting

the pieces of the pump. It appears that THOR has isolated the problem and that the field safety notice will likely correct the issue going forward."

154. Also, on April 4, 2013 analysts Steven Lichtman and Rosemary Liu of Oppenheimer issued a report titled, "Thoratec Corp. Over-Reaction on FDA Recall Confusion." The report stated in relevant part:

> This afternoon, THOR trading was halted briefly following a 13% decline in the shares on news of an FDA recall of the company's front-line device, the HeartMate II left ventricular assist device (LVAD). The headlines are deeply misleading as the FDA notice relates to a previous communication to physicians from THOR regarding the company's outflow graft that we describe below. The HeartMate II (HM II) continues to remain available for commercial use. As it relates to the outflow graft, we've written before that we believe it may have been the source of a previously discussed uptick in thrombosis with HMII. Our conversations with leading LVAD implanting centers over the past few weeks indicate that surgeons are not altering their implant rates based on the news and that implant technique changes appear to be working. Though THOR has since recuperated some of its earlier losses, we see an opportunity in the continued weakness and would be buyers on this dip.

155. On May 1, 2012, the Company issued a press release reporting financial results for the first quarter ended March 31, 2012. Specifically, the Company reported net income of $25.5 million, or $0.43 diluted EPS and sales of $126.8 million, as compared to net income of $16.5 million, or $0.27 diluted EPS and sales of $99.5 million for the same period a year ago.

156. In the press release, Defendant Burbach stated the following in relevant part:

> "I am encouraged by the ongoing success of our market development initiatives," Burbach added. "In particular, we believe our first quarter results reflect continued progress in generating referrals of well-qualified candidates for HeartMate II therapy, as well as in facilitating program expansion across a broad group of centers, including the increasingly important open heart center segment."
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> Thoratec also commented on the initial results from the DT post-approval study, which show encouraging trends toward improvement since the clinical trial. These initial results were presented at the International Society for Heart and Lung Transplantation by Dr. Ulrich Jorde from Columbia University. The DT post-approval study includes the first 247 DT patients enrolled into INTERMACS from 61 U.S. centers following FDA approval. The study is still ongoing and will reach full two-year follow-up for all patients this Fall. One-year survival for these patients reached 75%, demonstrating

> continuing improvement relative to the published results from the pivotal trial cohort as well as the DT Continued Access Protocol (CAP). In terms of critical adverse events, HeartMate II continued to demonstrate a low level of thromboembolic complications, while length of stay, bleeding, and infection are all showing favorable trends relative to the clinical trial.
>
> "HeartMate II continues to deliver excellent real-world clinical outcomes for patients with advanced heart failure, and we were excited to treat our 10,000th patient during the first quarter. We look forward to building upon this important milestone by continuing to invest in both our market development activities as well as our innovative pipeline of new technologies," Burbach commented.

157. On that same day, Defendant Burbach held a Q1 2012 Earnings Call. Defendant Burbach stated, in pertinent part, as follows:

> In terms of critical adverse events, **HeartMate II continued to demonstrate a low level of thromboembolic complications, while length of stay, bleeding and infection are all showing favorable trends relative to the clinical trial.** (emphasis added).
>
> ***
>
> Yeah. Last time, we – I don't really have kind of a lot new to report on that front. Last time, we did talk about some of what you're describing. Working with individual centers really to kind of understand what was going on. Making sure that kind of they're following best practices, be that anticoagulation, be that pump implantation. So I certainly hope that those activities are having a positive impact

158. The statements referenced in ¶¶ 146-157 above were materially false and/or misleading because Defendants continued to tout the safety of the device, specifically the low rates of thrombosis. However, this information was contradicted by the adverse event reports that the Defendants were receiving. Defendants failed to inform the public that there was an increase in pump thrombosis related to the HeartMate II. Specifically, Defendant Burbach chose to undermine new data and concern over increased rates of pump thrombosis, despite Defendants' own knowledge that there was increase in reported events of thrombosis.

159. On May 8, 2012, the Company filed a quarterly report with the SEC on a Form 10-Q for the first quarter ended March 31, 2012, which was signed, by Defendants Burbach and Oulman. In

addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Burbach and Oulman identical to the certifications referenced in ¶ 86.

160. The 10-Q represented the following in relevant part concerning HeartMate II:

> The HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients. Significantly smaller than the HeartMate XVE and with only one moving part, the HeartMate II is simpler and designed to operate more quietly than pulsatile devices.
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> ***
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> During the third quarter of 2009, we launched our new HeartMate external peripherals (GoGear), including new batteries, charger and power module, which are designed to provide an enhanced quality of life for HeartMate patients by providing them more freedom and mobility and the ability to more easily resume many aspects of a normal lifestyle.

161. On August 1, 2012, the Company issued a press release reporting financial results for the second quarter ended June 30, 2012. Specifically, the Company reported net income of $20.8 million, or $0.35 diluted EPS and sales of $118.7 million, as compared to net income of $21.8 million, or $0.36 diluted EPS and sales of $111.2 million for the same period a year ago.

162. In the press release, Defendant Burbach stated the following in relevant part:

> "We were particularly pleased with HeartMate II unit growth of 13 percent during the second quarter and 22 percent for the first half of 2012, demonstrating healthy underlying market trends and HeartMate II's strong competitive position," said Gary F. Burbach, President and Chief Executive Officer.
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> ***
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> "Based on the strength of our performance in the first half of the year, the underlying momentum in the VAD market, and our confidence in Thoratec's ongoing competitive position, we are increasing our revenue and earnings guidance for 2012," Burbach commented. "Looking forward, we remain focused on driving continued adoption of HeartMate II in the under-penetrated DT market through our range of market development initiatives, as well as on advancing our pipeline of exciting new technologies, with a goal of initiating pivotal trials for two major new product platforms, HeartMate III and HeartMate PHP, during 2013."

163. On August 2, 2012, the Company filed a quarterly report with the SEC on a Form 10-Q for the second quarter ended June 30, 2012 which was signed by Defendants Burbach and Oulman. In

addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Burbach and Oulman identical to the certifications referenced in ¶ 86.

164. The 10-Q represented the following in relevant part concerning HeartMate II:

> The HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients. Significantly smaller than previous ventricular assist devices and with only one moving part, the HeartMate II is simpler and designed to operate more quietly than pulsatile devices.

165. On September 19, 2012 Defendant Harris spoke at the UBS Global Life Sciences Conference. Defendant Harris stated, in pertinent part, as follows:

> And then in addition, **we've achieved the lowest rates of some critical adverse events that have been published in peer-reviewed literature, so specifically referring to rate of stroke, rate of thrombosis, rate of device replacement.** (emphasis added).

166. The statements referenced in ¶¶ 159-165 above were materially false and/or misleading because Defendants continued to tout the safety of the device, specifically the low rates of thrombosis. However, this information was contradicted by the adverse event reports that the Defendants were receiving. Defendants failed to inform the public that there was an increase in pump thrombosis related to the HeartMate II. Specifically, Defendant Burbach chose to undermine new data and concern over increased rates of pump thrombosis, despite Defendants' own knowledge that there was an increase in reported events of thrombosis.

167. On November 1, 2012, the Company issued a press release reporting financial results for the third quarter ended September 29, 2012. Specifically, the Company reported net income of $24.3 million, or $0.41 diluted EPS and sales of $117.8 million, as compared to net income of $18 million, or $0.30 diluted EPS and sales of $102.6 million for the same period a year ago.

168. In the press release, Defendant Burbach stated the following in relevant part:

> "Thoratec delivered excellent results during the third quarter, demonstrating continued momentum in the global VAD market as well as HeartMate II's strong competitive position," said Gary F. Burbach, President and Chief Executive Officer. "HeartMate II unit volume expanded by 27% during the third quarter and 23% for the first nine months

> of the year, driven by the U.S. Destination Therapy indication and healthy underlying trends in international markets," he added.
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> ***
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> "I am highly encouraged by the outlook for the investments we are making in both market development and product development," Burbach commented. "Our market development efforts continue to drive strong performance in our HeartMate II product line, and with respect to our product development portfolio, we remain on track to initiate pivotal clinical trials for both HeartMate III and HeartMate PHP™ during 2013."

169. On November 2, 2012, the Company filed a quarterly report with the SEC on a Form 10-Q for the third quarter ended September 29, 2012 which was signed by Defendants Burbach and Harris. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Burbach and Harris identical to the certifications referenced in ¶ 86.

170. The 10-Q represented the following in relevant part, "[t]he HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients.

171. On November 15, 2012, Defendant Harris spoke at the Credit Suisse Healthcare Conference. Defendant Harris stated, in pertinent part, as follows:

> **All of that in totality, those design features, we believe leads to an optimized flow of blood through the device, which leads to a relatively low risk of thrombosis, stroke, and what that allows for is a favorable anti-coagulation burden.** And that's important particularly as you think about long term support of these patients. (emphasis added).

172. The statements referenced in ¶¶ 169-171 above were materially false and/or misleading because Defendants continued to tout the safety of the device, specifically the low rates of thrombosis. However, this information was contradicted by the adverse event reports that the Defendants were receiving. Defendants knew that the device did not improve patients' quality of life. Specifically, Defendant Burbach chose to undermine new data and concern over increased rates of pump thrombosis, despite Defendants' own knowledge that there was an increase in reported events of thrombosis. Defedants failed to inform the investing public of the increasing rate of thrombosis. By

this time however, there were approximately 250 incidents of thrombosis reported to Thoratec during the Class Period.

173. On February 5, 2013, the Company issued a press release reporting financial results for the fourth quarter and year ended December 29, 2012. For the quarter, the Company reported net loss of $14.4 million, or ($0.25) diluted EPS and sales of $128.5 million, as compared to net income of $15.3 million, or $0.25 diluted EPS and sales of $109.4 million for the same period a year ago. For the year, the Company reported net income of $56.2 million, or $0.94 diluted EPS and sales of $491.7 million, as compared to net income of $71.5 million, or $1.19 diluted EPS and sales of $422.7 million for the same period a year ago.

174. In the press release, Defendant Burbach stated the following in relevant part:

> "Thoratec had an impressive year in 2012, with sales growth of 16 percent driven by our HeartMate II® and CentriMag® product lines, highlighting our leadership positions in chronic and acute mechanical circulatory support," said Gary F. Burbach, President and Chief Executive Officer.

175. On February 20, 2013, the Company filed an annual report with the SEC on a Form 10-K for the year ended December 29, 2012 which was signed by, among others, Defendants Burbach and Harris. In addition, the Form 10-K contained certifications pursuant to SOX signed by Defendants Burbach and Harris identical to the certifications referenced in ¶ 86.

176. The 10-K represented the following in relevant part, “HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients.”

177. On May 2, 2013, the Company issued a press release reporting financial results for the first quarter ended March 30, 2013. Specifically, the Company reported net income of $18.2 million, or $0.31 diluted EPS and sales of $117.7 million, as compared to net income of $25.5 million, or $0.43 diluted EPS and sales of $126.8 million for the same period a year ago.

178. On May 3, 2013, the Company filed a quarterly report with the SEC on a Form 10-Q for the first quarter ended March 30, 2013 which was signed by Defendants Burbach and Harris. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Burbach and Harris identical to the certifications referenced in ¶ 86.

179. The 10-Q represented the following in relevant part, "HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients."

180. On July 31, 2013, the Company issued a press release reporting financial results for the second quarter ended June 29, 2013. Specifically, the Company reported net income of $23.2 million, or $0.40 diluted EPS and sales of $130.5 million, as compared to net income of $20.8 million, or $0.35 diluted EPS and sales of $118.7 million for the same period a year ago.

181. In the press release, Defendant Burbach stated the following in relevant part:

> "Thoratec delivered strong results during the second quarter, supported by our leadership positions with HeartMate II® and CentriMag®, as well as our intense focus on driving continued growth in the global MCS market," said Gary F. Burbach, President and Chief Executive Officer.
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> ***
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> "HeartMate II has set a new standard for clinical performance and has facilitated broader adoption of VAD therapy. We remain committed to continuing to drive the field forward through our significant investments in market and product development."

182. On August 1, 2013, the Company filed a quarterly report with the SEC on a Form 10-Q for the second quarter ended June 29, 2013 which was signed by Defendants Burbach and Harris. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Burbach and Harris identical to the certifications referenced in ¶86.

183. The 10-Q represented the following in relevant part, "HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients."

184. On October 30, 2013, the Company issued a press release reporting financial results for the third quarter ended September 28, 2013. Specifically, the Company reported net income of $18.9

million, or $0.32 diluted EPS and sales of $126.4 million, as compared to net income of $24.3 million, or $0.41 diluted EPS and sales of $117.8 million for the same period a year ago.

185. In the press release, Defendant Burbach stated the following in relevant part:

> "Thoratec generated strong results during the third quarter, highlighted by continued growth in our HeartMate II® and CentriMag® product lines," said Gary F. Burbach, President and Chief Executive Officer. "We continue to drive expansion of the worldwide market for MCS therapy and delivered international revenue growth of 32% during the quarter," he added.

186. On October 31, 2013, the Company filed a quarterly report with the SEC on a Form 10-Q for the third quarter ended September 28, 2013 which was signed by Defendants Burbach and Harris. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Burbach and Harris identical to the certifications referenced in ¶ 86.

187. The 10-Q represented the following in relevant part, "HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients."

188. The statements referenced in ¶¶ 173-187 above were materially false and/or misleading because Defendants continued to tout the safety of the device, specifically the low rates of thrombosis. However, this information was contradicted by the adverse event reports that the Defendants were receiving. Defendants failed to inform the public that there was an increase in pump thrombosis related to the HeartMate II. Specifically, Defendant Burbach chose to undermine new data and concern over increased rates of pump thrombosis, despite Defendants' own knowledge that there was an increase in reported events of thrombosis. Defendants failed to inform the investing public of the increasing rate of thrombosis

THE TRUTH EMERGES

189. The truth began to trickle out on April 4, 2012. As detailed above, the FDA ordered a recall for the company's HeartMate II heart pumps because the bend relief component was becoming detached. On this same day, the Company attempted to alleviate market concerns, claiming "There is

no physical recall of the product. The action involved communicating to our hospitals new information on how to correctly attach the outflow bend relief to the sealed outflow graft so it doesn't become inadvertently disconnected." On the news, shares of THOR fell $1.52 or almost 4.5% to close at $32.83 on volume of 5,441,400 shares.

190. Analysts took note of the Company's statement alleviating the market concerns. On April 4, 2012, analyst Larry Biegelsen of Wells fargo, issued a report entitled "THOR FDA Posting On HMII Recall Was Not New Information" commenting on potential safety issues by stating, "We are told that the field safety notice issued by THOR was deemed a Class I recall by FDA in March and that the posting today did not include any new information or new classification. We think the bend relief graft issue is not related to a design problem with the HMII but rather to the mechanics of connecting the pieces of the pump. It appears that THOR has isolated the problem and that the field safety notice will likely correct the issue going forward."

191. The house of cards began to tumble after on November 27, 2013, after the market closed, The New England Journal of Medicine shocked the market by publishing an article disclosing the truth about HeartMate II's increasing thrombosis rates and safety issues. The article disclosed the following in relevant part:

> 1. Background
>
> We observed an apparent increase in the rate of device thrombosis among patients who received the HeartMate II left ventricular assist device, as compared with preapproval clinical-trial results and initial experience. We investigated the occurrence of pump thrombosis and elevated lactate dehydrogenase (LDH) levels, LDH levels presaging thrombosis (and associated hemolysis), and outcomes of different management strategies in a multi-institutional study.
>
> 2. Methods
>
> We obtained data from 837 patients at three institutions, where 895 devices were implanted from 2004 through mid-2013; the mean (±SD) age of the patients was 55±14 years. The primary end point was confirmed pump thrombosis. Secondary end points

were confirmed and suspected thrombosis, longitudinal LDH levels, and outcomes after pump thrombosis.

3. Results

A total of 72 pump thromboses were confirmed in 66 patients; an additional 36 thromboses in unique devices were suspected. Starting in approximately March 2011, the occurrence of confirmed pump thrombosis at 3 months after implantation increased from 2.2% (95% confidence interval [CI], 1.5 to 3.4) to 8.4% (95% CI, 5.0 to 13.9) by January 1, 2013. Before March 1, 2011, the median time from implantation to thrombosis was 18.6 months (95% CI, 0.5 to 52.7), and from March 2011 onward, it was 2.7 months (95% CI, 0.0 to 18.6). The occurrence of elevated LDH levels within 3 months after implantation mirrored that of thrombosis. Thrombosis was presaged by LDH levels that more than doubled, from 540 IU per liter to 1490 IU per liter, within the weeks before diagnosis. Thrombosis was managed by heart transplantation in 11 patients (1 patient died 31 days after transplantation) and by pump replacement in 21, with mortality equivalent to that among patients without thrombosis; among 40 thromboses in 40 patients who did not undergo transplantation or pump replacement, actuarial mortality was 48.2% (95% CI, 31.6 to 65.2) in the ensuing 6 months after pump thrombosis.

4. Conclusions

The rate of pump thrombosis related to the use of the HeartMate II has been increasing at our centers and is associated with substantial morbidity and mortality.

192. On this news, which was disseminated into the market the day before the Thanksgiving holiday, Thoratec shares tumbled $2.75 per share or 6.5%, to close at $39.37 per share on November 29, 2013. The market finally learned of the increasing thrombosis rates, which caused severe injuries and death. This news shocked the market since investors had believed the Defendants' statements throughout the Class Period that the device had low thrombosis rates and had a competitive edge over HeartWare as a result.

193. Also on November 27, 2013, the Journal of Heart and Lung Transplantation published a study titled: Interagency Registry for Mechanically Assisted Circulatory Support ("INTERMACS") analysis of pump thrombosis in the HeartMate II left ventricular device. The INTERMACS study also demonstrated a rise in thrombosis related to the HeartMate II. Their analysis demonstrated that

freedom from device exchange or death due to thrombosis went from 99% at 6 months in 2009 to 94% in 2012.

194. That same day, Barry Meier of the *New York Times* published an article titled, "Hospital Studies Link Heart Device to Clots." The article stated:

> Doctors at the Cleveland Clinic began to suspect in 2012 that something might be wrong with a high-tech implant used to treat patients with advanced heart failure like former Vice President Dick Cheney. The number of patients developing potentially fatal blood clots soon after getting the implant seemed to be rising. Then early this year, researchers completed a check of hospital records and their concern turned to alarm. The data showed that the incidence of blood clots among patients who got the device, called the HeartMate II, after March 2011 was nearly four times that of patients who had gotten the same device in previous years. Patients who developed pump-related clots died or needed emergency steps like heart transplants or device replacements to save them. "When we got the data, we said, 'Wow,' " said Dr. Randall C. Starling, a cardiologist at Cleveland Clinic.

195. The stock continued to tumble as the news trickled into the market when the Thanksgiving holiday break was over, another $3.34 per share to close at 36.03 on December 12, 2013.

Defendants Admit The Truth

196. On December 4, 2013, one week after the devastating news, Defendant Burbach spoke at the Piper Jaffray Health Care Conference, acknowledging that there was an increase in pump thrombosis as early as 2010 with continued increasing rates throughout the Class Period, despite the company's earlier misrepresentations that ignored the increased rates. Defendant Burbach stated, in pertinent part, as follows:

> If you look at that, there's a slight increase beginning in 2010 and then ranging through 2011 and 2012. And in 2012, it's kind of a decreasing rate of increase, if that makes sense hopefully. Which also, we're seeing –just to kind of put the increase into context, our internal data is consistent with that data that's in the – from the INTERMACS Registry that's published in the Journal of Heart and Lung Transplant.

197. On December 10, 2013 Defendant Harris spoke at the Oppenheimer Health Care Conference. Defendant Harris further acknowledged the increase in thrombosis and confirmed that

their internal data demonstrated an increase as well. Defendant Harris stated, in pertinent part, as follows:

> Sure. So, first I think I'll just give the full context here for HeartMate II in the commercial era, which is that since the clinical trial, survival rates have improved with HeartMate II and adverse event rates in general have come down – we've seen reductions in stroke, bleeding, infection, most of the key adverse event rates. **The New England Journal article did point to the fact that there has been an increase in the rate of pump thrombosis with HeartMate II.** I'll refer to the INTERMACS analysis, which has been – INTERMACS is the national registry, it covers 90% of implants, of VAD implants in the commercial environment, so it provides really the best overview of the multi-center aggregate data. And INTERMACS has shown that the rate has **increased from low single digits a few years ago gradually in the 2011, 2012 timeframe to about a 6% rate. We've seen stabilization in that rate, especially as we look at our internal database, which tracks INTERMACS very closely.** We've seen a stabilization in that rate for a little over a year. **So, Steve, as you mentioned there has been an increase and there is no one single factor that we would point to.** This is a – it's a complex therapy and it's a challenging patient population. So, certainly as we talk to centers, and there are centers who are above the average, at the average, below the average, it's been a complication that centers have been dealing with in VAD therapy for a while and with HeartMate II for a number of years. So, we've been in discussions with centers when they have rates that are above the average, in particular, about how can we really address this issue. There is no one single factor, but certainly we look at patient selection, anticoagulation levels, pump speed settings, pump placement techniques. There are a number of factors that can drive this adverse event. And there is no real magic bullet to it and you also don't want to overcompensate because certainly we don't want the solution to simply be, hey, raise INR levels significantly. We're comfortable with the consensus guidelines that are out there, which is for targeting an INR of two, understanding that there is going to be a range around that of 1.5 to 2.5 as the patient moves throughout the course of the day. And for some patients, patient specific factors might dictate a different level of anticoagulation. But certainly we wouldn't want to say, hey, universally you should raise anticoagulation levels, because there is going to bleeding and hemorrhagic stroke, potential consequences of that, which we've seen very nice reductions in over time. So, we try to approach it in a disciplined, methodical way with centers and really look at the range of possibilities for bringing down that rate. (emphasis added).

198. On January 13, 2014 Defendant Burbach spoke at the J.P. Morgan Healthcare Conference, again, admitting to the increasing pump thrombosis rates, albeit still undermining the serious nature of the problem, "… **our internal data is very consistent with the INTERMACS registry, showing a relatively small increase in pump thrombosis over time.**"

CLASS ACTION ALLEGATIONS

199. 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 those who purchased Thoratec' securities between April 29, 2010 and November 27, 2013, inclusive (the "Class Period") and who were damaged thereby (the "Class"). Excluded from the Class are Defendants and their families, 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.

200. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Thoratec securities were actively traded on National Association of Securities Dealers Automated Quotations Market ("NASDAQ"). While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Millions of Thoratec shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Thoratec 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.

201. Plaintiff's 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.

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

203. 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:

- Whether the federal securities laws were violated by Defendants' acts as alleged herein;

- Whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Thoratec;

- Whether the Individual Defendants caused Thoratec to issue false and misleading financial statements and false and misleading statements regarding the business, operations, and prospects of Thoratec;

- Whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- Whether when the material misstatements and omissions as described herein were disclosed, Plaintiff and members of the Class were damaged; and

- To what extent the members of the Class have sustained damages and the proper measure of damages.

204. 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.

205. The market for Thoratec'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, Thoratec's securities traded at artificially inflated prices during the Class Period. On June 16, 2010, the closing price of the Company's common stock reached a Class Period high of $47.08 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Thoratec's securities and market information relating to Thoratec, and have been damaged thereby when the material misstatements and omissions as described herein were disclosed.

206. During the Class Period, the artificial inflation of Thoratec's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff 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 Thoratec' business, prospects, and operations. Thoratec omitted to disclose that the device was not as safe and effect as the Defendants had proclaimed. These material misstatements and/or omissions created an unrealistically positive assessment of Thoratec 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 securities. When the material misstatements and omissions as described herein were disclosed, Plaintiff and members of the Class were damaged.

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

- Thoratec stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

- According to the Company's Form 10-Q filed August 10, 2010 the Company had more than 58 million shares outstanding as of July 31, 2010. During the Class Period, on average, 1.1 million shares of Thoratec stock were traded on a daily basis, demonstrating a very active and broad market for Thoratec stock and permitting a very strong presumption of an efficient market;

- Thoratec was qualified to file a less comprehensive Form S-3 registration statement with the SEC that is reserved, by definition, to well-established and largely capitalized issuers for whom less scrutiny is required;

- As a regulated issuer, Thoratec filed periodic public reports with the SEC and the NASDAQ;

- Thoratec 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;

- Thoratec was followed by securities analysts employed by major 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;

- Numerous National Association of Securities Dealers ("NASD") member firms were active market-makers in Thoratec stock at all times during the Class Period; and

- Unexpected material news about Thoratec was reflected in and incorporated into the Company's stock price during the Class Period.

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

COUNT I
(Against All Defendants For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder)

208. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

209. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

210. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted 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 employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Thoratec securities; and (iii) cause Plaintiff and other members of the Class to purchase Thoratec securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

211. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Thoratec securities and options. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Thoratec's finances and business prospects. Defendants were motivated to disseminate materially false or misleading statements, as well as omit to disclose material information about the Device, including, but not limited to, the increase in the rate of thrombosis during the Class Period, in order to, *inter alia*, counter the rising competition from Heart Ware in the VAS market and personally profit from sales of stock in their portfolios during the Class Period.

212. By virtue of their positions at Thoratec, the Individual Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

213. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of Thoratec, the Individual Defendants had knowledge of the details of Thoratec's internal affairs.

214. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants

were able to and did, directly or indirectly, control the content of the statements of Thoratec. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Thoratec's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Thoratec securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Thoratec's business and financial condition which were concealed by defendants, Plaintiff and the other members of the Class purchased Thoratec securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by defendants, and were damaged when the price of Thoratec stock declined following the disclosure of Defendants' wrongdoing.

215. During the Class Period, Thoratec securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased shares of Thoratec securities at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased said securities or would not have purchased them at the inflated prices that were paid. At the time of the purchases by Plaintiff and the Class, the true value of Thoratec securities were substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Thoratec securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

216. By reason of the conduct alleged herein, defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

217. As a direct and proximate result of defendants' wrongful conduct, Plaintiff 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, upon the disclosure that the Company had disseminated false financial statements to the investing public related to the HeartMate II.

COUNT II

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

218. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

219. During the Class Period, the Individual Defendants participated in the operation and management of Thoratec, and conducted and participated, directly and indirectly, in the conduct of Thoratec's business affairs. Because of their senior positions, they knew the adverse non-public information regarding Thoratec.

220. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Thoratec's financial condition and results of operations, and to correct promptly any public statements issued by Thoratec which had become materially false or misleading.

221. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Thoratec disseminated in the marketplace during the Class Period concerning Thoratec's financial prospects. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Thoratec to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Thoratec within the meaning of Section 20(a) of

the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Thoratec securities.

222. Each of the Individual Defendants, therefore, acted as a controlling person of Thoratec. By reason of their senior management positions and/or being directors of Thoratec, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Thoratec to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Thoratec and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

223. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Thoratec.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the Class, prays for judgment as follows;

A. Determining that this action is a proper class action, designating Plaintiff as Lead Plaintiff and certifying Plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' counsel as Lead Counsel;

B. Awarding compensatory damages in favor of Plaintiff 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 Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: June 20, 2014

Respectfully submitted,

By: /s/ *Leigh Handelman Smollar*

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PROOF OF SERVICE VIA ELECTRONIC POSTING PURSUANT TO NORTHERN DISTRICT OF CALIFORNIA LOCAL RULES AND LOCAL CIVIL RULE 5-1

I, the undersigned, say:

I am a citizen of the United States and am over the age of 18 and not a party to the within action. My business address is Ten South LaSalle Street, Suite 3505, Chicago, Illinois 60603.

On June 20, 2014, I served the following document:

AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

By posting the document to the ECF Website of the United States District Court for the Northern District of California, for receipt electronically by the parties as listed on the attached Court's ECF Service List.

And on any non-ECF registered parties:

By U.S. Mail: By placing true and correct copies thereof in individual sealed envelope: with postage thereon fully prepaid, which I deposited with my employer for collection and mailing by the United States Postal Service. I am readily familiar with my employer's practice for the collection and processing of correspondence or mailing with the United States Postal Service. In the ordinary course of business, this correspondence would be deposited by my employer with the United States Postal Service that same day.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on June 20, 2014, at Chicago, Illinois.

s/ Leigh Handelman Smollar
Leigh Handelman Smollar

Mailing Information for a Case 4:14-cv-00360-CW Cooper v. Thoratec Corporation et al

Electronic Mail Notice List

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Manual Notice List

The following is the list of attorneys who are **not** on the list to receive e-mail notices for this case (who therefore require manual noticing). You may wish to use your mouse to select and copy this list into your word processing program in order to create notices or labels for these recipients.

- (No manual recipients)