UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PLAINTIFF, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. HEARTWARE INTERNATIONAL, INC., DOUGLAS E. GODSHALL, and PETER McAREE, Defendants.	Civ. A. No. _____ **CLASS ACTION** **COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** JURY TRIAL DEMANDED **ECF CASE**

Plaintiff _____ _____ _____ ("Plaintiff") brings this securities class action pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder on behalf of all investors who purchased the common stock of HeartWare International, Inc. ("HeartWare" or the "Company") between June 10, 2014 and January 11, 2016, inclusive (the "Class Period"). The allegations herein are based upon Plaintiff's knowledge with respect to Plaintiff, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the HeartWare's public documents and press releases, HeartWare's public filings with the United States Securities and Exchange Commission ("SEC"), wire and media reports published regarding HeartWare, securities analysts' reports and advisories about the Company, transcripts of HeartWare investor conference calls, and other publicly available materials. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a securities class action brought on behalf of investors in HeartWare, a medical device company that develops and manufactures miniaturized implantable heart pumps, also known as "ventricular assist devices" or "VADs," to treat patients suffering from advanced heart failure. The Company presently produces one commercialized product, the HeartWare Ventricular Assist System ("HVAD"), which provides patients with additional blood flow in order to manage congestive heart failure.

2. HeartWare has developed a new device, named MVAD, which is based on the same technology as HVAD but is less than one-half HVAD's size. HeartWare and its senior executives have represented that MVAD will both revolutionize the VAD market and also be the key driver for HeartWare's future growth.

3. HeartWare has one facility, in Miami Lakes, Florida (the "Miami Lakes Facility"), where it manufactures both HVAD and MVAD devices. On June 2, 2014, the U.S. Food and Drug Administration ("FDA") issued a Warning Letter (the "Warning Letter") to HeartWare concerning the Miami Lakes facility. The FDA's Warning Letter identified several manufacturing and regulatory failures that were connected to numerous reports of death, serious injuries, and other complaints. The FDA required HeartWare to resolve the identified problems at the Miami Lakes Facility in a prompt and comprehensive manner, and the Company's failure to remedy the identified problems threatened to significantly delay MVAD's commercialization, including crucial clinical trials.

4. On June 10, 2014, HeartWare spoke publicly to assure investors that remedying the problems that the FDA identified was the Company's "Number 1 priority," and that Defendants would ensure that the Company was "***super-squeaky clean***," "***pristine***," "***perfect***," and "***bulletproof***." From that point forward, until the truth ultimately emerged, Defendants falsely and repeatedly represented to investors both that HeartWare was adequately addressing its regulatory failures and that those failures posed no risk to timely MVAD approval.

5. Contrary to Defendants' public statements, and as revealed through a series of events that informed the public of the truth, HeartWare failed to adequately address the serious manufacturing-related issues that the FDA identified and that threatened the Company's ability to bring MVAD to market. Moreover, the very same HVAD-related problems that the FDA identified caused an indefinite delay in commencing clinical trials of MVAD.

6. *First*, on September 1, 2015, HeartWare stunned investors when it announced a highly dilutive acquisition of Valtech Cardio, Ltd. ("Valtech"), a manufacturer of medical devices used to treat heart disease. Analysts and investors were "dumbfounded," asking why HeartWare

would engage in such a transaction if it were actually confident in its regulatory compliance and in MVAD's commercialization prospects and timeframe.

7. *Second*, on September 9, 2015, HeartWare disclosed that it had identified manufacturing problems with the device's controller – the same device component that the FDA had tied to previous injuries and deaths in HVAD users – and, as a result, was halting enrollment in the MVAD trial. Although HeartWare's stock again dropped on the news, HeartWare continued to reassure investors that they had "never been more confident" in MVAD, and that MVAD trials would resume in a timely manner.

8. *Third*, on October 12, 2015, HeartWare disclosed that patients in the MVAD trial had suffered adverse events, and the MVAD trial would be put on hold until 2016 at the earliest. The Company's disclosures revealed that HeartWare had not remedied the significant failures underlying the FDA Warning Letter, and that MVAD's commercial prospects were not nearly as promising as Defendants had represented. As a result, HeartWare shares plunged nearly 30%.

9. *Fourth*, on January 11, 2016, HeartWare confirmed that nearly half of all patients in the MVAD trial had suffered "serious adverse events" as a result of software issues with MVAD, including significant blood clotting problems. As a result, HeartWare admitted that there would be indefinite delays for the MVAD trial, and that a redesign of MVAD requiring an entirely new MVAD trial may be required. If a redesign is required, a new trial would not start for a minimum of 18 months – *i.e.*, mid-2017 at the earliest. In response to that disclosure, HeartWare shares dropped over 35%, from $40.84 on January 11, 2016 to close at $26.50 per share on January 12, 2016 on extraordinarily large volume – the largest single-day decline in almost seven years.

10. In total, on January 12, 2016, HeartWare stock closed ***72%*** below its Class Period high. Through this action, Plaintiff seeks to recover the damages that Plaintiff and other Class

members have suffered as a result of Defendants' fraud, and the precipitous decline in the value of their investment in HeartWare common stock.

II. JURISDICTION AND VENUE

11. The claims asserted arise under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. 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. Venue is proper pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). HeartWare common stock trades on the NASDAQ Stock Market ("NASDAQ"), which is located in this District, and acts giving rise to the violations complained of herein, including the preparation and/or dissemination of materially false and misleading statements, occurred in this District.

12. In connection with the acts alleged in this Complaint, Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including without limitation the mails, interstate telephone communications, and the facilities of the national securities exchanges.

III. PARTIES

13. Plaintiff _____ _____ _____ ("Plaintiff") is a non-profit organization formed in 1909 that provides retirement, survivor, and disability benefits to public school educators in St. Paul, Minnesota. As of June 30, 2015, St. Paul Teachers had assets of over $1 billion under management. St. Paul Teachers purchased HeartWare common stock at artificially inflated prices during the Class Period as set forth in the attached certification, and was damaged thereby.

14. Defendant HeartWare is a medical device company that develops and manufactures miniaturized implantable heart pumps, or so-called ventricular assist devices or VADs, used to treat patients suffering from advanced heart failure. HeartWare common stock is traded on the

NASDAQ under the symbol "HTWR."

15. Defendant Douglas E. Godshall ("Godshall") has been President and Chief Executive Officer ("CEO") of HeartWare since September 2006, and became a director of the Company in October 2006. As discussed below, Godshall made numerous false and misleading statements of material fact, including on conference calls with analysts and investors and in HeartWare's public SEC filings.

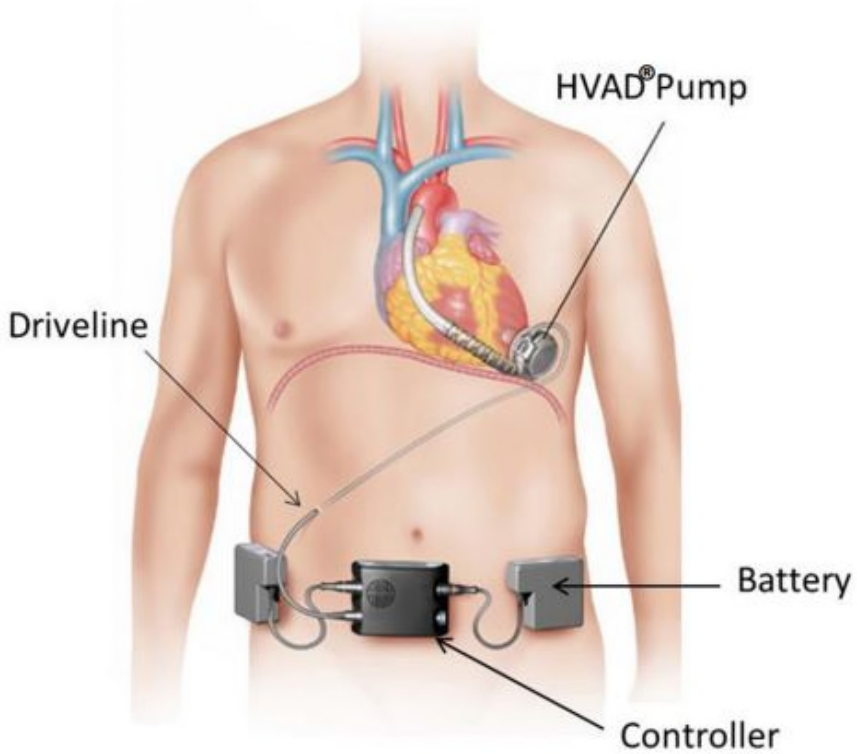
16. Defendant Peter McAree ("McAree") joined HeartWare in July 2012 as Chief Financial Officer and Treasurer. In that capacity, McAree is responsible for the Company's accounting and finance functions, as well as achieving operating plan and information technology goals. McAree participated in conference calls with investors and analysts during which, as discussed below, HeartWare made numerous false and misleading statements of material fact.

17. Defendants Godshall and McAree (collectively, the "Individual Defendants") possessed the power and authority to control the contents of HeartWare's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's public filings, press releases and other communications alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the contrary representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

IV. SUBSTANTIVE ALLEGATIONS

18. HeartWare, headquartered in Framingham, Massachusetts, develops and manufactures miniaturized implantable heart pumps, or VADs, to treat patients suffering from advanced heart failure. The Company's sole commercialized product, the HeartWare Ventricular Assist System or HVAD, is a continuous flow blood pump that is implanted adjacent to the heart. HeartWare operates only one manufacturing facility, which is located in Miami Lakes, Florida.

19. HVAD is used to address congestive heart failure, which results in the heart's pumping power being weaker than normal, generally through the weakening or improper functioning of the left ventricle. Specifically, HVAD is supposed to work by supporting the weak left ventricle and providing additional blood flow. HVAD is powered by both battery and AC power. A key component of HVAD is the "controller," which is positioned outside the body and regulates and monitors HVAD's pump, as shown below:



20. HeartWare developed a new and purportedly improved device, named MVAD, which is based on the same technology as HVAD but is significantly smaller, at less than one-half the size of HVAD. According to the Company, MVAD would require less invasive surgery than HVAD and allow HeartWare to treat a greater number of patients at earlier stages of heart disease. HeartWare represented to investors that MVAD represented the future of the VAD market and, in December 2014, the Company sought to commence a CE Mark study for the MVAD at nine international sites.[1]

21. As Defendants knew and repeatedly told investors, MVAD was and is critical to HeartWare's future growth and success. Several times throughout the Class Period, Defendant Godshall told investors that, in part because "MVAD is just going to totally wipe out HVAD," MVAD represented "the biggest deal in the VAD space probably for the next three or four years" and had "incredible upside potential"; enthusiasm for MVAD is "through the roof" and had "never been higher for this potentially game-changing technology"; was "the pump that everyone is waiting for" and was a reason Defendants were "most optimistic about the longer-term prospects for HeartWare." Godshall told investors that MVAD "will stimulate double-digit growth" and "will be a major driver of stronger growth in 2016, 2017, 2018, [and] beyond." Moreover, with particular regard to MVAD clinical trials, Godshall stated that the trials "are of critical importance long term for the Company."

22. The current and potential market for HeartWare's HVAD and MVAD comprises heart-disease patients – a particularly vulnerable population. Given that patients' lives may likely depend on those products' safety and efficacy, HeartWare's strict compliance with and adherence

[1] A "CE Mark" is the European equivalent of obtaining FDA approval, and indicates that a device has met the safety and other requirements to be approved for sale in the European Union.

to the highest manufacturing standards and practices is – and at all relevant times was – absolutely critical. Indeed, the Company was at all times required to comply with FDA quality-control standards, including current Good Manufacturing Processes ("cGMP"), at the Miami Lakes Facility – where it manufactures both HVAD and MVAD. As HeartWare itself acknowledges, failure to comply with the FDA's regulations may result in "fines, injunctions, civil or criminal penalties, or other sanctions."

23. Despite the importance of maintaining strict adherence with FDA requirements in HeartWare's sole manufacturing facility, the Company flouted those rules throughout the Class Period. Shortly before the beginning of the Class Period, on June 2, 2014, the FDA sent HeartWare the Warning Letter – to the attention of Defendant Godshall – concerning the January 2014 inspection of the Miami Lakes Facility. In the Warning Letter, the FDA notified the Company that HVAD was improperly adulterated and its manufacturing did not comply with cGMP.

24. The Warning Letter also stated that, following the January 2014 inspection of the Miami Lakes Facility, the FDA issued a Form 483 (the "Form 483") to Robert E. Yocher, HeartWare's Senior Vice President of Regulatory Affairs and Quality.[2]

25. In both the Warning Letter and the Form 483, the FDA notified HeartWare of numerous violations that directly tied the Company's poor manufacturing practices to serious adverse events suffered by HVAD patients, including:

[2] A "Form 483" is issued by the FDA to a company's management at the conclusion of an inspection when FDA investigators have observed conditions that may constitute violations of the Food Drug and Cosmetic Act, or any related Act, including that any food, drug, device, or cosmetic has been adulterated or is being prepared, packed, or held under conditions where it may be injurious to health. The Form 483 is presented and discussed with the company's senior management, and companies are encouraged to respond in writing with their corrective action plan and then implement that plan expeditiously.

- "Failure to establish and maintain procedures for validating the device design" to ensure that the device design is "properly understood by patients and caregivers;"
- "Failure to establish and maintain procedures for implementing corrective and preventive action" in light of prior serious problems;
- "Failure to maintain a record of the investigation by the formally designated unit when an investigation is made," as the Company "did not document the likely or potential root cause or document an attempt to obtain the complete nature and details of at least 10 complaints which were submitted to FDA as MDR [medical device reporting] events"; and
- "Failure to validate computer software . . . . used with the (b)(4) tester," which was "changed as part of a corrective action to address premature battery failure issues . . . . related to 238 complaints and 119 MDR events."

26. The FDA raised particular concerns that HeartWare had not adequately addressed severe past problems that caused harm to HVAD patients, including: (a) at least 27 complaints between February 2010 and November 2013, including reports of 2 deaths and 4 serious injuries, of HVAD controller failure; (b) at least 238 complaints and MDR events related to premature battery failure issues; and (c) loose driveline connectors.

27. The FDA notified HeartWare – and Godshall in particular – that "You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the [FDA] without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties." Moreover, the FDA warned that other proposed devices (such as MVAD) "will not be approved until the violations have been corrected." The FDA instructed HeartWare to "notify this office

within fifteen (15) business days from the date you receive this letter of the specific steps you have taken to correct the noted violations, as well as an explanation of how you plan to prevent these violations, or similar violations, from occurring again."

28. In addition, the Warning Letter warned that HeartWare may have committed additional violations, and reiterated that "[i]t is your responsibility to ensure compliance with applicable laws and regulations," as "[t]he specific violations noted in this letter and in the Form FDA 483 . . . may be symptomatic of serious problems in your firm's manufacturing and quality management systems."

29. In the aftermath of the Warning Letter, which raised serious concerns about practices at the Miami Lakes Facility and whether HeartWare would be able to bring MVAD to market, HeartWare downplayed the FDA's observed violations and reassured investors that the Company had taken the necessary steps to address them. For example, on June 10, 2014, the first day of the Class Period, during a conference call addressing the Warning Letter, Defendant Godshall stated that HeartWare's "new Number 1 priority" was to "address those concerns of the FDA," and that the Company was "doing an assessment just to make sure if the FDA didn't like some stuff we did with HVAD, let's make sure that we're not doing the same stuff they didn't like with MVAD."

30. Throughout the Class Period, HeartWare continued to reassure investors that the Company was doing everything it could to address the violations that the FDA identified, that the FDA's findings were uncharacteristic of the Company's practices generally, and that HeartWare would ensure that any potential regulatory issues would be adequately addressed before the Company commenced clinical trials for MVAD. For example, when asked to assess the impact of the Warning Letter during a June 12, 2014 conference call, Defendant Godshall explained that the

Company took the Warning Letter "very seriously" and would ensure that the issues the FDA raised would not affect HeartWare's efforts to commercialize MVAD.

31. Similarly, on June 17, 2014, Defendant Godshall again told investors that HeartWare was committed to ensuring that the Company was "super squeaky-clean on MVAD before we start any clinical activity." According to Godshall, because he had to certify the Company's compliance with FDA standards in connection with the MVAD trial, the Company had determined that before the trials began, "***[L]et's make sure that we are pristine. Our validations are perfect. Our software validations are perfect.*** So that we are not creating a hardship for ourselves by jumping in."

32. Defendants even went so far as to claim that the Company had delayed the MVAD trial specifically in order to ensure strict FDA compliance. In announcing the delay on a July 31, 2014 conference call, Defendant Godshall explained that "we want to make sure that everything that we used to test and validate MVAD is up to standard," that the Company performed a "full review of all the other documentation and testing" to "make sure that there is no question about the integrity of the test reports." According to Godshall, the Company would "make sure that we are bulletproof when we submit" the MVAD data to regulators. As Godshall explained, "it would be intolerable to leave regulatory risks in the [MVAD] program, particularly in light of our [FDA] current status."

33. Analysts and investors were reassured by HeartWare's representations, and relied on them to value the Company's shares. For example, JPMorgan analysts noted in an August 1, 2014 report that "management said that it would review the [FDA's] complaints to ensure that they wouldn't impact the MVAD," and that HeartWare ultimately "decided that it was better to be safe than sorry, electing to delay the start of the CE Mark trial until early 2015." Similarly, PiperJaffray

analysts upgraded their ratings on HeartWare in an October 14, 2014 report based on Defendants' representations that the "MVAD CE Mark Study appeared on-track for an early 2015 start," and that the only source of delay was waiting for "process controls around the development of the device that were deemed to be impacted by the recent FDA Warning Letter to be confirmed."

34. On July 20, 2015, HeartWare announced the first implantations in the MVAD trial, reporting that the Company was "encouraged by the initial implant and early post-operative experience with the MVAD System" – disclosures that prompted immediate analyst and investor praise. For example, JPMorgan reported that the first MVAD implantation was a "significant milestone for the company." Similarly, Canaccord analysts noted that there were "positive initial patient outcomes reported by management to-date," and Wells Fargo reported that management's "early feedback regarding the device has been strong."

V. DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS OF MATERIAL FACTS

35. The Class Period begins on June 10, 2014, eight days after the FDA issued the Warning Letter to HeartWare, when Defendants first represented to investors that the Warning Letter and the concerns raised therein would not in any way delay commercialization of MVAD. Specifically, Defendant Godshall told investors at a William Blair & Company LLC Growth Stock Conference that addressing the FDA's concerns was the Company's "new Number 1 priority," and "we're not seeing any impact on our US launch" of MVAD. Godshall further assured investors that, for any problems the FDA identified regarding HVAD, HeartWare would "make sure that we're not doing the same stuff . . . with MVAD."

36. Throughout the Class Period, Defendants made numerous similar representations concerning HeartWare's steps to address the FDA's serious concerns, and reassurances that MVAD's commercialization schedule was not affected. For example, on June 12, 2014, Defendant

Godshall told investors at a Goldman Sachs Healthcare Conference that the Company took necessary steps to "[m]ake sure that if an FDA reviewer shows up in three months they don't say . . . you had a warning letter and you did the same thing again." Godshall stated that the Company would resolve any problems "before we start any clinical activities [for MVAD] so that we are more than squeaky clean." Godshall again told investors on June 17, 2014 at a Wells Fargo Healthcare Conference that, because HVAD "is the same system that we designed MVAD with," the Company would "make sure we are super squeaky-clean on MVAD before we start any clinical activity," and "make sure that we are pristine."

37. On July 31, 2014, in connection with its earnings announcement for the second quarter of 2014, HeartWare issued a press release filed with the SEC on Form 8-K. That July 31, 2014 press release quoted Defendant Godshall as representing that "our highest internal priority remains addressing and remedying the observations raised by FDA following an inspection at our Miami Lakes, Florida facility earlier this year," as HeartWare prepared to "initiate the clinical evaluation of our next-generation MVAD System."

38. Also on July 31, 2014, on the Company's earnings conference call, Godshall expanded on his earlier representations, telling investors that the Warning Letter "made quite apparent that we needed to do a bit of structural reinforcement," and, "from the moment it arrived, it became our highest priority." Godshall represented that the Company had taken steps to "expedite the mitigation process," because "[i]t was imperative that we confirm that the sorts of issues that concern the agency were not present in our MVAD program, since the last thing we can afford to do is to make the same mistakes twice," and "it would be intolerable to leave regulatory risks in the program" – so the Company would "make sure that we are bulletproof" when MVAD is submitted for clinical trials. Godshall further told investors that HeartWare would commence

the CE Mark trial for MVAD "towards the end of [2014] or early [2015]," and that responding to the Warning Letter could actually "result in a faster regulatory review."

39. On August 14, 2014, at a Canaccord Genuity Growth Conference, a Canaccord analyst asked Defendant Godshall why Godshall was confident that HeartWare would meet its stated timeline for MVAD trials and approvals. Godshall downplayed the Company's regulatory compliance failures identified in the Warning Letter, stating that "there is really nothing . . . that needs to change technically with the system," and although "[w]e had incremental documentation cleanup that we had to do" to address the FDA's concerns, "documentation is not a hard thing to manage." Accordingly, Godshall explained, MVAD's commercialization schedule remained on track.

40. Defendants continued to tell investors that the Company had taken all necessary steps to address the FDA's identified failures at the Miami Lakes Facility, and that investors should not be concerned. On October 30, 2014, on an earnings conference call to discuss HeartWare's earnings for the third quarter of 2014, Defendant Godshall stated that "we have made significant progress in our effort to address the FDA warning letter issues," including that HeartWare had "upgraded many of our key procedures," was "substantially more capable," and "the majority of our deliverables are on track." At that time, Godshall further stated that, with regard to MVAD's CE Mark trial, HeartWare was "at final stages" to submit MVAD for the trial – which would happen by "early next year" at the latest.

41. Similarly, during a November 20, 2014 presentation at the Canaccord Genuity Medical Technologies & Diagnostics Forum held in New York, New York, Defendant Godshall told investors that the MVAD trial and approval schedule was proceeding apace, and that "we are submitting end of this year, beginning of next." Godshall stated that, with respect to MVAD, "we

are finally really there," and "[w]here it's now just tidying up final documentation, getting everything packaged, getting it in front of competent authorities, and then soon thereafter in front of the FDA." Godshall remarked that "how well the device works" was "rather stunning."

42. On December 10, 2014, at the Oppenheimer Healthcare Conference held in New York City, Defendant Godshall again told investors that "[w]e're on the cusp of starting a trial with MVAD early next year." Godshall said that HeartWare was "narrowing in on the end zone here," stating, "let's assume it's January that we get the submission and its usually three months before you get approval."

43. Indeed, Defendants continued to tell investors that rather than calling MVAD commercialization into question, the Warning Letter and HeartWare's response to it actually made MVAD trials' success and the product's eventual approval more likely. On February 26, 2015, on the Company's earnings call in connection with its earnings for the fourth quarter of 2014 and fiscal year 2014, Defendant Godshall told investors that despite "internal and external forces challenging us," HeartWare "used the year to grow stronger, including overhauling a major portion of our quality management system." Godshall stated that "these clean-up type activities of legacy issues are a clear sign of the improving strength and health of our quality system," and that "2014 will be remembered as the year when we strengthened the foundation of the Company and put ourselves in a better position to succeed, well into the future."

44. At a Goldman Sachs Healthcare Conference on June 11, 2015, Defendants continued to assure investors that the schedule for MVAD commercialization was on track, with Godshall telling investors that "everything [wa]s coming together very nicely," and "the first implant is probably going to be [in] July." Godshall stated that Defendants "can't even imagine what would go wrong," and predicted MVAD approval by the end of 2016.

45. Likewise, on July 30, 2015, on the Company's earnings call for the second quarter of 2015, Defendant Godshall assured investors that the Company was "still on track for first [MVAD] implants towards the end of this year." Godshall again represented that the Company was actively and adequately remedying the problems that the FDA identified in the Warning Letter, stating that during the prior quarter, HeartWare "took additional measures that we expect will move us closer to remediation of the Warning Letter issued last year."

46. On August 5, 2015, the FDA issued a Safety Communication (the "August 5 Letter") to VAD patients, caregivers, and healthcare providers warning of "serious adverse events" related to HVAD, including that nearly 30% of HVAD patients had experienced one or more strokes over the prior two years.

47. However, analysts at Wells Fargo reported later that day that the FDA's concerns were "nothing new." Indeed, Godshall reassured investors at an August 13, 2015 Canaccord Genuity Growth Conference that the previously reported adverse events were not a concern, and that the MVAD trial had been progressing as planned as a result of the Company's "major quality overhaul" that ensured a "heavy-duty execution and rigorous product development process." Godshall told investors that the Company's stated timeline for MVAD was "still conservative and reasonable."

48. The statements above in ¶¶35-47 were materially false and misleading. The statements concerning the Company's response to the Warning Letter were false and misleading because, as would later be revealed, the Company had not addressed the manufacturing and compliance issues identified by the FDA. In fact, the same manufacturing and compliance issues impacting the HVAD and that gave rise to the Warning Letter continued to persist and had jeopardized the MVAD, the putative driver of HeartWare's future growth. The statements

concerning the MVAD trials and approval were similarly false and misleading because, as would later be revealed, the Company's regulatory compliance and manufacturing failures were never adequately addressed, leading to significant and ultimately indefinite delays in MVAD's clinical trials.

VI. INVESTORS SUFFER LOSSES AS THE TRUTH BEGINS TO EMERGE

49. Contrary to HeartWare's repeated assurances that the Company had investigated and remedied all deficiencies identified by the FDA before initiating the MVAD trial, a series of disclosures revealed that the Company's manufacturing issues had not been fixed, and that the Company's failures had placed patients at extreme risk of injury or death.

50. On September 1, 2015, HeartWare stunned investors by announcing a highly dilutive acquisition of a private, Israeli-based company, Valtech, a manufacturer of medical devices used to treat heart valve disease. That disclosure stunned investors, with analysts labeling this "surprise" deal as an expensive endeavor – which could cost the Company up to a billion dollars and dilute existing HeartWare investors by up to 30% – that presented extraordinary risk.

51. Analysts and investors immediately recognized that HeartWare's acquisition of Valtech called into question the Company's prior representations concerning its regulatory compliance and MVAD's commercial prospects. As one major HeartWare investor stated, the Company's "efforts to execute on the MVAD clinical trials, improve regulatory compliance, and defend market share all require management's undivided attention," and "[w]e are dumbfounded that the Board would consider now to be the appropriate time for [HeartWare] to pursue a 'bet the company' acquisition." A Wells Fargo analyst similarly asked, if HeartWare was "so confident in MVAD, why dilute your current shareholders by about 30% when your stock could be much higher in 6 to 12 months if MVAD goes smoothly?" – leading Wells Fargo to report that "it's unclear to us why HTWR management would dilute its shares by up to 35% if it were bullish on . . . MVAD."

52. JPMorgan likewise expressed concern that the Valtech acquisition "represents a dramatic departure from Heartware's history to date," which was "a surprise to investors" and, "combined with the up-front dilution . . . is likely to lead to a negative initial stock reaction." Indeed, JPMorgan noted that prior to the deal's announcement, the analyst had "viewed the path to value creation at Heartware as a simple one based principally on proving out MVAD's competitiveness." JPMorgan accordingly described the acquisition of Valtech as "a significant change for a company that we had previously expected to deliver rapidly improving profitability over the next 2-3 years."

53. In response to analysts' and investors' concerns, Defendants falsely represented that rather than any problems with VAD products, the Valtech acquisition was "only possible because of the strength of our core VAD business."

54. Just a week later, however, on September 9, 2015, HeartWare disclosed that it was halting enrollment in the MVAD trial after identifying a manufacturing problem with the device's controller – the same device component that the FDA had tied to cGMP violations at the Miami Lakes Facility and to numerous previous injuries and deaths.

55. JPMorgan analysts immediately viewed this revelation as damaging "management's credibility," and the disclosure prompted a 5% decline in HeartWare shares. However, HeartWare continued to reassure investors that the setback was only temporary. Defendant Godshall explained that, notwithstanding the controller manufacturing issue, he had "never been more confident" in the device, "the enthusiasm we have for MVAD has never been higher." According to Godshall, HeartWare was "thrilled with how the device is performing," and "we tested it so much that we really weren't worried and I think it suggests we have good reason for not having been worried." Godshall further told investors that HeartWare was "making

phenomenal progress" responding to the Warning Letter, and the MVAD trial would resume in November 2015.

56. Next, on October 12, 2015, HeartWare disclosed that patients in the MVAD trial had suffered adverse events and the Company was "in the process of implementing manufacturing improvements as well as software updates" to address them. Moreover, HeartWare disclosed that the MVAD trial would not resume in November, and in fact would be further delayed.

57. Indeed, the cause of the reported adverse events was traced to the same deficient manufacturing practices that the FDA had previously highlighted in the Warning Letter and the Form 483 at the Miami Lakes Facility. In fact, HeartWare subsequently revealed that ***the first patient implanted with MVAD had numerous issues with the device's controller, and that several other patients had experienced adverse events*** even though the trial had just begun with about a dozen patients so far enrolled.

58. In response to the October 12, 2015 disclosures, HeartWare shares plunged nearly 30%, from $50.07 per share on October 9, 2015 to close at $35.21 per share on October 13, 2015. However, HeartWare continued to reassure investors concerning the MVAD trial, and Defendants' representations served to maintain artificial inflation in the Company's stock price. For example, on October 13, 2015, the Company filed a Form 8-K with the SEC that stating that MVAD clinical-trial delays were "typical of . . . other clinical trials" for VADs, and that "HeartWare remains confident in its MVAD System and the potential for the MVAD design to meaningfully improve outcomes for ventricular assist patients."

59. Analysts accepted Defendants' representations and relied on them to value the Company's shares. For example, after the filing of the Form 8-K, Canaccord Genuity asked HeartWare management whether the Company would need to redesign the pump itself. In

response, Canaccord Genuity reported on October 13 that HeartWare "management is confident that there is no need to make any significant design changes to the MVAD pump," and any delay was due only "to their desire to be comprehensive and answering all outstanding issues on the controller, and any questions from investigators on the possible adverse events. . . . [M]anagement still believes that it is possible that the trial can restart in November." Piper Jaffray likewise reported on October 13, 2015 that "Godshall . . . expressed confidence in the MVAD pump design" and stressed that "fundamental design changes" were not necessary.

60. HeartWare's false reassurances continued. On November 19, 2015, at the Canaccord Genuity Medical Technology & Diagnostics Forum held in New York City, Defendant Godshall acknowledged that HeartWare "did pause our trial after 11 patients" due to "some quality issues, or yield issues really, with our controller," but reassured investors that HeartWare "worked through that fix," so that MVAD trials and commercialization were no longer threatened. With specific regard to the MVAD pump, Godshall stated that HeartWare was "not seeing anything that suggests that we will need to change the fundamental pump design," and agreed that "it's sooner rather than later that . . . we should see MVAD back in patients and that clinical trial."

61. Defendant Godshall likewise told investors at the December 1, 2015 Piper Jaffray Health Care Conference held in New York City that there were no extant problems that would further delay the MVAD trial and commercialization schedule, and HeartWare was "building clinical-ready type units now." Godshall again represented that "[w]e remain very optimistic that the core design is actually quite excellent." On December 8, 2015, at the Oppenheimer Health Care Conference held in New York City, Godshall likewise stated that HeartWare had "paused" enrollment in the MVAD trial, and its "design is sound," reiterating that the trial was "just paused" rather than informing investors that endemic problems posed obstacles to re-starting the trial.

62. Then, on January 11, 2016, in sharp contrast the Company's prior representations, the Company disclosed that HeartWare never addressed the underlying design and manufacturing problems that threatened MVAD approval and commercialization, and which Defendants repeatedly represented had been addressed. Specifically, HeartWare announced that a software issue with MVAD caused significant blood clotting problems, leading to additional indefinite delays of at least several months for the MVAD trial, and the possibility that a redesign of MVAD requiring an entirely new MVAD trial will be necessary. Indeed, HeartWare admitted that five out of the 11 patients implanted with the MVAD thus far have experienced "serious adverse events." In fact, HeartWare disclosed that one of device components that was supposed to "reduce chronic bleeding events" and "improve aortic valve function" actually caused severe blood clots. The Company further disclosed that, if it was forced to redesign the MVAD, trials will not start for a minimum of 18 months – *i.e.*, mid-2017 at the earliest.

63. In response to the October 12, 2015 disclosures, HeartWare shares plunged more than 35%, from $40.84 per share on January 11, 2016 to close at $26.50 per share on January 12, 2016.

64. In all, disclosures of the true facts concerning HeartWare's compliance with FDA regulations and the safety and approval obstacles facing MVAD commercialization caused massive losses to investors, with HeartWare shares falling nearly 72% from their Class Period high of $94.47 to close at $26.50 on January 12, 2016.

VII. SCIENTER ALLEGATIONS

65. As alleged herein, Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated in or acquiesced in the issuance or dissemination of such

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

VIII. PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

66. Throughout the Class Period, HeartWare common stock traded on NASDAQ, an efficient market that promptly digested current information with respect to HeartWare from publicly available sources and reflected such information in the prices of HeartWare's common shares.

67. The evidence that HeartWare's common shares traded on an efficient market at all relevant times includes the following:

i. HeartWare's common stock was listed and actively traded on NASDAQ, one of the most highly efficient markets in the world;

ii. As a regulated issuer, HeartWare filed periodic and other public reports with the SEC;

iii. The average daily trading volume for HeartWare common shares during the Class Period was over 258,000 shares;

iv. During the Class Period, HeartWare was followed by multiple securities analysts who wrote reports about HeartWare that were distributed to their clients. Each of these reports was publicly available and entered the public marketplace;

v. HeartWare regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

vi. HeartWare securities were liquid and traded with moderate to heavy volume during the Class Period.

68. Based on these indicia, a presumption of reliance applies.

69. A Class-wide presumption of reliance is also appropriate here under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's persistent manufacturing and compliance problems that jeopardized the MVAD's commercialization, as well as the schedule and prospects for MVAD clinical trials – information that Defendants were obligated to disclose – positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the MVAD to HeartWare's operations and growth, as discussed above, that requirement is satisfied here.

IX. LOSS CAUSATION/ECONOMIC LOSS

70. By misrepresenting HeartWare's compliance with FDA regulations and cGMP, including the adequacy of the Company's response to the Warning Letter and the Form 483, Defendants presented a misleading picture of HeartWare's operations and compliance with the law. Instead of truthfully disclosing during the Class Period that the Miami Lakes Facility suffered

from serious cGMP violations and other problems that posed significant obstacles to the testing, commercialization, and efficacy of MVAD, Defendants falsely reported that HeartWare had adequately addressed the FDA's concerns and that MVAD trials would occur in a timely fashion.

71. The Company's statements concerning its compliance with FDA regulations and cGMP, including its response to the Warning Letter and the Form 483 as described herein, caused and maintained the artificial inflation in the price of HeartWare common shares throughout the Class Period, until the truth was revealed to the market.

72. Defendants' false and misleading statements had the intended effect and caused HeartWare common shares to trade at artificially inflated levels throughout the Class Period.

73. As alleged herein, the truth about HeartWare's regulatory compliance and MVAD's commercial prospects emerged in a series of partial disclosures between September 1, 2015 and January 11, 2016. As a result of those corrective disclosures of the truth, the Company's stock price fell nearly 68%, from $81.81 per share at the close of trading on September 1, 2015, to $26.50 per share at the close of trading on January 12, 2016.

X. NO SAFE HARBOR

74. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements described in this Complaint. Many of the specific statements described herein were not identified as "forward-looking" when made. To the extent that there were any forward-looking statements, there was no meaningful cautionary language identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements described herein, Defendants are liable for those false forward-looking statements because at the time each was made, the particular speaker knew that the particular forward-looking statement was false, and/or

that the forward-looking statement was authorized and/or approved by an executive officer of HeartWare who knew that those statements were false when made.

XI. CLASS ACTION ALLEGATIONS

75. Plaintiff brings this action as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired HeartWare common shares during the period of June 10, 2014 through and including January 11, 2016 (the "Class"), and who were damaged thereby. Excluded from the Class are Defendants, other officers and directors of HeartWare 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.

76. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, HeartWare common shares were traded on NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by HeartWare 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.

77. The disposition of the claims in a class action will provide substantial benefits to the parties and the Court. Millions of HeartWare shares were traded publicly during the Class Period on NASDAQ, and Plaintiff believes that there are at least hundreds or thousands of members of the proposed Class.

78. 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 misrepresented material facts about the business, operations and management of HeartWare;
- whether the Defendants caused HeartWare to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of HeartWare common shares during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

79. Plaintiff's claims are typical of the claims of the other members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of the federal law that is complained of herein.

80. Plaintiff will adequately protect the interests of the Class and has retained competent counsel experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

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

COUNT ONE

For Violations of Section 10(b) of the Exchange Act and Rule l0b-5 Against HeartWare and the Individual Defendants

82. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

83. Plaintiff asserts this Count pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against HeartWare and the Individual Defendants.

84. During the Class Period, Defendants disseminated or approved the false statements set forth above, which they knew or deliberately disregarded were false and misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

85. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

a. employed devices, schemes and artifices to defraud;

b. made untrue statements of material facts or 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; or

c. engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiffs and other members of the Class and in connection with their purchases of HeartWare common stock during the Class Period.

86. By virtue of their positions at HeartWare, 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.

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

88. 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 HeartWare. 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 HeartWare's business, 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 HeartWare common shares was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning HeartWare's business that were concealed by defendants, Plaintiff and the other members of the Class purchased or otherwise acquired HeartWare common shares 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 thereby.

89. Plaintiff and the other members of the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for HeartWare common

shares. Plaintiff and the other members of the Class would not have purchased HeartWare common shares at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

COUNT TWO

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

90. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

91. Plaintiff asserts this Count pursuant to Section 20(a) of the Exchange Act against the Individual Defendants.

92. The Individual Defendants, by virtue of their executive leadership positions in HeartWare, had the power and authority to cause HeartWare to engage in the wrongful conduct complained of herein, and to control the contents of HeartWare's annual and quarterly reports and press releases. They were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected.

93. 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 HeartWare's financial condition and results of operations, and to correct promptly any public statements issued by HeartWare that had become materially false or misleading.

94. Because of their positions of control and authority as senior executive officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which HeartWare disseminated in the marketplace during the Class Period concerning HeartWare's regulatory compliance and the development and commercial

viability of MVAD. Each of the Individual Defendants exercised control over the general operations of HeartWare, 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. The Individual Defendants therefore, were "controlling persons" of HeartWare within the meaning of Section 20(a) of the Exchange Act. In that capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of HeartWare securities.

95. The Individual Defendants were at all relevant times also controlling persons within the meaning of Section 20(a) of the Exchange Act, as alleged herein.

96. HeartWare violated Section 10(b) and Rule 10b-5 by its acts and omissions as alleged in the Complaint, and as a direct and proximate result of those violations, Plaintiff and the other members of the Class suffered damages in connection with their purchases of the Company's common shares during the Class Period.

97. By reason of their control of HeartWare, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for HeartWare's violations of Section 10(b) and Rule l0b-5, to the same extent as HeartWare.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

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

B. Awarding Plaintiff and the other members of the Class damages, including interest;

C. Awarding Plaintiff reasonable costs and attorneys' fees; and

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

XIII. JURY DEMAND

Plaintiff, on behalf of the Class, hereby demands a trial by jury.