Manager of Company Announcements
ASX Limited
Level 6
20 Bridge Street
SYDNEY NSW 2000

27 January 2010
BY E-LODGEMENT

Dear Sir / Madam

Public Offering of Common Stock

Please see the attached Media Release regarding a public offering of HeartWare common stock.

Also attached is an additional document, titled Form 8-K, which was filed with the Securities & Exchange Commission earlier today and which provides additional disclosure regarding the Company.

Yours faithfully

David McIntyre
Chief Financial Officer &
Chief Operating Officer

HeartWare International, Inc.
Announces Commencement of Public Offering of Common Stock

(SYDNEY, AUSTRALIA / FRAMINGHAM, MA), January 27, 2010 - HeartWare International, Inc. (NASDAQ: HTWR, ASX: HIN) ("HeartWare") announced today a public offering of 1,500,000 shares of its common stock. HeartWare has granted the underwriters an option to purchase up to an additional 225,000 shares of common stock to cover over-allotments. HeartWare expects to use the net proceeds of the offering for general corporate and working capital purposes.

J.P. Morgan Securities Inc. is acting as the sole book-running manager of the offering. The offering will be made pursuant to a shelf registration statement filed with the Securities and Exchange Commission (the "SEC") on December 24, 2009 and that was declared effective on January 20, 2010.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any securities nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state. The offering of these securities will be made only by means of a prospectus and the related prospectus supplement. Before you invest, you should read the prospectus and the related prospectus supplement and any other document HeartWare has filed with the SEC for more complete information about HeartWare and this offering. You may get these documents for free by visiting EDGAR on the SEC Website at *www.sec.gov*. Alternatively, copies of the prospectus and the related prospectus supplement can be obtained by contacting J.P. Morgan Securities Inc., c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, New York 11717.

About HeartWare International

HeartWare International develops and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat Class IIIb and Class IV patients suffering from advanced heart failure. The HeartWare® Ventricular Assist System features the HVAD™ pump, a small full-output circulatory support device (up to 10L/min flow) designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant competing devices. HeartWare has received CE Marking for the HeartWare® Ventricular Assist System in the

European Union. The device is currently the subject of a 150-patient clinical trial in the United States for a Bridge-to-Transplant indication.

Forward-Looking Statements

This announcement contains forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to the progress of clinical trials. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. We may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in the prospectus and the related prospectus supplement and any other document HeartWare files with the SEC.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 26, 2010

HEARTWARE INTERNATIONAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-34256**	**26-3636023**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

205 Newbury Street, Suite 101 **Framingham, Massachusetts**	**01701**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: +1 508 739 0950

(Former name or former address if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

TABLE OF CONTENTS

Item 8.01 Other Events

In connection with a proposed common stock offering of HeartWare International, Inc. (the "Company") pursuant to a shelf registration statement on Form S-3 (File No. 333-164004), the Company updated the description of its business and its risk factors. The Company will include the following disclosure under the heading "Summary — Overview" and "Risk Factors" in the prospectus supplement forming part of the registration statement. This information, together with the other information contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and its quarterly reports on Form 10-Q for the quarterly periods ended March 31, June 30 and September 30, 2009 and the other information that we filed with the Securities and Exchange Commission, should be carefully considered in evaluating the Company's business.

Summary — Overview

HeartWare is a medical device company focused on developing the world's smallest implantable blood pumps for the treatment of advanced heart failure.

The HeartWare Ventricular Assist System (the "HeartWare System"), which includes a left ventricular assist device ("LVAD"), patient accessories and surgical tools, is designed to provide circulatory support for patients with advanced heart failure. The core of the HeartWare System is a proprietary continuous flow blood pump, the HVAD Pump, which is a full-output device capable of pumping up to 10 liters of blood per minute.

In April 2008, we received conditional Investigational Device Exemption ("IDE") approval from the US Food & Drug Administration ("FDA") to enroll patients in a bridge-to-transplant clinical study in the United States. In August 2008, our first patient in the United States received the HeartWare System at Washington Hospital Center in Washington, D.C., marking the commencement of our bridge-to-transplant clinical trial in the United States. Under the terms of the study 150 patients awaiting heart transplantation will be enrolled, of which there were 114 patients enrolled as of December 31, 2009. In September 2008, we received full IDE approval for the HeartWare System from the FDA. In October 2009, we received FDA approval to expand the number of participating sites from 28 to 40 centers. In addition, on November 23, 2009, we filed a submission for an IDE approval with the FDA relating to the proposed use of the HeartWare System in a U.S. destination therapy clinical study. As of the date of this prospectus supplement, this submission with the FDA has not been finally adjudicated by the FDA.

In January 2009, the HeartWare System received Conformite Europenne ("CE") Marking, which allows us to market and sell the device in Europe.

Beyond the HeartWare System, we are also evaluating our next generation device, the Miniaturized Ventricular Assist Device ("MVAD"). The MVAD is based on the same technology platform as the HeartWare System but adopts an axial flow, rather than a centrifugal flow, configuration and is being developed in multiple configurations. The MVAD and its related products, which are currently at the prototype stage and undergoing animal studies focused on minimally invasive implantation techniques, are each approximately one-third the size of the HVAD Pump. We believe that the MVAD and its related products will be implantable by surgical techniques that are even less invasive than those required to implant the HVAD Pump. The MVAD has also been modified to create two separate products with differing surgical implant procedures which are designed to be less invasive.

We began generating revenue from our product sales in August 2008 and have incurred net losses in each year since our inception. We expect our losses to continue and to increase as we expand our clinical trial activities, seek regulatory approvals and initiate commercialization activities.

We have financed our operations primarily through the issuance of shares of our common stock. Most recently, in August 2009, we sold approximately 2.74 million shares through private placements in the United States and Australia, which raised net proceeds of approximately $58.8 million. The issuance of approximately 1.4 million shares of the total number of shares sold to the investors in the private placement was subject to stockholder approval and, as a result, approximately $30.7 million of the proceeds from the private placement were held in escrow by an independent third party until such approval was obtained. As such, these shares and the related proceeds were not reflected in our unaudited condensed consolidated financial statements for the quarter ended September 30, 2009. Such proceeds were released to us and the 1.4 million shares were issued following stockholder approval, which was obtained at a special meeting held on October 26, 2009.

We are headquartered in Framingham, Massachusetts. We have an operations and manufacturing facility in Miami Lakes, Florida and a research and development facility in Sydney, Australia.

Risk Factors

Risks Related to Our Business and Industry

We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses for the foreseeable future.

We have incurred net losses since our inception, including net losses of $19.0 million for the nine months ended September 30, 2009 and $23.8 million and $21.9 million for the fiscal years ended December 31, 2008 and 2007, respectively. We also expect to incur a net loss for the fiscal year ended December 31, 2009. As of September 30, 2009, our accumulated deficit was $96.0 million. Currently we only have one product approved for sale in Europe. None of our products are approved for commercial sale in the United States although we presently derive revenue from reimbursed clinical trials in the United States. We continue to incur substantial clinical trial expenditure, significant research and development costs and costs related to our operations. We expect to continue to incur significant operating losses for the foreseeable future as we incur costs associated with:

- manufacturing product,
- continuing to conduct clinical trials,
- continuing further product research and development,
- growing, maintaining and protecting our intellectual property,
- seeking regulatory approvals,
- expanding our sales and marketing capabilities on a global basis,
- increasing our manufacturing capabilities,
- broadening our infrastructure in order to meet the needs of our operations, and
- complying with the requirements related to being a public company in both the United States and Australia.

To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us to succeed in a range of challenging activities, including all of the activities listed above. We may never succeed in these activities,

and we may never obtain regulatory approvals in the markets in which we expect to operate or otherwise generate revenues sufficient to achieve profitability. Further, the markets in which we operate may contract or we may not otherwise obtain significant market share so as to support our ongoing business operations. If we do achieve profitability, we may not be able to sustain it.

We currently rely entirely on sales of our sole product, the HeartWare System, to generate revenues. Our products may never achieve market acceptance. In addition, any factors that negatively impact sales of this product will adversely affect our business, financial condition and results of operations.

Our sole product is the HeartWare System, which we introduced to the international market in January 2009 and which does not have regulatory approval in the United States. We expect to continue to derive substantially all of our revenue from the sale of this product and its related devices. Accordingly, our ability to generate revenue is entirely reliant on our ability to market and sell the devices.

Even if we obtain the necessary regulatory approvals in all jurisdictions to commercialize the HeartWare System or any other product that we may develop, our products may not gain market acceptance among physicians, patients, health care payers or the medical community. The degree of market acceptance of any of the devices that we may develop will depend on a number of factors, including:

- the perceived effectiveness of the product;
- the prevalence and severity of any adverse events or side effects especially as it relates to survival, quality of life, stroke and bleeding;
- potential advantages over alternative treatments or competitive products;
- the strength of marketing and distribution support; and
- sufficient third party coverage or reimbursement.

If the HeartWare System, or any other product that we may develop, does not achieve an adequate level of acceptance by physicians, patients, health care payers and the medical community, we may not generate product revenue and we may not become profitable or be able to sustain profitability. If we do achieve market acceptance of our products, we may not be able to sustain it or otherwise achieve it to a degree which would support the ongoing viability of our operations.

Our ability to achieve profitability from a current net loss level will depend on our ability to reduce the per unit cost of producing the HeartWare System by increasing our customer orders and manufacturing volume.

Currently, the gross profit from the sale of the HeartWare System is not sufficient to cover our operating expenses. To achieve profitability, we need to, among other things, reduce the per unit cost of our products. This can be achieved by increasing our manufacturing volume, which will allow for volume purchase discounts to reduce our raw material costs and improve absorption of manufacturing overhead costs. Our maximum manufacturing capacity at December 30, 2009 was approximately 60 units per month. If we are unable to reduce raw material and manufacturing overhead costs through volume purchase discounts and increased production capacity, our ability to achieve profitability will continue to be severely constrained. Any

increase in manufacturing volumes must be supported by a concomitant increase in customer orders. The occurrence of one or more factors that negatively impact sales of our products may prevent us from achieving our desired increase in manufacturing volume, which would prevent us from attaining profitability.

We have limited sales, marketing and distribution experience.

To develop and increase sales, distribution and marketing capabilities, we would have to invest significant amounts of financial and management resources. In developing sales, marketing and distribution functions ourselves, we could face a number of risks, including:

- we may not be able to attract and build a significant, capable, successful or qualified marketing or sales force;
- the cost of establishing, training and providing regulatory oversight for a marketing or sales force may be substantial; and
- there are significant legal and regulatory risks in medical device marketing and sales, and any failure to comply with all legal and regulatory requirements for sales, marketing and distribution could result in enforcement action by the FDA or other authorities that could jeopardize our ability to market the product or could subject us to substantial liability.

We have limited capabilities and manufacturing personnel, and if our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently manufacture our HeartWare System at our facilities in Miami Lakes, Florida. If there were a disruption to our existing manufacturing facility, for example, due to a hurricane, we would have no other means of manufacturing our HeartWare System until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities.

If we are unable to produce sufficient quantities of our HeartWare System for sale or for use in our current and planned clinical trials, or if our manufacturing process yields substandard product, our development and commercialization efforts will be delayed. Further, even if we are able to produce sufficient quantities of our HeartWare System or any other product we are developing, we will not be able to attain sufficient profitability on that production or any resultant sales.

We currently have limited resources, facilities and experience to commercially manufacture our products. In order to produce our products in the quantities that we anticipate will be required to meet anticipated market demand, we will need to increase substantially the production process and efficiency over the current level of production. There are significant technical and regulatory challenges to increasing manufacturing capacity and efficiency, and developing commercial-scale manufacturing facilities would require the investment of additional funds and hiring and retaining additional qualified management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required increase in a timely or economically viable manner or at all. If we are unable to do so, we may not be able to produce the HeartWare System or any other product we are developing in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, if at all.

If we are unable to manufacture a sufficient or consistent supply of the HeartWare System or any other product we are developing, or if we cannot do so efficiently, our revenues, business and financial prospects would be adversely affected.

Fluctuations in foreign currency exchange rates could adversely affect our financial results.

Changes in foreign currency exchange rates can affect the value of our assets, liabilities, costs and revenues. To date, the majority of our revenues have been sourced from international sales, mainly in Europe and denominated in Euro while most of our expenditures are incurred in US dollars. We presently derive revenue in the United States but until our products receive regulatory approval in the United States, which may never happen, our United States sourced and denominated revenue will constitute less than half of our net revenues.

With limited exceptions our international sales will be denominated in Euro or in local currencies, not US dollars and fluctuations in foreign currency exchange rates, especially an appreciation of the US dollar against major international currencies, could materially impact our revenues and earnings. Due to the size and stage of development of our operations and revenues, we do not presently mitigate our exposure to exchange risk other than by holding the majority of our funds in US dollars.

We may need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Revenue generated from the HeartWare System is currently limited to commercial sales outside of the US and from our clinical trial within the United States. Depending on a range of outcomes, especially our achievement of regulatory approval of our products and the growth of revenue, we will need to seek additional funding in the future. Additional funding may not be available on terms favorable to us, or at all. If we raise additional funding through the issuance of equity securities, our shares may suffer dilution. If we are unable to secure additional funding, our product development programs and our commercialization efforts would be delayed or reduced or may cease entirely.

In addition, our operating subsidiary, HeartWare, Inc., issued Series A-1 and Series A-2 Preferred Stock to certain creditors of Kriton Medical, Inc., or Kriton, when HeartWare, Inc. purchased substantially all of the assets of Kriton in July 2003. The Series A-1 and Series A-2 Preferred Stock do not have any voting rights or the right to receive dividends but entitle the holders thereof to receive upon certain liquidation events (including deemed liquidation events, which are defined as a merger or consolidation of HeartWare, Inc., the sale of all or substantially all of its assets or the sale of a majority of its voting power) of HeartWare, Inc. an amount equal to $10 per share of Series A-1 and an amount equal to $21 per share of Series A-2, which currently represent an aggregate liquidation preference of $15 million. Such rights or any other similar rights in the future, to receive a payment if there is a deemed liquidation event of HeartWare, Inc. may restrict our ability to restructure our Company and its operations and could inhibit our ability to obtain financings.

Our products have not yet been approved for commercial sale within the United States, and our success will depend heavily on the success of our clinical trial program for our lead device,

the HeartWare System. If we are unable to complete, or experience significant delays of, our US trial, our ability to obtain regulatory approval to commercialize our products within the United States, the largest medical device market in the world, and our ability to generate revenues will be materially adversely affected.

On January 30, 2009, we received approval for CE Marking and we have generated net sales in Europe totaling approximately $5.6 million during the period from the receipt of CE Marking to September 30, 2009. However, future revenue will be limited if we do not receive regulatory approval to commercially sell our products in the United States or we are unable to maintain CE Marking or achieve regulatory approval in other jurisdictions.

In 2008, we received full IDE from the FDA to conduct a bridge-to-transplant clinical trial in the United States for our HeartWare System and commenced the trial in September 2008. The purpose of the study is to evaluate the safety and effectiveness of the HeartWare System in 150 patients eligible for cardiac transplantation with refractory, advanced heart failure. As of December 31, 2009, our clinical trial sites have completed implants in 114 patients.

In November 2009, we made a submission to the FDA for an IDE to commence a destination therapy clinical trial in the United States for our HeartWare System approval. As of January 26, 2010, we have not concluded our discussions with the FDA relating to this submission and there can be no certainty that we will receive a full IDE or that it will be in such a form that will enable us to successfully enroll or complete a clinical trial for this designation.

Completion of our clinical trial program could be delayed or adverse events during the trial could cause us to repeat or terminate the trial. If this were to happen our costs associated with the trial will increase, and it will take us longer to obtain regulatory approvals and commercialize the product or we may never obtain such regulatory approvals. Our clinical trials may also be suspended or terminated at any time by regulatory authorities, the Data Safety and Monitoring Board or by us including during the closing stages of enrollment of the trial and the subsequent patient date follow-up period lasting six months in the event that, for example, there should be a series of adverse clinical events such as stroke, bleeding or pump exchanges. Any failure or significant delay in completing clinical trials for our products will harm our financial results and the commercial prospects for our products.

The completion of our clinical trial program could be substantially delayed or prevented by several factors, including:

- slower than expected rates of patient recruitment and enrollment, including as a result of our competitors undertaking similar clinical trials or having equivalent products that have received approval for sale;
- failure of patients to complete the clinical trial;
- patients preferring to use approved devices or other experimental treatments or devices rather than our HeartWare System;
- unforeseen safety issues;
- lack of efficacy during clinical trials;
- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols;

- inability to monitor patients adequately during or after treatment;
- risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product is effective;
- governmental and regulatory delays or changes in regulatory requirements, policies or guidelines; and
- varying interpretation of data by regulatory agencies.

The process of obtaining marketing approval or clearance from the FDA for our HeartWare System, or any future products or enhancements or modifications to any products, could:

- take a significant period of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing;
- require changes to our products; and
- result in limitations on the indicated uses of the products.

There can be no assurance that we will receive the required approvals from the FDA or**,** if we do receive the required approvals, that we will receive them on a timely basis or that we will otherwise be able to satisfy the conditions of such approval, if any. The failure to receive product approval clearance by the FDA will have a material adverse effect on our business, financial condition or results of operations.

We may not meet regulatory quality standards applicable to our manufacturing and quality processes, which could have an adverse effect on our business, financial condition or results of operations.

Even after products have received marketing approval or clearance, product approvals and clearances by the FDA or other regulatory bodies can be withdrawn due to failure to comply with regulatory standards or the occurrence of problems following initial approval. As a device manufacturer, we are required to demonstrate and maintain compliance with a variety of regulatory requirements, including the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA enforces the QSR through periodic unannounced site inspections. In addition, the US federal medical device reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. Our failure to comply with the QSR or to take satisfactory corrective action in response to an adverse QSR inspection could result in enforcement actions, including a public warning letter, a shutdown of or restrictions on our manufacturing operations, delays in approving or clearing a product, refusal to permit the import or export of our products, a recall or seizure of our products, fines, injunctions, civil or criminal penalties, or other sanctions, any of which could cause our business and operating results to materially suffer.

In the European Union, we are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. In October 2008, we received a Certificate of Registration certifying that the Company's Quality Management System complies with the requirements of ISO 13485:2003. If we fail to continue to comply with ISO regulations the FDA or European Union organizations may withdraw clearance to market, require a product recall or take other enforcement action.

Product issues could result in substantial costs and write-downs leading to delay or termination of our trials.

Our products are subject to various regulatory guidelines and are perishable. Identified quality problems, such as failure of critical components such as batteries or controllers, or the failure of third parties to supply us with sufficient quantities of these products or components, could lead to adverse clinical events during the trial, which could cause us to repeat or terminate such trials. In addition, product improvements or failure to sell product before it expires could result in scrapping or expensive rework of product and our business, financial or results of operations could suffer. Quality issues could result in the rework, recall or replacement of entire lots of products, substantial costs and write-offs and harm to our business reputation and financial results. Further such activities could adversely affect our relationships with our customers or affect our reputation which could materially adversely affect our earnings, results and financial viability.

We plan to operate in multiple regulatory environments that require costly and time consuming approvals.

Even if we obtain regulatory approvals to commercialize the HeartWare System or any other product that we may develop, sales of our products in other jurisdictions will be subject to regulatory requirements that vary from country to country. The time and cost required to obtain approvals from these countries may be longer or shorter than that required for FDA approval, and requirements for licensing may differ from those of the FDA. Laws and regulations regarding the manufacture and sale of our products are subject to future changes, as are administrative interpretations and policies of regulatory agencies. If we fail to comply with applicable foreign, federal, state or local market laws or regulations, we could be subject to enforcement actions. Enforcement actions could include product seizures, recalls, withdrawal of clearances or approvals, and civil and criminal penalties, which in each case would harm our business.

If we fail to obtain an adequate level of reimbursement for our products by third party payers, there may be no commercially viable markets for our product or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third party payers affects the market for our product candidates. Reimbursement and health care payment systems vary significantly by country, and include both government sponsored health care and private insurance. Payers may attempt to limit coverage of and the level of reimbursement for new therapeutic products. Government and other third party payers also continually attempt to contain or reduce the costs of health care by challenging prices charged for health care products and services.

To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our products to other available therapies. In addition, the efficacy, safety, performance and cost-effectiveness of our product in comparison to any competing products may determine the availability and level of reimbursement for our product.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third party payers may adversely affect the demand for our products currently under development and limit our ability to sell our product candidates on a profitable basis. The current US administration has set forth a number of proposed initiatives to reform healthcare and contain costs and the US Congress is currently considering health care reform legislation. We cannot predict how pending or future legislative and regulatory proposals would influence the manner in which medical devices, including ours, are purchased or covered and reimbursed. For example, the American Recovery and Reinvestment Act of 2009 includes funding to study the comparative effectiveness of health care treatments and strategies. This funding will be used, among other things, to conduct, support or synthesize research that compares and evaluates the risk and benefits, clinical outcomes, effectiveness and appropriateness of medical products. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact coverage, reimbursement or other third-party payer policies.

If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and our future revenues would be materially adversely affected. During 2009, we were unable to implant a significant number of patients under our IDE in the United States as the relevant insurance providers refused to provide reimbursement for our products on the basis that our products are “experimental” and do not have the requisite regulatory approval in the United States. If this practice was to continue or to broaden then this would materially adversely affect our revenues, earnings, business and stock price.

If hospitals do not conduct destination therapy procedures using the HeartWare System, market opportunities for our product will be diminished.

If hospitals do not conduct destination therapy procedures using our products, our market opportunities will be diminished. The number of destination therapy procedures actually performed depends on many factors, most of which are out of our direct control, including:

- the number of sites approved for destination therapy by relevant regulatory agencies;
- the clinical outcomes of destination therapy procedures;
- cardiology and referring physician education, and their commitment to destination therapy;
- the economics of the destination therapy procedure for individual hospitals, which includes the costs of the LVAD and related pre- and post-operative procedures and their reimbursement; and
- the economics of hospitals not conducting a destination therapy procedure, including the costs and related reimbursements of long-term hospitalization.

The different outcomes of these and other factors, and their timing, may have a material and adverse effect on our future results.

Adverse changes in general economic conditions in the United States could adversely affect us.

We are subject to the risks arising from adverse changes in general economic market conditions. The U.S. economy remains extremely sluggish as it seeks to recover from a severe recession and unprecedented turmoil. The U.S. economy continues to suffer from market volatility, difficulties in the financial services sector, tight credit markets, softness in the housing markets, concerns of inflation, reduced corporate profits and capital spending, significant job losses, reduced consumer spending, and continuing economic uncertainties. The turmoil and the uncertainty about future economic conditions could negatively impact our current and prospective customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our expenses and ability to obtain financing of our operations, cause delays or other problems with key suppliers and increase the risk of counterparty failures. We cannot predict the timing, strength or duration of this severe global economic downturn or subsequent recovery. Healthcare spending in the United States has been, and is expected to continue to be, negatively affected by these recessionary trends. For example, patients who have lost their jobs may no longer be covered by an employee-sponsored health insurance plan and patients reducing their overall spending may eliminate purchases requiring co-payments. Since the sale of the HeartWare System to a new patient is generally dependent on the availability of third-party reimbursement and normally requires the patient to make a significant co-payment, the impacts of the recession on our potential customers may reduce the referrals generated by our sales force and thereby reduce our customer orders. Similarly, the impacts of the recession on our existing customers may cause some of them to cease purchasing HeartWare Systems and this will reduce our revenues, which in turn will make it more difficult to achieve the per unit cost-savings which are expected to be attained through increases in our manufacturing volume.

The severe recession has impacted the financial stability of many private health insurers. As a result, it has been reported that some insurers are scrutinizing claims more rigorously and delaying or denying reimbursement more often. Since the sale of the HeartWare System is generally dependent on the availability of third-party reimbursement, any delay or decline in such reimbursement will adversely affect our revenues.

Healthcare reform legislation could adversely affect our revenue and financial condition.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs. Recently, President Obama and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform and a number of bills have been proposed in Congress. A leading proposal includes an excise tax on the medical device industry that would be payable based on revenue, not income.

In addition, recent legislation and many of these proposed bills include funding to assess the comparative effectiveness of medical devices. It is unclear what impact the excise tax proposal or the comparative effectiveness analysis would have on our products or our financial results. The

ultimate content or timing of any future healthcare reform legislation, and its impact on medical device companies such as us, is impossible to predict. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may have a material adverse effect on our financial condition and results of operations.

Our manufacturing facilities and the manufacturing facilities of our suppliers must comply with applicable regulatory requirements. If we fail to achieve regulatory approval for these manufacturing facilities, our business and our results of operations would be harmed.

Completion of our clinical trials and commercialization of our products require access to, or the development of, manufacturing facilities that meet applicable regulatory standards to manufacture a sufficient supply of our products. In addition, the FDA must approve facilities that manufacture our products for US commercial purposes, as well as the manufacturing processes and specifications for the product with similar, additional, approvals required in order to achieve CE marking in Europe. Suppliers of components of, and products used to manufacture, our products must also comply with FDA and foreign regulatory requirements, which often require significant time, money, resources and record-keeping and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages. If we or our suppliers fail to comply with the regulatory requirements for our manufacturing operations, our commercialization efforts could be delayed, which would harm our business and our results of operations.

We rely on specialized suppliers for certain components and materials.

We depend on a number of suppliers to successfully manufacture sufficient quantities of the components we use in our products. We rely on suppliers for critical components including the center post, housing and impeller that are assembled into our primary product, the HeartWare System, as well as finished products that comprise our peripheral and external equipment that is included in the HeartWare System. Lead times for our components are significant and can be up to as long as sixteen weeks and many of our components are manufactured to very tight tolerances or specifications. We do not presently have supply agreements with our key suppliers but have extensive purchase orders in place with these vendors.

We have second-source suppliers for some, but not all, of our components. In particular, we do not have second-source suppliers for our controllers, battery chargers and monitors. Our reliance on third-party suppliers also subjects us to other risks that could harm our business, including:

- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- some of our components are extraordinarily complex and must be manufactured to extremely tight tolerances and specifications with the result that our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of our products or cause our components not to be delivered on time or at all or to be delivered outside of specifications;
- the availability of second-source suppliers may be extremely limited or their implementation as a supplier may be lengthy due to the tight tolerances and specifications in which we typically operate;

- switching components or changes to our components, specifications or designs may require product redesign and submission to the FDA or a PMA supplement;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver products to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

Any interruption or delay in obtaining products from our third-party suppliers, or our inability to obtain products from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competing products.

We are in the process of negotiating a production services agreement with Minnetronix, Inc., located in Minnesota, as the supplier of the patient monitor and controllers. A prior agreement expired on August 17, 2008. Though we continue to receive production services from Minnetronix, we cannot guarantee that we will be able to successfully negotiate a new agreement. Even if we do reach a new agreement, and although we submit 12-month forecasts to Minnetronix, we cannot assure you that they will be able to have the capacity to accommodate our demand in a timely manner.

While we have identified second-source suppliers for other key components, we have not entered into written agreements with these suppliers and we cannot assure you that we will be able to maintain our manufacturing schedule without undue delay or substantial cost if any of these arrangements is terminated.

Additionally, we may experience problems or delays in our own manufacturing process, which may be harmful to our financial status or reputation and therefore make it more difficult or expensive for us to continue with or enter into relationships with specialized suppliers. Our business plan is predicated on maintaining strong relationships and supply with a series of external parties to manufacture components of our technology. If we are unsuccessful in this regard or are unable to secure or maintain agreements with these manufacturers on favorable terms or at all, then our ability to commercialize our technology and expand our operations will be dramatically impaired.

We may not be able to effectively protect our intellectual property rights which could have an adverse effect on our business, financial condition or results of operations.

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our technology and products. As of January 25, 2010, we have 19 issued US patents, 10 issued Australian patents, and 4 issued patents in each of Germany, France, the United Kingdom, as well as patents issued in the Netherlands, Japan, Spain, Italy, Korea, Canada, Italy, and Israel. Our patent portfolio consists of internally developed technology as well as patents and patent applications which we acquired in 2003 in connection with a plan of liquidation for Kriton Medical, Inc. and which pertain to technology used in the HeartWare System. As a result, we may have less complete knowledge and records with respect to the development and ownership of such Kriton technology, patents and intellectual property than we would otherwise have for technology, patents and intellectual property developed internally by us. We also have 27 pending US patent applications and a number of international patent applications filed under the Patent Cooperation Treaty, as well as in Japan, Europe, Australia, China, India, Korea and Israel.

Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us with any meaningful protection or any competitive advantage. Even if issued, existing or future patents may be challenged, including with respect to the development and ownership thereof, or narrowed, invalidated or

circumvented, which could limit our ability to stop competitors from developing and marketing similar products or limit the length of terms of patent protection we may have for our products. Further, other companies may design around technologies we have patented, licensed or developed. Moreover, changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In addition, in November 2005, we entered into a settlement agreement with Ventrassist Pty., Limited, Ventracor Limited (collectively "Ventracor") and the University of Technology, Sydney, under which the parties resolved all of the claims and counterclaims filed by the parties in the United States District Court for the Southern District of Florida in 2004 and 2005, and agreed to mutual non-assertion covenants. As part of that agreement, we agreed not to sue Ventracor or the University of Technology, Sydney, or any of their respective successors, assigns, affiliates, customers or suppliers for infringement of 29 of our issued U.S. and worldwide patents existing as of the date of the agreement or any patents that issue from any patent applications existing as of such date (including any type of patent that claims priority or shares common priority to such patents). We also agreed not to sue such parties for infringement of all of our issued patents existing as of September 30, 2005, or any patents that issue from any patent applications existing as of such date, in respect of Ventracor's blood pump devices existing as of the date of the agreement or any device embodying a modification of such devices which does not give rise to a new independent claim for patent infringement. As a result, Ventracor, the University of Technology, Sydney, or their respective successors or assigns may commercialize competing technology or products that would have otherwise been precluded by our patents subject to the agreement. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from developing and commercializing our products. The occurrence of these events may have a material adverse effect on our business, financial condition or results of operations.

Claims that our current or future products infringe or misappropriate the proprietary rights of others could adversely affect our ability to sell those products and cause us to incur additional costs.

Substantial litigation over intellectual property rights exists in the medical device industry. We expect that we could be increasingly subject to third-party infringement claims as our revenues increase, the number of competitors grows and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents on which our current or future products or technologies may infringe. For example, we are aware of certain patents and patent applications owned by third parties that cover different aspects of mechanical circulatory support, methodologies for the pumping of blood and other fluids and the related devices and technologies. Any of these third parties might make a claim of infringement against us.

In particular, Jarvik Heart, in a letter received in August 2008, invited us to discuss "an exclusive license" as it relates to a Jarvik patent concerning hybrid blood pumps. The patent referenced by this letter relates to technology that is material to our business. We have not had any substantive discussions with Jarvik Heart concerning this matter since our receipt of this letter and we do not believe that our blood pump infringes this patent. In addition, in a letter received in September 2009, Abiomed suggested that we "may be interested in licensing Abiomed's technology" as it relates to an Abiomed patent concerning bearingless blood pumps. The patent referenced by this letter relates to technology that is potentially material to our business. We have had discussions with Abiomed regarding this patent however, we believe that the HeartWare System does not infringe this patent.

Any litigation, regardless of its outcome, would likely result in the expenditure of significant financial resources and the diversion of management's time and resources. In addition, litigation in which we are accused of infringement may cause negative publicity, adversely impact prospective customers, cause product shipment delays, prohibit us from manufacturing, marketing or selling our current or future products, require us to develop non-infringing technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenues may decrease substantially and we could be exposed to significant liability. A court could enter orders that

temporarily, preliminarily or permanently enjoin us or our customers from making, using, selling, offering to sell or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our reputation, business, financial condition or results of operations.

We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

- assert claims of infringement;
- enforce our patents;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of others.

Any lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. Despite these measures, any of our intellectual property rights could, however, be challenged, invalidated, circumvented or misappropriated. We generally seek to protect this information by confidentiality, non-disclosure and assignment of invention agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may be disclosed to or otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. If, for any of the above reasons, our intellectual property is disclosed or misappropriated, it would harm our ability to protect our rights and have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims that our employees or we have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers of our employees.

We employ individuals who were previously employed at other medical device companies, including our competitors or potential competitors. To the extent that our employees are involved in research areas that are similar to those in which they were involved with their former employers, we may be subject to claims that such employees have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of the former employers. Litigation may be necessary to defend against such claims.

We are subject to federal and state laws prohibiting "kickbacks" and false or fraudulent claims, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

A federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. These laws constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. Because we may provide some coding and billing information to purchasers of the HeartWare System and our other products, and because we cannot assure that the government will regard any billing errors that may be made as inadvertent, these laws are potentially applicable to us. In addition, these laws are potentially applicable to us because we provide reimbursement to healthcare professionals for training patients on the use of the HeartWare System and our other products. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be substantial. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could have a material adverse effect on our business, financial condition or results of operations.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil

or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

If we are unable to manage our expected growth, we may not be able to commercialize our product candidates.

We expect to continue to expand our operations and grow our research and development, product development, regulatory, manufacturing, sales, marketing and administrative operations. This expansion has placed, and is expected to continue to place, a significant strain on our management, infrastructure and operational and financial resources. To manage any further growth and to commercialize our products, we will be required to improve existing and implement new operational and financial systems, procedures and controls and expand, train and manage our growing employee base. Specifically, our information technology and back-up systems and access to such systems will need to be improved and upgraded to accommodate our growth. In addition, we will need to manage relationships with various manufacturers, suppliers and other organizations, including various regulatory bodies in the United States and other jurisdictions. Our ability to manage our operations and growth will require us to improve our operational, financial and management controls, as well as our internal reporting systems and controls. We may not be able to implement such improvements to our management information and internal control systems in an efficient and timely manner and may discover deficiencies in existing systems and controls. Our failure to accomplish any of these tasks could materially adversely affect our business.

If we expand, or attempt to expand, into additional foreign markets, we will be subject to new business risks that may adversely impact our business, financial condition and results of operations.

If we expand, or attempt to expand, into additional foreign markets, we will be subject to new business risks, including:

- failure to fulfill foreign regulatory requirements on a timely basis or at all to market the HeartWare System or other future products;
- availability of, and changes in, reimbursement within prevailing foreign health care payment systems;
- adapting to the differing laws and regulations, business and clinical practices, and patient preferences in foreign countries;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign partners, distributors or sales or marketing agents;
- limited protection for intellectual property rights in some countries;
- difficulty in collecting accounts receivable and longer collection periods;
- costs of enforcing contractual obligations in foreign jurisdictions;
- recessions in economies outside of the United States;
- political instability and unexpected changes in diplomatic and trade relationships;
- currency exchange rate fluctuations; and
- potentially adverse tax consequences.

If we are successful in introducing our current or future products into foreign markets, we will be affected by these additional business risks, which may adversely impact our business, financial condition and results of operations. In addition, expansion into additional foreign markets imposes additional burdens on our executive and administrative personnel, research and sales departments and general managerial resources. Our efforts to introduce our current or future products into foreign markets may not be successful, in which case we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the results of operations generated from this expansion.

If we choose to acquire or invest in new businesses, products or technologies, instead of developing them ourselves, these acquisitions or investments could disrupt our business and could result in the use of significant amounts of equity, cash or a combination of both.

From time to time we may seek to acquire or invest in new businesses, products or technologies, instead of developing them ourselves. Acquisitions and investments involve numerous risks, including:

- the inability to complete the acquisition or investment;
- disruption of our ongoing businesses and diversion of management attention;
- difficulties in integrating the acquired entities, products or technologies;
- risks associated with acquiring intellectual property;
- difficulties in operating the acquired business profitably;
- the inability to achieve anticipated synergies, cost savings or growth;
- potential loss of key employees, particularly those of the acquired business;
- difficulties in transitioning and maintaining key customer, distributor and supplier relationships;
- risks associated with entering markets in which we have no or limited prior experience; and
- unanticipated costs.

In addition, any future acquisitions or investments may result in one or more of the following:

- dilutive issuances of equity securities, which may be sold at a discount to market price;
- the use of significant amounts of cash;
- the incurrence of debt;
- the assumption of significant liabilities;
- increased operating costs or reduced earnings;
- financing obtained on unfavorable terms;
- large one-time expenses; and

- the creation of certain intangible assets, including goodwill, the write-down of which in future periods may result in significant charges to earnings.

Any of these factors could materially harm our stock price, business, financial condition and results of operations.

We compete against companies that have longer operating histories, more established or approved products and greater resources than we do, which may prevent us from achieving further market penetration or improving operating results.

Competition in the medical device industry is intense. Our products will compete against products offered by public companies, such as Thoratec Corporation and World Heart Corporation, as well as several private companies, such as Jarvik Heart, Inc, Circulite, Evaheart and Terumo Heart, Inc. Some of these competitors have significantly greater financial and human resources than we do and have established reputations or approved products or significantly greater name recognition, as well as distribution channels and sales and marketing capabilities that are larger and more established than ours. For example, Thoratec Corporation has received marketing approval in the United States for HeartMate II both destination and bridge-to-transplant indications. Additional competitors may enter the market, and we are likely to compete with new companies in the future. We also face competition from other medical therapies which may focus on our target market as well as competition from manufacturers of pharmaceutical and other devices that have not yet been developed. Competition from these companies could adversely affect our business.

In addition, in Europe our customers are geographically dispersed and, at this stage, a significant portion of our revenue is sourced in Germany among a small number of clinical sites, which also use other competing products. If these sites were to cease using our products or use our products on a reduced or inconsistent basis, such events would have a material adverse effect on our financial condition and results of operations.

Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products. Factors affecting our competitive position include:

- product performance and design;
- product safety;
- sales, marketing and distribution capabilities;
- comparable clinical outcomes;
- success and timing of new product development and introductions; and
- intellectual property protection.

The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.

Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We face intense competition for such personnel, and we may not be able to attract, retain and motivate these individuals. We compete for talent with numerous companies, as well as universities and non-profit research organizations. Our future success also depends on the personal efforts and

abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations and maintain a cohesive and stable environment. Although we have employment and incentive compensation agreements with all of our executive officers and incentive and compensation plans for our other personnel providing them with various economic incentives to remain employed with us, these incentives may not be sufficient to retain them. We do not maintain key man life insurance on the lives of any of the members of our senior management. The loss of key personnel for any reason or our inability to hire, retain and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

Product liability claims could damage our reputation or adversely affect our business.

The design, manufacture and marketing of human medical devices, particularly implantable life-sustaining medical devices, carries an inherent risk of product liability claims and other damage claims. Such liability claims may be expensive to defend and may result in large judgments against us. A product liability or other damages claims, product recall or product misuse, regardless of the ultimate outcome, could require us to spend significant time and money in litigation or to pay significant damages and could seriously harm our business. We maintain clinical trial insurance and limited product liability insurance. We cannot be certain that such insurance will be sufficient to cover all claims that may be made against us. Our insurance policies generally must be renewed on an annual basis. We may not be able to maintain or increase such insurance on acceptable terms or at reasonable costs. A successful claim brought against us in excess, or outside, of our insurance coverage could seriously harm our financial condition and results of operations. Generally, our clinical trials will be conducted in patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists, and, during the course of treatment, these patients could suffer adverse medical effects or die for reasons that may or may not be related to our medical devices. Any of these events could result in a claim of liability. For example, in 2009 we received a claim in connection with the death of a patient from multiple organ failure participating in our clinical trial in Germany. We may receive similar claims from time to time in the future. Such claims against us, regardless of their merit, could result in significant awards against us that could materially adversely harm our business, financial condition, results of operations and prospects. A product liability or other damages claims, product recall or product misuse could also materially and adversely damage our reputation and affect our ability to attract and retain customers.

Investors could lose confidence in our financial reports, and the value of our shares may be adversely affected, if our internal controls over financial reporting are found not to be effective by management or by our independent registered public accounting firm or if we make disclosure of existing or potential significant deficiencies or material weaknesses in those controls.

Management's assessment of our internal controls over financial reporting is discussed in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2008. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures, and internal control over financial reporting as of December 31, 2008. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures, and internal control over financial reporting were effective as of December 31, 2008.

We continue to evaluate our existing internal controls over financial reporting against the standards adopted by the Public Company Accounting Oversight Board, or PCAOB. During the course of our ongoing evaluation of the internal controls, we may identify areas requiring improvement and will design enhanced processes and controls to address any issues identified through this review. As we continue to commercialize our products, we will need to enhance our accounting and financial controls functions, particularly as they relate to accounting for revenue and inventory, and we will need to add more personnel to our financial reporting group. Remediating any deficiencies, significant deficiencies or material weaknesses that have been or could be identified by us or our independent registered public accounting firm may require us to incur significant costs and expend significant time and management resources. We cannot assure you that any of the measures we implement to remedy any such deficiencies will effectively mitigate or remedy such deficiencies. The existence of one or more such deficiencies or weaknesses could affect the accuracy and timing of our financial reporting. Investors could lose confidence in our financial reports, and the value of our shares may be adversely affected if our internal controls over financial reporting are found not to be effective by management or by our independent registered public accounting firm or if we make disclosure of existing or potential significant deficiencies or material weaknesses in those controls.

Risks Related to Our Common Stock

The price of our common stock may fluctuate significantly.

The ordinary shares of HeartWare Limited had been traded on the ASX from January 31, 2005 until November 13, 2008 when the shares of common stock of HeartWare International, Inc. started trading on the ASX in the form of CDIs, each representing one thirty-fifth of a share of our common stock. The trading price of the common stock and the CDIs, as applicable, has been, and is likely to continue to be, volatile, which means that it could decline substantially within a short period of time. For example, the closing price of our CDIs (and previously ordinary shares of HeartWare Limited) traded on the ASX has ranged from AU$0.56 to AU$1.17 in the 12 months ended December 31, 2009. In addition, our shares of common stock began trading on the NASDAQ Global Market on February 24, 2009. Prior to that time, there had been no public market for our common stock in the United States. The price of our common shares, whether traded in the form of common stock or CDIs, could fluctuate significantly for many reasons, including the following:

- future announcements concerning us or our competitors;
- regulatory developments, enforcement actions bearing on advertising, marketing or sales, and disclosure regarding completed, ongoing or future clinical trials;
- quarterly variations in operating results, which we have experienced in the past and expect to experience in the future;
- introduction of new products or changes in product pricing policies by us or our competitors;
- acquisition or loss of significant customers, distributors or suppliers;
- business acquisitions or divestitures;
- changes in third party reimbursement practices;
- fluctuations of investor interest in the medical device sector; and
- fluctuations in the economy, world political events or general market conditions.

In addition, stock markets in general and the market for shares of health care stocks in particular, have experienced extreme price and volume fluctuations in recent years, fluctuations that frequently have been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our shares. The market price of our shares could decline below its current price and the market price of our shares may fluctuate significantly in the future. These fluctuations may be unrelated to our performance.

Your interests may differ or conflict with those of the Company's largest shareholder.

As of December 31, 2009, Apple Tree Partners I, L.P. ("Apple Tree") owned approximately 22.7% of our outstanding shares. As a result, Apple Tree has and will continue to have significant influence over the outcome of any matter, including a change of control, requiring approval of holders of shares. The interests of Apple Tree may differ from or conflict with the interests of other shareholders regarding a potential change of control of us or other matters requiring a vote of shareholders. Apple Tree's significant influence over us and our subsidiaries may delay or prevent a change in control even if desired by the other holders of shares, which could adversely affect the trading price of the shares.

If there are substantial sales of common stock, our share price could decline.

If our existing shareholders sell a large number of shares or the public market, should one develop, perceives that existing shareholders might sell a large number of shares, the prices at which our shares trade could decline significantly. Sales of substantial amounts of shares by shareholders in the public market, or even the potential for such sales, are likely to adversely affect the market price of the shares.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividends on our shares, and we currently do not anticipate paying any cash dividends in the foreseeable future. We intend to retain any earnings to finance the development and expansion of our products and business. Accordingly, our shareholders will not realize a return on their investment unless the trading price of our shares appreciates.

Anti-takeover provisions in our charter documents and Delaware law may discourage a third party from acquiring us, which could limit our stockholders' opportunities to sell their shares at a premium.

Certain provisions of our Certificate of Incorporation and By-laws may be considered as having an anti-takeover effect, such as those provisions establishing a classified board of directors, consisting of three classes of directors, and requiring that directors be removed only for cause, authorizing the board of directors to issue from time to time any series of preferred stock and fix the designation, powers, preferences and rights of the shares of such series of preferred stock, prohibiting stockholders from acting by written consent in lieu of a meeting, requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting, and prohibiting stockholders from calling a special meeting of stockholders. We are also subject to Section 203 of the Delaware General Corporation Law which in general prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless certain conditions specified therein are satisfied. These provisions could have the effect of depriving our stockholders of an opportunity

to sell their shares at a premium over prevailing market prices by discouraging third parties from seeking to obtain control of us in a tender offer or similar transaction.

We may be subject to arbitrage risks.

Investors may seek to profit by exploiting the difference, if any, in the price of our shares of common stock as reflected by the trading price of our CDIs, each representing one thirty-fifth of a share of our common stock, on the ASX and the trading price of our shares of common stock on the NASDAQ Global Market. Such arbitrage activities could cause the price of our securities (as adjusted to reflect the fact that each CDI represents one thirty-fifth of a share of common stock) in the market with the higher value to decrease to the price set by the market with the lower value.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HeartWare International, Inc.

Date: January 26, 2010

By: /s/ David McIntyre
Name: David McIntyre
Title: Chief Financial Officer