VASOMEDICAL INC Form 10-K August 29, 2011

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

# FORM 10-K

[X] ANNUAL REPORT UNDER SECTION 13 OR 150 For the fiscal year ended May 31, 2011  [ ]TRANSITION REPORT UNDER SECTION 13 OR 150 For the transition period from to	d) OF THE SECURITIES EXCHANGE ACT OF 1934 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934		
Commission l	File No. 0-18105		
	DICAL, INC. t as specified in Its Charter) 11-2871434 (IRS Employer Identification No.)  11590 (Zip Code)		
Registrant's telephone number, including area code: (516) 997-4600 Securities registered under Section 12(b) of the Act: None Securities registered under Section 12(g) of the Act:			
Common Stock, \$.001 par value (Title of Class)	OTCQB  Name of each exchange on which registered		
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. [ ]			
Indicate by check mark if the registrant is not required to a Act. [ ]	file reports pursuant to Section 13 or Section 15(d) of the		
Securities Exchange Act of 1934 during the past 12 month to file such reports), and (2) has been subject to such filing Yes [X] No []			
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if			

any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T

(§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required

to submit and post such files) Yes [ X] No [ ]
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. Large accelerated filer [ ] Accelerated filer [ ] Non-accelerated filer [ ] Smaller reporting company [X]
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [ ] No [ X ]
The aggregate market value of common stock held by non-affiliates was approximately \$22,065,523 based on the closing sales price of the common stock as quoted on the OTCQB on August 22, 2011.
At August 22, 2011, the number of shares outstanding of the issuer's common stock was 117,078,704.
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#### PART I

# ITEM 1 – BUSINESS

Except for historical information contained in this report, the matters discussed are forward-looking statements that involve risks and uncertainties. When used in this report, words such as "anticipates", "believes", "could", "estimates" "expects", "may", "plans", "potential" and "intends" and similar expressions, as they relate to the Company or its management identify forward-looking statements. Such forward-looking statements are based on the beliefs of the Company's management, as well as assumptions made by and information currently available to the Company's management. Among the factors that could cause actual results to differ materially are the following: the effect of business and economic conditions; the effect of the dramatic changes taking place in the healthcare environment; the impact of competitive procedures and products and their pricing; medical insurance reimbursement policies; unexpected manufacturing or supplier problems; unforeseen difficulties and delays in the conduct of clinical trials and other product development programs; the actions of regulatory authorities and third-party payers in the United States and overseas; uncertainties about the acceptance of a novel therapeutic modality by the medical community; continuation of the GEHC agreement; and the risk factors reported from time to time in the Company's SEC reports. The Company undertakes no obligation to update forward-looking statements as a result of future events or developments.

#### General Overview

Vasomedical, Inc. was incorporated in Delaware in July 1987. Unless the context requires otherwise, all references to "we", "our", "us", "Company", "registrant", "Vasomedical" or "management" refer to Vasomedical, Inc. and its subsidiaries 1995, we have been primarily engaged in designing, manufacturing, marketing and supporting EECP® Enhanced External Counterpulsation systems based on our unique proprietary technology currently indicated by the United States Food & Drug Administration (FDA) for use in cases of stable or unstable angina, congestive heart failure (CHF), acute myocardial infarction (i.e., heart attack, (MI)) and cardiogenic shock. In April 2010, the Company, through its wholly-owned subsidiary Vaso Diagnostics d/b/a VasoHealthcare, organized a group of medical device sales professionals in the anticipation of entering into the sales representation business for other equipment manufacturers. On May 19, 2010, VasoHealthcare signed a sales representative agreement with GE Healthcare (the "GEHC Agreement"), the healthcare business unit of General Electric Company (NYSE: GE), for the sale of select GE Healthcare Diagnostic Imaging products. Under the GEHC Agreement, VasoHealthcare has been appointed the exclusive representative for these products to specific market segments in the 48 contiguous states of the United States and the District of Columbia. The GEHC Agreement has an initial term of three years commencing July 1, 2010, subject to extension and also subject to earlier termination under certain circumstances. We now report VasoHealthcare activities under our Sales Representation reportable segment and EECP® and other medical device operations under our Equipment reportable segment (see Note C).

During the last several years, the Company has incurred operating losses. We have sought to achieve profitability by launching the VasoHealthcare business, and by expanding our U.S. market product portfolio to include ambulatory monitoring devices (the BIOX series ECG Holter recorders, ambulatory blood pressure monitors and analysis software) and patient management devices (the EZ ECG and EZ O2 products). We also are looking for accretive acquisitions in the medical device market.

In fiscal 2011, the Company's aggregate revenues increased from \$4,205,942 to \$16,373,424 oe 289% from. the prior fiscal year. While the Company incurred operating losses due in large part to the revenue recognition rules associated with its VasoHealthcare business, it generated significant operating cash flows in excess of \$4.1 million.

Market Overview - EECP®

Cardiovascular disease (CVD) is the leading cause of death in the world and is among the top three diseases in terms of healthcare spending in nearly every country. CVD claimed approximately 813,000 lives in the United States in 2007 and was responsible for 1 of every 2.9 deaths, according to The American Heart Association (AHA) Heart and Stroke Statistical 2011 Update (2011 Update). An estimated 82.6 million American adults suffer from some form of cardiovascular disease. Among these, 16.3 million have coronary heart disease (CHD).

We have FDA clearance to market our EECP® therapy for use in the treatment of stable and unstable angina, congestive heart failure, acute myocardial infarction, and cardiogenic shock; however, our current marketing efforts are mostly limited to the treatment of chronic stable angina and congestive heart failure. Medicare and other third-party payers currently reimburse for the treatment of angina pectoris patients with moderate to severe symptoms who are refractory to medications and who, in the opinion of a cardiologist or cardiothoracic surgeon, are not candidates for invasive procedures. Patients with co-morbidities of heart failure, diabetes, peripheral vascular disease, etc. are also reimbursed under the same criteria, provided the primary diagnosis and indication for treatment with EECP® therapy is refractory angina symptoms.

#### Angina

Angina pectoris is the medical term for a recurring pain or discomfort in the chest or near the neck due to coronary artery disease (CAD). The number of angina patients in the United States is approximately 10.9 million, according to the 2011 Update. There are approximately 100,000 to 150,000 new refractory angina patients each year who do not adequately respond to medication, and are not amenable to invasive revascularization procedures such as percutaneous coronary interventions (PCI), with angioplasty and coronary stent placement or coronary artery bypass grafting (CABG). Currently our EECP® therapy is mostly prescribed for these patients because of the potential to meet the guidelines for reimbursement of EECP® therapy.

In February 1999, the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers the Medicare program for more than 46.6 million beneficiaries in 2010, issued a national coverage policy for the use of external counterpulsation therapy in the treatment of refractory angina. Medicare reimbursement guidelines have a significant impact in determining the available market for EECP® therapy. We believe that the majority of the patients who receive EECP® therapy are Medicare patients, and many of the younger patients are covered by third-party payers. Medicare guidelines limit reimbursement for EECP® therapy to patients who do not adequately respond to medical therapy and are not readily amenable to invasive therapy. As a result, an important element of our strategy is to grow the market for EECP® therapy by expanding reimbursement coverage to include a broader range of angina patients than the current coverage policy provides and enable EECP® therapy to compete more with other therapies for ischemic heart disease. To this end, we have engaged a consulting firm in a two-year agreement to assist us in promoting EECP therapy as a first line option in the treatment of CCS Class III/IV angina with both Medicare and a major healthcare third-party payer, and extending Medicare coverage to heart failure and Class II angina. Please see the "Reimbursement" section of this Form 10-K for a more detailed discussion of reimbursement issues.

# Congestive Heart Failure (CHF)

CHF is a condition in which the heart loses its pumping capacity to supply the metabolic needs of all other organs. The condition affects both sexes and is most common in people over age 50. Symptoms include angina, shortness of breath, weakness, fatigue, swelling of the abdomen, legs and ankles, rapid or irregular heartbeat and low blood pressure. CHF is treated with medication surgery, and, in certain severe cases, heart transplants. Left ventricular assist devices (LVADs) and the use of cardiac resynchronization and implantable defibrillators are useful in selected patients with heart failure. Still, no consensus therapy currently exists for CHF and patients must currently suffer their symptoms chronically and have a reduced life expectancy.

According to the 2011 Update, in 2007 approximately 5.7 million adults in the United States were suffering heart failure and about 670,000 new cases of the disease occur each year. The prevalence of the disease is growing as a result of the aging of the population and the improved survival rate of people after heart attacks. Because the condition frequently entails visits to the emergency room and in-patient treatment centers, two-thirds of all hospitalizations for people over age 65 are due to heart failure. The economic burden of congestive heart failure is enormous, with an estimated cost of \$39.2 billion to the health care system in the United States in 2010. Congestive

heart failure offers a good strategic fit with our current angina business and offers an expanded market opportunity for EECP® therapy. Unmet clinical needs in CHF are greater than those for angina, as there are few consensus therapies, invasive or otherwise, beyond medical management for the condition. It is noteworthy that data collected from the International EECP® Patient Registry<sup>TM</sup> (IEPR) at the University of Pittsburgh Graduate School of Public Health shows that approximately one-third of angina patients treated with EECP® also have a history of CHF and 70% to 80% have demonstrated positive outcomes from EECP® therapy.

We sponsored a pivotal, randomized clinical trial to demonstrate the efficacy of EECP® therapy in the most prevalent types of heart failure patients. This trial, known as PEECH™ (Prospective Evaluation of EECP® in Congestive Heart Failure), completed in 2005, was intended to provide additional evidence of the safety and efficacy of EECP® therapy in the treatment of mild-to-moderate heart failure and to support our application for expansion of the Medicare national reimbursement coverage policy to include mild-to-moderate heart failure as a primary indication. The PEECH™ trial was a positive clinical trial, having met the statistical requirement of meeting at least one of its co-primary endpoints, a significant difference in the proportion of patients satisfying a pre-specified threshold of improvement in exercise duration. The trial also demonstrated significant improvements in favor of EECP® therapy on several important secondary endpoints, including exercise duration and improvement in symptom status and quality of life. The results of the PEECH™ trial were published by the Journal of the American College of Cardiology (JACC) in its September 19, 2006 issue. JACC is the official journal of the American College of Cardiology.

On June 20, 2005, CMS accepted our application for expansion of reimbursement coverage of EECP® therapy to include patients with New York Heart Association (NYHA) Class II/III stable heart failure symptoms with an ejection fraction of less than or equal to 35% (i.e. chronic, stable, mild-to-moderate systolic heart failure as a primary indication), as well as patients with Canadian Cardiovascular Society Classification (CCSC) II (i.e. chronic, stable mild angina). On March 20, 2006, CMS issued their Decision Memorandum regarding this reconsideration with the opinion that the evidence was not adequate to support an extension of coverage. It did, however, reiterate in the decision memorandum that "Current coverage as described in Section 20.20 of the Medicare National Coverage Determination (NCD) manual will remain in effect" for refractory angina patients.

In the November-December 2006 issue of the journal Congestive Heart Failure, a second report of results from the PEECH<sup>™</sup> trial was published, focusing on a pre-specified subgroup analysis in trial patients age 65 and over. This analysis demonstrated a statistically positive response on both co-primary endpoints of the trial in patients receiving EECP® therapy versus those who did not, i.e. a significantly larger proportion of patients undergoing EECP® therapy met or exceeded pre-specified thresholds of improvement in exercise duration and peak oxygen consumption. Moreover, the patients age 65 and older who received EECP® therapy demonstrated the greatest differences in exercise duration, peak oxygen consumption and functional class (symptom status) compared with those who did not receive EECP® therapy. These papers were submitted to CMS and we were advised to continue to gather more clinical evidence for future submission.

We will continue to educate the marketplace that EECP® therapy is a therapy for ischemic cardiovascular disease and that patients with a primary diagnosis of heart failure, diabetes, peripheral vascular disease, etc. are also eligible for reimbursement under the current coverage policy, provided the primary indication for treatment with EECP® therapy is angina or angina equivalent symptoms and the patient satisfies other listed criteria. Additionally, we have engaged a consulting firm in a two-year agreement to assist us in extending CMS coverage and reimbursement to NYHA Class II/III heart failure. Please see the "Reimbursement" section of this Form 10-K for a more detailed discussion of reimbursement issues.

#### Other Potential Applications of EECP® Therapy

While currently we only have FDA clearance to market EECP® therapy in the United States for the treatment of stable and unstable angina, congestive heart failure, acute myocardial infarction and cardiogenic shock, there are many clinical papers published in peer reviewed medical journals demonstrating the safety and effectiveness in off-label applications by physicians, both domestic and overseas. During the past several years, many studies have been carried out to provide scientific evidence-based explanation on the mechanisms of action of EECP® therapy. Results of these studies show that EECP® therapy improves endothelial function in dilating vasculature, stimulates angiogenesis in forming new blood vessels, reduces inflammatory responses in deactivating signaling proteins and attenuates the atherosclerotic process by limiting smooth muscle cells proliferation and migration. These actions have led

physicians to using EECP® therapy in the treatment of many different cardiovascular symptoms, such as:

• Cerebral vascular disease (CVD): Specifically ischemic stroke. There were many case reports published in Chinese medical literature since the 1980s and 1990s concerning the benefits of external counterpulsation in the treatment of cerebral vascular disease. In 2003 Dr. Werner and coworkers in Germany reported EECP® therapy increased cerebral blood flow (Acta Neurologica Scandinavica. Vol. 107, p. 405). This finding was confirmed by Dr Alexandrov of University of Alabama in 2008 (Stroke. Vol. 39, p. 2760). In the same year Dr. Han and Dr. Wong of the Chinese University in Hong Kong published a review paper on the use of EECP® therapy in ischemic stroke (Cerebrovasc Dis. Vol. 26, p. 97) and another paper in a randomized, crossover study demonstrating the efficacy of EECP® therapy in treating ischemic stroke patients with large artery occlusion (Stroke. Vol. 39, p. 1340).

- Cardiac Syndrome X (CSX): A condition where patients present with abnormal stress perfusion scan and chest pain but normal coronary arteries shown by angiography, most probable due to impaired coronary microvascular dilatory function related to endothelial dysfunction. In 2008, Dr. Pennell in an editorial published in J American College of Cardiology (Vol. 51, p. 473) illustrated the achievement of normal cardiac perfusion after EECP® therapy in a 68-year-old woman with CSX. In the same year, Dr. Kronhaus and Dr. Lawson showed results in 30 cases of refractory angina due to CSX improved 100% of perfusion defects immediately after a course of EECP® therapy and 87% sustained their improvement at 1-year follow up. They concluded that EECP® therapy may be an effective and durable treatment for this often difficult to treat problem.
- Erectile Dysfunction (ED): Reduction of penile arterial vasodilation as early as 1998 Dr. Froschermaier and co-workers in Germany demonstrated dramatic improvement in ED symptoms with an 88% increase in penile artery peak systolic flow (Urologia Internationalis. Vol. 61, p. 168). In 2007 Dr. Lawson of New York reported improvement of International Index of Erectile Function after a course of EECP® therapy in patients with severe coronary disease and ED (International J of Clinical Practice. Vol. 61, p. 757). This result was confirmed in the same year by Dr. El-Sakka and colleagues of Egypt and Saudi Arabia in a 2-part paper (J of Sexual Medicine. Vol. 4(3), p. 771 and Vol. 4(5), p. 448). EECP® Therapy has been shown to improve endothelial function, increase the release of nitric oxide to dilate vasculature, forming the physiological base of using EECP® to treat ED. The critical issue to examine is the treatment protocol, how long and how often should EECP® therapy be given. The answer may depend on the severity of ED.
- Chronic Kidney Disease (CKD): Associated with an increased risk for stroke, peripheral arterial disease and all-cause mortality, common among patients with hypertension, dyslipidemia and diabetes mellitus. In 1999 Dr. Werner of Germany reported significant increase of blood flow to the brain, liver, kidneys and the heart after just 1-hour of EECP® therapy (American J of Cardiology. Vol. 84, p. 950). Subsequently in 2005, this group of investigators demonstrated the improvement of renal function in patients with liver cirrhosis after a course of EECP® Therapy (Nephrology Dialysis Transplantation. Vol. 20, p. 920). In July 2008, Dr. Ajith of Kerala, India, reported the doubling of the urine output of a diabetic patient with liver and kidney failure waiting for renal transplantation (Khaleej Times Online). EECP® therapy is effective in augmenting excretory function and may be effective in stopping the progression of CKD.
- Diabetes Mellitus (DM): An established two-fold excess risk factor for coronary heart disease and ischemic stroke and poor responders to conventional therapeutic interventions. In 2003 Dr. Linnemeier reported the safety and effectiveness of EECP® therapy in treating diabetic refractory angina patients with 1-year mortality similar to non-diabetes and coronary intervention registry population (American Heart J. Vol. 146, p. 453). Diabetic patients with coronary artery disease are known to have poor outcomes after coronary bypass and percutaneous coronary intervention. Diabetics have accelerated diffuse macro and microvascular disease. Invasive revascularization may open or bypass occluded macrovascular conductive vessel, but not microvascular resistive vessels. EECP® therapy enhances development of microvasculature collateral, improves endothelial cell function and may be the complementary or front-line therapy to invasive therapies.

It is clear that there are sufficient clinical and scientific evidence in each of the five potential applications listed above to demonstrate EECP® therapy's safety and efficacy. However, large randomized control studies appear to be needed to confirm the preliminary findings and drive market clearance and reimbursement.

We will continue to observe development in the use of EECP® therapy in new applications and may sponsor clinical studies seeking regulatory clearance and reimbursement as funding becomes available.

# The EECP® Therapy Systems

The EECP® therapy systems are noninvasive treatment systems utilizing fundamental hemodynamic principles to augment coronary blood flow and, at the same time, reduce the workload of the heart while improving the overall vascular function. The treatment is completely noninvasive and is administered to patients on an outpatient basis, usually in daily one-hour sessions, five days per week over seven weeks for a total of 35 treatments. The procedure is well tolerated and most patients begin to experience relief of chest pain caused by their coronary artery disease after 15 to 20 hours of therapy. As demonstrated in our clinical studies, positive effects have been shown in most patients to continue for years following a full course of therapy.

During EECP® therapy, the patient lies on a contoured treatment table while three sets of inflatable pressure cuffs, resembling oversized blood pressure cuffs, are wrapped around the calves, and the lower and upper thighs, including the buttocks. The system is synchronized to the individual patient's cardiac cycle triggering the system to inflate the cuffs rapidly and sequentially -- via computer-interpreted ECG signals -- starting from the calves and proceeding upward to the buttocks during the relaxation phase of each heartbeat (diastole). This has the effect of creating a strong retrograde arterial wave in the arterial system, forcing freshly oxygenated blood towards coronary arteries and myocardium at a time when resistance to coronary blood flow is at its lowest level. The inflation of cuffs also simultaneously increases the volume of venous blood that is returned to the heart when the heart is filling up for ejection in the following contracting phase. Just prior to the next heartbeat when the heart begins to eject blood by contracting (systole), all three cuffs simultaneously deflate, leaving an empty vascular space to receive blood ejecting from the heart, thereby significantly reducing the workload of the heart. This is achieved because the vascular beds in the lower extremities are relatively empty when the cuffs are deflated, significantly lowering the resistance, and provide vascular space to receive the blood ejected by the heart, reducing the amount of work the heart must do to pump oxygenated blood to the rest of the body. The inflation/deflation activity is monitored constantly and coordinated by the computerized system that interprets electrocardiogram signals from the patient's heart, monitors heart rhythm and rate information, and actuates the inflation and deflation in synchronization with the cardiac cycles. Many safety features are also built into the system to cope with irregular or unexpected cardiac events and external interferences or artifacts.

Independent research aiming to fully explain the precise scientific means by which EECP® therapy achieves its long-term beneficial effects continues to be conducted and published every year. There is evidence to suggest that the EECP® therapy triggers a neurohormonal response that induces the production of growth and vasodilatation factors that promotes recruitment of new arteries and dilates existing blood vessels. The recruitment of new arteries, known as collateral blood vessels, bypass blocked or narrowed vessels and increase blood flow to ischemic areas of the heart muscle that were receiving an inadequate supply of blood. There is also evidence to support a mechanism related to improved function of the endothelium (the inner lining of the blood vessels), which regulates the luminal size of the arteries and controls the dilation of the arteries to ensure adequate blood flow to all organs, thus reducing constriction of blood vessels that supply oxygenated blood to the body's organs and tissues and as a result the reduced workload of the heart.

#### Clinical Studies on EECP® Therapy

The effectiveness of EECP therapy and its mechanisms of action have been demonstrated in numerous clinical studies and journal publications, as follows:

The MUST-EECP® Study

In 1995, we began a randomized, controlled and double-blinded multicenter clinical study (MUST-EECP®) at seven leading university hospitals in the United States to provide definitive scientific evidence of EECP® therapy's effectiveness. MUST-EECP® was completed in July 1997 and the results were published in the Journal of the American College of Cardiology (JACC), a major peer-review medical journal, in June 1999.

This 139 patient study, which included a sham-EECP® control group, demonstrated that patients treated with EECP® therapy were able to increase the amount of time on exercise testing before they showed signs of cardiac ischemia (i.e. ST-segment depression on their electrocardiogram) and experienced a reduction in the frequency of their angina attacks compared to patients who did not receive EECP® therapy. In 1999, physician collaborators completed a quality-of-life study with the EECP® system in a subset of the same patients that participated in MUST-EECP®. Two highly regarded standardized means of measurement were used to gauge changes in patients' outlook and ability to participate in normal daily living during the treatment phase and for up to 12 months after treatment. Results of this study, which have been presented at major scientific meetings and published in the January 2002 Journal of Investigative Medicine, show that after one-year of follow-up the group of patients receiving EECP® therapy enjoyed significantly improved aspects of health-related quality of life compared to those who received a sham treatment.

# The PEECH<sup>TM</sup> Study

The protocol for the study required that patients have NYHA II or III symptoms, have an LVEF of 35% or less, be able to undergo exercise testing and complete patient examinations 1-week, 3-months and 6-months following treatment that evaluated changes from baseline in exercise capacity, symptom status and quality of life. Patients were randomized to receive either optimal (i.e. guideline-recommended) pharmaceutical therapy (OPT) or EECP® therapy in addition to OPT. The 187 patient trial was completed in 2004 and the results were published by the Journal of the American College of Cardiology (JACC) in its September 19, 2006 issue.

The PEECH<sup>TM</sup> trial was designed to demonstrate that the EECP® therapy combined with OPT, compared to OPT alone, could increase patients' exercise duration and peak oxygen consumption. Additional endpoints include changes in NYHA functional classification, changes in quality of life, adverse experiences and pre-defined clinical outcomes. The study was a positive clinical trial on the basis that a significantly greater proportion of patients who underwent EECP® therapy improved their exercise duration by 60 seconds or more six months following completion of therapy compared to those who received OPT alone. The proportion of patients achieving a 1.25 mL/kg/min improvement in peak oxygen consumption was not significantly different between the two groups at six months. The trial also demonstrated an improved quality of life during follow up. Lastly, EECP® therapy was deemed safe and well tolerated in this group of patients, as patients in the EECP®-treated group did not suffer more adverse events than those in the control group.

In the November-December 2006 issue of the journal Congestive Heart Failure, a second report of results from the PEECH<sup>TM</sup> trial was published, focusing on the results of a prespecified subgroup analysis in trial patients age 65 and over. This analysis demonstrated a statistically positive response on both co-primary endpoints of the trial in patients receiving EECP® therapy versus those who did not, i.e. a significantly larger proportion of patients undergoing EECP® therapy met or exceeded prespecified thresholds of improvement in exercise duration and peak oxygen consumption. Moreover, the patients age 65 and older who received EECP® therapy demonstrated the greatest differences in exercise duration, peak oxygen consumption and functional class (symptom status) compared with those who did not receive EECP® therapy.

The results of the PEECH<sup>TM</sup> trial indicate that EECP® therapy provides beneficial adjunctive therapy in patients with NYHA Class II-III systolic heart failure receiving optimal pharmacological therapy, especially in those 65 years of age or older.

The International EECP® Patient Registry (IEPR<sup>TM</sup>)

In 1998 we sponsored the International Patient EECP® Registries (IEPR<sup>TM</sup>) with the Department of Epidemiology Data Center at the University of Pittsburgh, Graduate School of Public Health as the coordinating center responsible for

data collection, processing, as well as performing error and consistency checks and analysis. The IEPR<sup>TM</sup> is a voluntary registry recording consecutive patients enrolled in clinical sites undergoing for at least 1 hour of EECP® therapy. The objective of IEPR<sup>TM</sup> was to document the baseline characteristics, safety and effectiveness of EECP® therapy in the treatment of chronic angina. Over 5,000 patients have been enrolled from 84 sites, constituting Phase I of the International EECP® Patient Registry (IEPR<sup>TM</sup>-1). Patients in IEPR<sup>TM</sup>-1 were to be followed for 3 years, and the data collection was completed in September 2004. Phase II of the International EECP® Patient Registry (IEPR<sup>TM</sup>-2) was initiated in January 2002 and reached the target enrollment of 2,500 patients in September 2004. Data captured at the beginning of treatment include patient demographic characteristics, medical history and pre-treatment quality of life (Duke Activity Status Index, or DASI). IEPR<sup>TM</sup>-2 also added heart failure specific data (including the Kansas City Cardiomyopathy Questionnaire). After treatment completion, data was collected on improvement in anginal symptoms, quality of life, and on any adverse events occurring during the treatment period. Patients were contacted for follow-up at 6 and 12 months and then annually up to 2 years.

There are 26 papers published in medical peer-reviewed journals and more than 85 presentations in major scientific/clinical conferences using data collected in IEPR<sup>TM</sup>.

#### IEPRTM-1

The design, methods, baseline characteristics of patients enrolled in IEPR<sup>TM</sup>-1 and acute results of the first 978 patients was published in Clinical Cardiology in June 2001, reporting data on patients considered to be candidates for revascularization compared with those not considered suitable. Of the 978 patients analyzed, 70% had Canadian Cardiovascular Society Classification (CCSC) class III or IV angina before starting EECP® treatment, and 62% used nitroglycerin. Most (81%) had been previously revascularized, and 69% were considered unsuited for either PCI or CABG at the time of starting EECP® treatment. A full treatment course (usually 35 hours) was completed in 86% of the patients, of whom 81% reported improvement of at least one angina class immediately after the last treatment. In a broad patient population, EECP® therapy has been shown to be a safe and effective treatment.

Follow-up results of the two-year outcomes of 1,097 patients from the IEPR<sup>TM</sup>-1 were published in American Journal of Cardiology in February 2004. Seventy-three percent (73%) of patients in this cohort had a decrease in their angina symptom status upon completion of EECP® therapy and the average number of angina episodes for the group was reduced from 10.6 to 2.8 per week. The improvement was significant and correlated with the reduction in Canadian Cardiovascular Society Classification. The authors summarized the results by stating "Most patients experienced a significant reduction in angina and improvement in quality of life after EECP® therapy, and this reduction was sustained in most patients at 2-year follow-up."

Three-year outcomes of 1,424 patients from 36 centers registered in the IEPR<sup>TM</sup>-1 were published in Clinical Cardiology in April 2008, with a median of follow-up of 37 months. Two hundred and twenty patients (15.4%) died, while 1,061 patients (74.4%) completed their follow-up. The mean age was 66±11 years and 72% were men. Seventy-six percent (76%) had multivessel coronary disease for 11±8 years. Eighty-eight percent (88%) had a prior percutaneous or surgical revascularization and 82% were unsuitable for further coronary intervention. Immediately post-EECP® treatment, the proportion of patients with severe angina CCS class III/IV was reduced from 89% to 25%. The CCS class was improved by at least 1 class in 78% of the patients and by at least 2 classes in 38% of the patients. This was sustained in 74% of the patients during follow-up. Thirty-six percent (36%) of the patients had CCS II or less angina, which was better than pre-EECP® state without a major adverse cardiovascular event during follow-up. More severe baseline angina and a history of heart failure or diabetes were independent predictors of unfavorable outcome. EECP® treatment improves angina and quality of life immediately after a course of treatment. For most of the patients, these beneficial effects are sustained for 3 years.

# $IEPR^{TM}-2$

Results of the two-year clinical outcomes from IEPR<sup>TM</sup>-2 in 363 patients who had refractory angina and left ventricular dysfunction (LVD – a form of heart failure) with ejection fraction less than or equal to 35% were published in American Journal of Cardiology in January 2006. Most patients in this cohort reported quality of life as poor. After completion of treatment, there was a significant decrease in severity of angina class, and 72% of patients improved from severe angina to no angina or mild angina. Fifty-two percent (52%) of patients discontinued nitroglycerin use. Quality of life improved substantially. At 2 years this decrease in angina was maintained in 55% of patients. The 2-year survival rate was 83%, and the major adverse cardiovascular event-free survival rate was 70%. Forty-three percent (43%) had not reported cardiac hospitalization; 81% had no reported congestive heart failure events. Repeat EECP® treatment was performed in 20% of these patients. The only significant independent predictor of repeat EECP® in a proportional hazard model was failure to complete the first EECP treatment course (hazard ratio 2.9, 95% confidence interval 1.7 to 4.9). Improvements in angina symptoms and quality of life were maintained at 2 years. In conclusion, for patients who have high-risk LVD, EECP® therapy offers an effective, durable therapeutic approach for refractory angina. Decreased angina and improvement in quality of life were

maintained at 2 years, with modest repeat EECP® treatment and low major cardiovascular event rates.

In addition to collecting data on patients with history of heart failure, IEPR<sup>TM</sup>-2 also gathered data on patients who failed to complete an initial 35-hour EECP® treatment course, published in Cardiology in November 2006. In 2,311 patients, 86.5% completed their EECP® treatment course (Complete cohort) and 13.5% patients failing to complete (Incomplete cohort). The predictors of failure to complete the initial course of EECP® treatment course were: female gender, heart failure, use of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, and use of nitroglycerin. For the Complete group, 83.4% had a reduction of at least one CCS class after their initial EECP® course, vs. 21.7% in the Incomplete group. After repeat EECP® treatment, 66.2% of the Incomplete group achieved at least one CCS class reduction vs. 69.4% of the Complete group undergoing retreatment. The independent predictors for those who return to successfully complete their second course were patients who stopped their first course because of clinical events, and candidacy for coronary artery bypass grafting at the time of initial treatment. The results of retreatment of those who failed to complete their initial EECP® course were comparable to those who completed their initial treatment, with similar reductions of CCS angina class.

#### Significant Economic Benefits of EECP® therapy

IEPR-2 also examined the economic impact of EECP® treatment by collecting data on emergency department (ED) visits and hospitalizations in patients with refractory angina and LVD. Patients with refractory angina and LVD exert an enormous burden on health care resources primarily because of the number of recurrent emergency department (ED) visits and hospitalizations. Results from 450 patients with LVD (ejection fraction no more than 40%) treated with EECP® therapy for their refractory angina with data on all-cause ED visits and hospitalization rates within 6-months before EECP® therapy were compared with those at 6-months after EECP® therapy were analyzed and published in Congestive Heart Failure in February 2007. Despite the unfavorable risk profile, refractory angina patients with LVD achieved a substantial reduction in all-cause ED visits and hospitalization rates at 6-month follow-up. The proportion of patients reporting at least 1 ED visit in the 6 months after the start of treatment was 11.8%, and the proportion of patients reporting at least 1 hospital admission was 23.5%. The mean number of ED visits per patient decreased from 0.9±2.0 pre-EECP to 0.2±0.7 at 6 months, and hospitalizations were reduced from 1.1±1.7 to 0.3±0.9, a reduction of 82%. EECP® therapy has the potential to save billions in healthcare costs each year, and the Company is educating payers on these benefits as part of its campaign to expand reimbursement.

Registry data, while considered a valuable source of complementary clinical data, is deemed by researchers and others to be less convincing than data from randomized and blinded clinical trials and from certain other well-controlled clinical study designs. There can be no assurance that the Company will be able to obtain regulatory, reimbursement or other types of approvals, or a favorable standing in medical professional practice guidelines, based only upon results observed in patients enrolled in registries.

#### Other studies and publications

There are at least 155 papers published in peer-reviewed medical journals related to external counterpulsation therapy since 1992, and many more published in scientific and medical conferences all over the world. Most of these journal publications are clinical reports on the results in patients with chronic stable angina and/or heart failure. With only a few exceptions, these reports are generated using Vasomedical EECP® therapy systems. In summary, this body of literature contains evidence from a variety of institutions and investigators demonstrating the pathophysiological mechanisms underlying the benefits of EECP® therapy and the beneficial clinical outcomes of EECP® therapy, as follows:

#### Mechanisms of Action

In the past five years, the mechanisms of action of EECP® therapy have been the subjects of many investigations. It is now clear that during EECP® therapy the hemodynamic effect increases the pressure gradient across coronary stenosis, induces higher shear stress on the endothelial monolayer, promotes angiogenesis and collateral development,

improves endothelial functions, and reduces circulating proinflammatory cytokines, arterial stiffness and smooth muscle cells proliferation and migration, slowing down the progression of atherosclerotic processes. EECP® therapy:

- produces significant increase in coronary blood flow, cardiac output, LV unloading documented by in intracoronary pressure ultrasound Doppler study;
- stimulates development of angiogenesis and arteriogenesis resulting in recruitment of collateral circulation documented by intracoronary pressure wire measurements;
- improves endothelial function by increased plasmas nitric oxide and decreased endothelin-1 levels, producing vasodilation:
- neutralizes reactive oxygen species by reduction of 8-isoprostance and asymmetrical dimethylarginine, reducing cells injury;
- reduces inflammatory cytokines including tumor necrosis factor-, monocyte chemoattractant protein-1, soluble vascular cell adhesion molecule and high-sensitivity C-reactive protein;
- increases release of endothelial progenitor cell, improves endothelial functions and reduces smooth muscle cells migration and proliferation;
- increases release of neurohormonal factors including angiotensin-II, ANP, BNP, improving control of vascular tone;
- reduces arterial stiffness, reducing blood pressure and resistance to blood flow; and
- increases flow-mediated dilation of the brachial and femoral arteries.

#### Beneficial clinical outcomes of EECP® therapy

- increases myocardial perfusion to ischemic regions of the heart in patients with coronary artery disease (CAD), documented by radionuclide stress tests, improving cardiac functions;
- eliminates or reduces angina and heart failure symptoms;
- improves exercise capacity in patients with CAD;
- improves angina function class determined by Canadian Cardiovascular Society, improving functional capacity in patients with CAD and heart failure;
- reduces frequency of angina episodes and nitroglycerin usage in patients with refractory angina;
- improves quality of life in patients with angina and heart failure;
- eliminates or reduces the use of anti-angina medications;
- Benefits are sustained for up to three to five years.

#### Sales and Marketing - EECP®

### **Domestic Operations**

We sell EECP® therapy systems to treatment providers such as hospitals, clinics and physician private practices in the United States through a combination of employees and independent sales representatives managed by a vice president of sales and marketing, along with in-house administrative support. The efforts of our sales organization are further supported by clinical educators who are responsible for the onsite training of physicians and therapists as new centers are established. This clinical applications group also engages in training and certification of new personnel at each site, as well as in updating providers on new clinical developments relating to EECP® therapy.

Our marketing activities support physician education and physician outreach programs, exhibition at national, international and regional medical conferences, as well as sponsorship of seminars at professional association meetings. These programs are designed to support our field sales organization and increase awareness of EECP® therapy in the medical community. Our marketing activities also include promotion of awareness among third-party payers and potential patients of the benefits of EECP® treatment for patients suffering from CHF as well as angina. Additional marketing projects completed this year include an iPhone App for EECP® therapy and the creation of an online company store to promote the online sale of specific products, accessories and supplies. The

Company's marketing resources have been expanded to include an additional marketing manager and an in-house telemarketing group.

We employ service technicians responsible for the repair and maintenance of EECP® systems and, in some instances, on-site training of a customer's biomedical engineering personnel. We provide a service arrangement (usually one year) that includes: service by factory-trained service representatives, material and labor costs, emergency and remedial visits, software upgrades, technical phone support and preferred response times. We service our customers after the service arrangement expires either under separately purchased annual service contracts or on a fee-for-service basis.

#### **International Operations**

We distribute our products in the international market primarily through a network of independent distributors. It has generally been our policy to appoint distributors with exclusive marketing rights to EECP® therapy systems in their respective countries or regions, in exchange for their commitment to meet the duties and responsibilities required of a distributor. Each distribution agreement contains a number of requirements that must be met for the distributor to retain exclusivity, including minimum performance standards. Duties of the distributors include registering the product and obtaining any required regulatory or clinical approvals to support local registration or reimbursement for EECP® therapy, as well as clinical and technical support to the therapy providers in their respective territories.

Our international marketing activities include, among other things, assisting distributors in obtaining regulatory clearance and national or third-party healthcare insurance reimbursement approval, participating in trade shows and medical conferences to create greater awareness and acceptance of EECP® therapy by clinicians, and identifying additional distribution channels in those countries in which we do not currently have a presence.

International sales may be subject to certain risks, including export/import licenses, tariffs, and other trade regulations. However, tariff and trade policies, domestic and foreign tax and economic policies, currency exchange rate fluctuations and international monetary conditions have not significantly affected our business to date. In addition, there can be no assurance that we will be successful in maintaining our existing distribution agreements or entering into any additional distribution agreements, or that our international distributors will be successful in marketing EECP® therapy.

#### Competition - EECP®

Presently, we are aware of at least three direct competitors with an external counterpulsation device on the market. Some other companies have also received FDA 510(k) clearance for external counterpulsation systems since 1998, although we have not seen these systems commercially available in the marketplace. While we believe that these competitors' involvement in the market is limited, there can be no assurance that these companies will not become a significant competitive factor or that other companies will not enter the external counterpulsation market.

We view other companies engaged in the development of device-related, biotechnological or pharmacological approaches to the management of cardiovascular disease as potential competitors in the marketplace as well. These include such common and well-established medical devices and treatments as the intra-aortic balloon pump (IABP), ventricular assist devices (VAD), coronary artery bypass graft surgery (CABG), coronary angioplasty, mechanical circulatory support (MCS), transmyocardial laser revascularization (TMR), total artificial hearts, cardiac resynchronization devices, ranolazine and nesiritide (Natrecor®); as well as newer technologies such as gene therapy and spinal cord stimulation (SCS).

### Government Regulations - EECP®

We are subject to extensive regulation by numerous government regulatory agencies, including the FDA and similar foreign agencies. Where applicable, we are required to comply with laws, regulations and standards governing the

development, preclinical and clinical testing, manufacturing, quality testing, labeling, promotion, import, export, and distribution of our medical devices.

#### Premarket Review

Our EECP® therapy systems are currently classified by the US FDA as Class III devices, which include devices for which there is insufficient information demonstrating that general and special controls will provide reasonable assurance of safety and effectiveness and which are life-sustaining, life-supporting or implantable devices, are of substantial importance in preventing impairment of human health, or pose a potential unreasonable risk of illness or injury. The FDA generally must clear a Class III device for marketing in the United States by a premarket approval or PMA, unless it is considered as a preamendments device – device that was commercially distributed before May 28, 1976 – and thus can be cleared by premarket notification, or 510(k). The company's initial system received FDA 510 (k) clearance in 1995, with later models receiving clearance at various times between 2000 and 2003.

Modifications to a previously cleared medical device that do not significantly affect its safety and effectiveness or constitute a major change in the intended use can be made without having to submit a new 510(k). Vasomedical followed relevant FDA guidance and concluded that the changes incorporated into its Model TS4 did not require a new 510(k) prior to its introduction to market. Vasomedical subsequently obtained a 510(k) that applied to the Model TS4 and all of its models in March 2004, when it made changes to the labeling of all of its EECP® therapy systems. In November 2004, Model Lumenair and AngioNew®-VI were introduced, and again it was concluded that the changes did not require a new 510(k).

There can be no assurance that all the necessary FDA clearances or approvals, including approval of any PMA required by the promulgation of a regulation, will be granted for our products, future-generation upgrades or newly developed products, on a timely basis or at all. Failure to receive, or delays in receipt of such clearances, could have a material adverse effect on our financial condition and results of operations.

#### Clinical Trials

If human clinical trials of a device are required, whether to support a 510(k) or PMA application, the trials' sponsor, which is usually the manufacturer of the device, first must obtain the approval of the appropriate institutional review boards. If a trial is of a significant risk device, the sponsor also must obtain an investigational device exemption, or IDE, from the FDA before the trial may begin. For all clinical testing, the sponsor must obtain informed consent from the patients participating in each trial. There is no guarantee that the sponsor, whether Vasomedical or others, will obtain all necessary approvals, exemptions and consents before future clinical trials, and furthermore, the results of clinical testing that a sponsor undertakes may be insufficient to obtain clearance or approval of the tested product.

# Pervasive and Continuing FDA Regulation

We are also subject to other FDA regulations that apply prior to and after a product is commercially released. These include the current Good Manufacturing Practice (cGMP) requirements, set forth in FDA's Quality System Regulation (QSR), that require manufacturers to have a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of medical devices intended for commercial distribution in the United States. This regulation covers various areas including management and organization, device design, purchase and handling of components, production and process controls such as those related to buildings and equipment, packaging and labeling control, distribution, installation, complaint handling, corrective and preventive action, servicing, and records. We are subject to periodic inspection by the FDA for compliance with the cGMP requirements and Quality System Regulation.

The FDA also enforces post-marketing controls that include the requirement to submit medical device reports to the agency when a manufacturer becomes aware of information suggesting that any of its marketed products may have caused or contributed to a death or serious injury, or any of its products has malfunctioned and that a recurrence of the

malfunction would likely cause or contribute to a death or serious injury. The FDA relies on medical device reports to identify product problems and utilizes these reports to determine, among other things, whether it should exercise its enforcement powers. The FDA also may require post-market surveillance studies for specified devices.

We are subject to the Federal Food, Drug, and Cosmetic Act's, or FDCA's, general controls, including establishment registration, device listing, and labeling requirements. If we fail to comply with any requirements under the FDCA, we, including our officers and employees, could be subject to, among other things, fines, injunctions, civil penalties, and criminal prosecution. We also could be subject to recalls or product corrections, total or partial suspension of production, denial of premarket notification clearance or PMA approval, and rescission or withdrawal of clearances and approvals. Our products could be detained or seized, the FDA could order a recall, repair, replacement, or refund of our devices, and the agency could require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health.

The advertising of our products is subject to regulation by the Federal Trade Commission, or FTC. The FTC Act prohibits unfair or deceptive acts or practices in or affecting commerce. Violations of the FTC Act, such as failure to have substantiation for product claims, would subject us to a variety of enforcement actions, including compulsory process, cease and desist orders and injunctions, which can require, among other things, limits on advertising, corrective advertising, consumer redress and restitution, as well as substantial fines or other penalties.

As a sales channel partner, we are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws.

#### Foreign Regulation

In most countries to which we seek to export our EECP® systems, a local regulatory clearance must be obtained. The regulatory review process varies from country to country and can be complex, costly, uncertain, and time-consuming. Vasomedical EECP® systems are all manufactured in accordance with ISO 13485, the international standard for medical devices. All our current systems are UL listed, as well as CE marking certified for European Union countries, and covered by our Health Canada license.

We are also subject to periodic audits by organizations authorized by foreign countries to determine compliance with laws, regulations and standards that apply to the commercialization of our products in those markets. Examples include auditing by a European Union Notified Body organization (authorized by a member state's Competent Authority) to determine conformity with the Medical Device Directives (MDD) and by an organization authorized by the Canadian government to determine conformity with the Canadian Medical Devices Regulations (CMDR).

There can be no assurance that we will obtain desired foreign authorizations to commercially distribute our products in those markets or that we will comply with all laws, regulations and standards that pertain to our products in those markets. Failure to receive or delays in receipt of such authorizations or determinations of conformity could have a material adverse effect on our financial condition and results of operations.

#### **Patient Privacy**

Federal and state laws protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of that protected information. The U.S. Department of Health and Human Services (HHS) published patient privacy rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA privacy rule) and the regulation was finalized in October 2002. Currently, the HIPAA privacy rule affects us only indirectly in that patient data that we access, collect and analyze may include protected health information. Additionally, we have signed some Business Associate Agreements with Covered Entities that contractually bind us to protect protected health information, consistent with the HIPAA privacy rule's requirements. We do not expect the costs and impact of the HIPAA privacy rule to be material to our business.

#### **Practice Guidelines**

Medical professional societies periodically issue Practice Guidelines to their members and make them available publicly. The American College of Cardiology (ACC) and the American Heart Association (AHA) have jointly engaged in developing practice guidelines since 1980 to critically evaluate the use of diagnostic procedures and therapies in the management or prevention of cardiovascular diseases. These guidelines are meant to "improve the effectiveness of care, optimize patient outcomes and affect the overall cost of care favorably by focusing resources on the most effective strategies." Recommendations incorporated into the guidelines are based upon an assessment of the strength of evidence for or against a treatment or procedure and estimates of expected health outcomes stemming from a formal review of peer-reviewed published literature. These guidelines may not be updated for some time.

The ACC/AHA 2002 Guideline Update for the Management of Patients with Chronic Stable Angina was issued in 2003. Comments on external counterpulsation appear in a section entitled Recommendations for Alternative Therapies for Chronic Stable Angina in Patients Refractory to Medical Therapy Who Are Not Candidates for Percutaneous Intervention or Surgical Revascularization and include a so-called Class IIb recommendation. ACC/AHA guideline classifications I, II and III are used to "provide final recommendations for both patient evaluation and therapy" and a Class IIb rating is defined as "Usefulness/efficacy is less well established by evidence/opinion."

An Update to the 2002 ACC/AHA Guidelines has been under review by the ACC Guidelines Committee for the Guideline Update for the Management of Patients with Chronic Stable Angina and was originally scheduled for release in spring 2011. Based upon the publication of numerous randomized, controlled studies in the last five years on the mechanisms of action of EECP® therapy, the Company made a formal request, and has contacted all domestic EECP® providers and key opinion leaders in the field of cardiology to support its request, for an upgrade from the Class IIb classification to a IIa level, consistent with the current published scientific evidence. The update has been delayed with no new release date available.

The ACC/AHA 2005 Guidelines for the Diagnosis and Management of Chronic Heart Failure in the Adult was issued in 2005. External counterpulsation is listed as one of the devices under investigation in a section entitled "Drugs and Interventions Under Active Investigation." The 2006 Comprehensive Heart Failure Practice Guideline, issued in February 2006 by the Heart Failure Society of America, does not include any comments on the use of external counterpulsation therapy for treating heart failure patients.

In summary, while there is still some reluctance in the cardiology community about the broader use of EECP® therapy, positive evaluations of its application for patients with chronic angina and heart failure continue to appear in presentations at major scientific meetings and in peer-reviewed publications each year. We believe the new evidence from completed and ongoing studies regarding the efficacy of EECP® therapy and its long lasting effect will be sufficient to warrant a modification of practice guidelines to a more favorable recommendation, increased acceptance by the medical community, and broader reimbursement coverage.

#### Reimbursement for EECP® Therapy

In addition to regulatory approvals by government agencies for commercialization, reimbursement coverage and payment rates are factors in the sales of our products and we depend in large part on the availability of reimbursement programs. Medicare, Medicaid, as well as private health care insurance and managed-care plans determine eligibility for coverage of a product or therapy based on a number of factors, including the payer's determination that the product is reasonable and necessary for the diagnosis or treatment of the illness or injury for which it is administered according to the scope of clinical evidence available, accepted standards of medical care in practice, the product's cost effectiveness, whether the product is experimental or investigational, impact on health outcomes and whether the product is not otherwise excluded from coverage by law or regulation. The decision process for Medicare reimbursement is legislated by Congress and administered by the Centers for Medicare and Medicaid Services (CMS), and is highly variable in the commercial market. There may be significant delays in obtaining coverage for newly-approved products, and coverage may be more limited than the purposes for which the product is approved or cleared by FDA. Even when we obtain clearance from the US FDA or a foreign authority to begin commercial distribution of a device, there may be limited demand for the device until reimbursement approval is granted by governmental and private third-party payers. Moreover, eligibility for coverage does not imply that a product will be reimbursed in all cases or at a rate that allows us to market our EECP® systems at a price that will enable us to make a profit or even cover our costs. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data. In addition, demand for products may be driven more by the

scope of peer-reviewed evidence and acceptance, endorsement by regulatory and clinical bodies, or foreign country authorities than by the reimbursement rates available. Securing coverage at adequate reimbursement rates from government and third party payers can be a time consuming and costly process that could require us to provide supporting scientific, clinical, and cost-effectiveness data for the use of our products to each payer. If favorable coverage and profitable reimbursement rates from government-funded and private payers for our products are not obtained in a timely manner and maintained, there may be a material adverse effect on our financial condition and operating results.

Our reimbursement strategies are currently focused in the following areas: expanding coverage to include heart failure and mild angina, modifying reimbursement policy language to allow for EECP® therapy as a first line treatment for severe angina, increasing the reimbursement rate of current coverage, and obtaining coverage in selected international markets.

#### Current Medicare Coverage in Angina

In February 1999, CMS, the federal agency that administers the Medicare program for more than 46.6 million beneficiaries now, issued a national coverage policy under HCPCS code G0166 for the use of the EECP® therapy system. Key excerpts from the coverage read as follows:

"Although ECP devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered, since only that use has developed sufficient evidence to demonstrate its medical effectiveness."

"... for patients who have been diagnosed with disabling angina (class III or class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical interventions such as balloon angioplasty and cardiac bypass because:

- 1. their condition is inoperable, or at high risk of operative complications or post-operative failure;
  - 2. their coronary anatomy is not readily amenable to such procedures; or
    - 3. they have co-morbid states, which create excessive risk."

The physician office setting and the hospital outpatient facility are the only entities currently authorized to receive reimbursement for the EECP® therapy under the Medicare program and reimbursement is not permitted to other individuals or entity types, which include, but are not limited to, nurse practitioners, physical therapists, ambulatory surgery centers, nursing homes, comprehensive outpatient rehabilitation facilities, outpatient dialysis facilities, and independent diagnostic testing facilities. The 2011 national average payment rate per hourly EECP® therapy session in the physician office setting and the hospital outpatient facility is \$153.23 and \$101.62, respectively. Actual reimbursement rates vary throughout the country and range from \$140 to \$216 per hourly EECP® therapy session in the physician office setting. The national average payment rate varied considerably (from \$130 in 2000 to \$208 in 2003 for physician offices), but has become stable since 2004, as in the summary below:

Year	Physician Office	Hospital
2004	\$137	\$113
2005	\$138	\$102
2006	\$138	\$104
2007	\$147	\$107
2008	\$156	\$109
2009	\$150	\$102
2010	\$148	\$104
2011	\$153	\$102

If there were any material change in the availability of Medicare coverage, or if the reimbursement level for treatment procedures using the EECP® therapy system is determined to be inadequate, it would adversely affect our business, financial condition and results of operations. Moreover, we are unable to forecast what additional legislation or

regulation, if any, relating to the health care industry or Medicare coverage and payment level may be enacted in the future, or what effect such legislation or regulation would have on our business.

Application to Expand Medicare Coverage to include Class II Angina and Class II/III CHF

On May 31, 2005, we submitted to CMS, and on June 20, 2005, CMS accepted our application for expansion of reimbursement coverage of EECP® therapy to include patients with NYHA Class II/III stable heart failure symptoms with an ejection fraction of less than or equal to 35%, i.e. chronic, stable, mild-to-moderate systolic heart failure as a primary indication, as well as patients with CCSC II, i.e. chronic, stable mild angina.

On March 20, 2006, CMS issued their Decision Memorandum regarding the applications with the opinion "that the evidence is not adequate to conclude that external counterpulsation therapy is reasonable and necessary for the treatment of" the additional indications as requested. They did, however, reiterate in the Decision Memorandum that "Current coverage as described in Section 20.20 of the Medicare National Coverage Determination (NCD) manual will remain in effect" for refractory angina patients. We had subsequently submitted to CMS more data and publications from our PEECH<sup>TM</sup> study and were advised to continue to gather more clinical evidence for future submission.

Based on the new clinical evidence in the past five years, we have started an initiative campaigning for a positive medical necessity decision in support of the use of EECP® therapy in the treatment of heart failure. At the same time, we will continue to educate the marketplace that EECP® therapy is a therapy for ischemic cardiovascular disease and that patients with a primary diagnosis of heart failure, diabetes, peripheral vascular disease, etc., are also eligible for reimbursement under the current coverage policy, provided the primary indication for treatment with EECP® therapy is angina or angina equivalent symptoms and the patient satisfies other listed criteria.

### Coverage with Other Third-Party Payers

Since the establishment of reimbursement for EECP® therapy by the federal government, an increasing number of private third-party payers have routinely provided coverage for the use of EECP® therapy for the treatment of angina and have issued positive coverage policies, which are generally similar to Medicare's coverage policy in scope. We estimate that over 300 private insurers are providing reimbursement coverage for EECP® therapy for the treatment of angina today at favorable payment levels, and we expect that the number of private insurers and their related health plans that provide for EECP® therapy as a covered benefit will continue to increase. In addition, some third-party payers began limited coverage of EECP® therapy for the treatment of CHF. On the other hand, there are private insurance carriers that continue to adjudicate EECP® treatment claims on a case-by-case basis.

We continue to pursue a constructive dialogue with many private insurers for the establishment of positive and expanded coverage policies for EECP® treatment that include CHF patients and have engaged a consulting firm to assist us in co-sponsoring a study with a major commercial healthcare third-party payer demonstrating the efficacy, efficiency, and/or cost effectiveness of EECP® therapy for NYHA Class II/III heart failure.

If there were any significant reduction in the availability of third-party private insurers or the adequacy of the reimbursement level for treatment procedures using the EECP® therapy system, it would adversely affect our business, financial condition and results of operations. Moreover, we are unable to forecast what additional legislation or regulation, if any, relating to the health care industry or third-party private insurers' coverage and payment levels may be enacted in the future or what effect such legislation or regulation would have on us.

#### Reimbursement in International Markets

The reimbursement environment for EECP® therapy in international markets is fragmented and coverage varies. Our reimbursement strategy has changed to be more proactive and create opportunities through our distribution partners. Our current efforts on behalf of EECP® therapy in both the private and public healthcare sectors of selected international markets are being initiated jointly by the company and its distributors in their designated territories. We

do not anticipate a significant impact on financial performance in the next fiscal year, given the long lead time from submission to approval of international dossiers for each reimbursement authority.

#### Other Medical Equipment

In our effort to diversify our medical equipment offering, in May 2008 we first obtained exclusive distribution rights for BIOX series ECG Holter and ambulatory blood pressure monitoring products in the North American market. The growing market for ECG Holter and ambulatory blood pressure monitoring products worldwide is expected to exceed \$150 million by 2015. While there are multiple competitors in the marketplace, we believe that due to certain special features of our products, and through our sales and marketing efforts in niche markets, we will increase sales revenue and create opportunities for other products the Company manufactures or distributes.

In April 2009 the Company received its first 510(k) clearance to begin marketing the BIOX Model 1305 3-Channel ECG Holter and CB Series Analysis Software. In April 2010, the Company received its 510(k) clearance to market its Model 2301 Combined 3-Channel ECG Holter and Ambulatory Blood Pressure Monitor, believed to be the first of its kind ever cleared by the US FDA. In June 2011, the Company received 510(k) clearances for four additional BIOX series products: Model 2302 Combined 12-Channel ECG Holter and Ambulatory Blood Pressure Monitor; Model 1804 Ambulatory Blood Pressure Monitor; Model 1304 12-Channel ECG Holter Recorder; and the Model 1303 Ultra Compact 3-Channel ECG Holter Recorder, one of the world's smallest and lightest ECG Holter recorders. The Company's BIOX product line now offers the clinician a complete and unique line of diagnostic products to meet all their ambulatory monitoring needs.

The BIOX series ECG Holter and ambulatory blood pressure monitoring products are manufactured by BIOX Instruments Co. Ltd. in Wuxi, China, under the current Good Manufacturing Practice (cGMP) requirements as set forth in the FDA Quality System Regulation as well as ISO 13485 standard, the international quality standard for medical devices. BIOX' manufacturing facility has also been certified to conform to full quality assurance system requirements of the EU Medical Device Directive and other requirements by various government authorities. These medical products have been classified by the U.S. FDA as Class II products.

In cooperation with BIOX Instruments Co. Ltd., the Company is also promoting its joint R&D and manufacturing capabilities to secure OEM opportunities in the United States, as well as pursue international sales opportunities for the product line through its global distribution channel outside of its designated North American territory.

Additionally, the Company continues to distribute a line of private label patient management products first introduced in April 2009. These products include the hand held EZ ECG<sup>TM</sup> Monitor, the EZ O2<sup>TM</sup> Adult and EZ O2<sup>TM</sup> Pediatric Pulse Oximeters, and the EZ O2<sup>TM</sup> Wrist Oximeter.

#### VasoHealthcare Business

In April 2010 we established VasoDiagnostics (d/b/a VasoHealthcare), a wholly-owned subsidiary of Vasomedical, Inc. as a professional specialized sales channel partner for the healthcare industry. On May 19, 2010 we signed our first sales representative agreement with GE Healthcare (GEHC), the healthcare business unit of GE, to sell certain GEHC diagnostic imaging products, financial services, and point of sale maintenance agreements on an exclusive basis to assigned healthcare providers in the 48 contiguous states of the United States and District of Columbia. The GEHC Agreement is for an initial term of three years commencing July 1, 2010, subject to extension and also earlier termination under certain circumstances. We report VasoHealthcare activities under our Sales Representation reportable segment.

The Company earns commissions under the GEHC Agreement based upon achieving certain calendar year targets. Our commission rate increases as targets are met, resulting in higher rates, should we meet our targets, as the year progresses. The progressive nature of our agreement can thus result in significantly higher commissions due us in our fourth and first fiscal quarters as compared to the second and third fiscal quarters.

# Sales and Marketing

We sell diagnostic imaging products to our assigned market through a nationwide team of sales employees managed by a vice president of sales and several regional managers, supported by in-house administrative support and product specialists, as well as applicable GEHC employees.

# Competition

In the U.S. diagnostic imaging market, our main competitors are Philips, Siemens, Hologic and Toshiba. Key competitive factors in the market include price, quality, delivery speed, service and support, innovation, distribution network, breadth of product and service offerings and brand name recognition. We believe GEHC is a leading competitor in this market.

#### Strategic Objectives

Our short- and long-term plans for the growth of the Company and its stockholder value are:

- a) Maintain and grow our equipment business, by
- i) Continuing to align the cost structure with revenue growth, including increased funding of marketing initiatives;
- ii) Expanding our direct sales force to significantly increase revenue, particularly from EECP® equipment and service sales; and
  - iii) Increasing our international efforts to grow international sales of all our device offerings.
    - b) Continue to diversify our product offerings, by
- i) Identifying and introducing other medical device products and opportunities that fit into our target market; and
  - ii) Working with select partners to develop our medical device OEM business.
  - c) Work with consultants to expand reimbursement coverage for EECP® therapy, by
- i) Submitting up-to-date treatment effectiveness data and cost saving evidence to CMS and third party payers for consideration of EECP® as a first line treatment option for angina and for expansion of coverage to include heart failure: and
- ii) If necessary, organizing and/or conducting clinical trials to demonstrate the cost saving benefits of EECP® therapy.
  - d) Maintain and improve business performance in our sales representation segment by expanding the GE Healthcare product modalities we represent, and possibly building new teams to represent other vendors.

The above-listed strategic objectives are forward-looking statements. We review, modify and change our strategic objectives from time to time based upon changing business conditions. There can be no assurance that we will be able to achieve our strategic objectives and, even if these results are achieved, risks and uncertainties could cause actual results to differ materially from anticipated results. Financial resource availability may reduce our ability to achieve these strategic objectives. Please see the section of this Form 10-K entitled "Risk Factors" for a description of certain risks, among others that may cause our actual results to vary from the forward-looking statements.

#### Patents and Trademarks

We own eleven US patents including eight utility and three design patents that expire at various times between now and 2023. We will from time to time file other patent applications regarding specific enhancements to the current

EECP® models, future generation products, and methods of treatment in the future. Moreover, trademarks have been registered for the names "EECP", "AngioNew", "Natural Bypass", "Vasomedical", "Vasomedical EECP" and "VasoHealthcar

We pursue a policy of seeking patent protection, both in the US and abroad, for our proprietary technology. We believe that we have a solid patent foundation in the field of external counterpulsation devices and that the number of patents and applications demonstrates our technical leadership, dating back to the mid-1980s. Our patent portfolio focuses on the areas of external counterpulsation control and the overall design and arrangement of the external counterpulsation apparatus, including the console, treatment bed, fluid distribution, and inflatable cuffs. None of our current competitors have a significant patent portfolio in the area of external counterpulsation devices.

There can be no assurance that our patents will not be violated or that any issued patents will provide protection that has commercial significance. As with any patented technology, litigation could be necessary to protect our patent position. Such litigation can be costly and time-consuming, and there can be no assurance that we will be successful. The loss or violation of our EECP® patents and trademarks could have a material adverse effect upon our business.

#### **Employees**

As of May 31, 2011, we employed 109 full-time persons. None of our employees are represented by a labor union. We believe that our employee relations are good.

The Company also uses several part-time employees and consultants from time to time for various purposes.

#### Manufacturing

Vasomedical maintains its manufacturing capacity in the Westbury, NY location to satisfy domestic and international needs for the TS4 and Lumenair EECP® systems, and contracts with Life Enhancement Technology Co. Ltd. for the manufacture of AngioNew® and Lumenair EECP® systems. Life Enhancement Technology was, until 2009, the manufacturing facility of AngioNew® systems for Living Data Technology Corp., a stockholder of Vasomedical. All EECP® systems that it makes now are exclusively for Vasomedical.

All manufacturing operations in Vasomedical and Life Enhancement Technology are conducted under the current Good Manufacturing Practice (cGMP) requirements as set forth in the FDA Quality System Regulation as well as ISO 13485 standard, the international quality standard for medical device manufacturers. We are also certified to conform to full quality assurance system requirements of the EU Medical Device Directive and can apply the CE marking to some of our products ourselves. Lastly, we are certified to comply with the requirements of the Canadian Medical Device Regulations (CMDR) and with all UL safety requirements. All these regulations and standards subject us to inspections to verify compliance and require us to maintain documentation and controls for the manufacturing and quality activities.

We believe our manufacturing capacity and warehouse facility are adequate to meet the current and immediately foreseeable future demand for the production of EECP® systems. We believe our suppliers of the other medical devices we distribute or represent are capable of meeting our demand for the foreseeable future.

## Subsequent Event

Effective August 19, 2011, the Company, through its newly formed subsidiary, Vasomedical Acquisition Corp., signed an agreement to purchase Life Enhancement Technology Limited and Biox Instruments Co., Ltd., both of which are based in the People's Republic of China.

The purchase agreement for these acquisitions provides for a cash payment at closing of \$1,000,000 and the issuance of 5,000,000 restricted shares of the Company's common stock together with two year purchase warrants to acquire an aggregate of 1,500,000 additional shares of common stock at market price, as defined, but in no event at a price less than \$.50 per share nor greater than \$1.00 per share. The sellers also have the right to acquire up to 2,400,000 additional shares of common stock entirely based on calendar 2011 financial performance.

#### ITEM 1A - RISK FACTORS

Investing in our common stock involves risk. You should carefully consider the following information about these risks together with the other information contained in this Annual Report on Form 10-K. If any of the following risks actually occur, our business could be harmed. This could cause the price of our stock to decline, and you may lose part or all of your investment.

#### Financial Risks

We have incurred recurring losses over the past few years and may continue to sustain losses.

During the last few fiscal years we incurred large operating losses, and we may continue to sustain operating losses. Our ability to achieve profitability is dependent on many factors, including the sufficient and timely generation and recognition of revenue in our Sales Representation segment, the success of our marketing and sales efforts in the Equipment segment, as well as the success of our other strategic initiatives.

#### Risks Related to Our Business

We currently derive a significant amount of our revenue from our agreement with GEHC and our continued growth is relationship dependent.

On May 19, 2010, we signed a sales representation agreement with GEHC, the healthcare business unit of the General Electric Company, for the sale of select GEHC diagnostic imaging products. Under the GEHC Agreement, we have been appointed the exclusive representative for these products to specific market segments in the 48 contiguous states of the United States and the District of Columbia. The GEHC Agreement has an initial term of three years commencing July 1, 2010, subject to extension and also subject to earlier termination under certain circumstances.

A significant amount of our fiscal 2011 revenue arose from activities under this contract. Moreover, our growth depends partially on the territories assigned to VasoHealthcare by GEHC, and thus relies on our ability to demonstrate our added value as a channel partner, and maintain a positive relationship with GEHC. We believe we have met or exceeded the contractual obligations and expectations of this agreement and have built a positive relationship with GEHC; however, there is no assurance that the agreement will be renewed before it expires. Should GEHC not renew the contract, it would have a material adverse effect on our financial condition and results of operations.

We are materially dependent on the expansion of medical reimbursement for treatment procedures using EECP® therapy in order to achieve significant growth in the domestic EECP® market.

Our domestic EECP® business is dependent on current medical reimbursement policies, which provide coverage for a restricted class of heart patients. While we continue our dialogue with CMS and commercial payers to obtain expanded coverage for EECP® therapy, there is no assurance that the Company will succeed in such efforts.

If we do not receive expanded medical coverage for the use of EECP® therapy, it will adversely affect our domestic EECP® therapy business.

Material changes in the availability of Medicare, Medicaid or third-party reimbursement at adequate price levels could adversely affect our domestic EECP® business.

Health care providers, such as hospitals and physician private practices in the U.S., that purchase or lease medical devices such as the EECP® therapy system for use on their patients generally rely on third-party payers, principally Medicare, Medicaid and private health insurance plans, to reimburse all or part of the costs and fees associated with the procedures performed with these devices. If there were any significant reduction in the availability of Medicare, Medicaid or other third-party coverage or the adequacy of the reimbursement level for treatment procedures using the EECP® therapy system, it would adversely affect our domestic EECP® business, financial condition and results of operations. Moreover, we are unable to forecast what additional legislation or regulation, if any, relating to the health care industry or Medicare or Medicaid coverage and payment level may be enacted in the future or what effect such legislation or regulation would have on our business. Even if a device has FDA clearance, Medicare, Medicaid and other third-party payers may deny reimbursement if they conclude that the device is not "reasonable and necessary" according to their criteria. In addition, reimbursement may not be at, or remain at, price levels adequate to allow medical professionals and hospitals in the U.S. to realize an appropriate return on the purchase of our products.

Increased acceptance of EECP® therapy by the medical community is important for the growth of our EECP® business.

While positive evaluations of the application of EECP® therapy continue to appear in presentations at major scientific meetings and in peer-reviewed publications each year, there is still skepticism concerning EECP® therapy methodology. The American Heart Association and the American College of Cardiology Practice Guidelines currently list EECP® as a therapy currently under investigation for treatment of heart failure and have a classification rating of IIb as a treatment for angina patients who are refractory to medical therapy and are not candidates for percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). A classification rating of IIb indicates the usefulness/efficacy of EECP® therapy is less well established by evidence/opinion. The medical community utilizes these guidelines when considering the various treatment options for their patients. Certain cardiologists, in cases where the EECP® therapy is a viable alternative, still appear to prefer percutaneous coronary interventions (e.g. balloon angioplasty and stenting) and cardiac bypass surgery for their patients. Additional evidence regarding the efficacy of EECP® therapy continues to evolve, however the evidence may not be sufficient to warrant a modification of these guidelines to a more favorable recommendation and increased acceptance by the medical community. We are dependent on consistency of favorable research findings about EECP® therapy and increasing acceptance of EECP® therapy as a safe, effective and cost effective alternative to other available products by the medical community for growth.

We face competition from other companies and technologies.

We compete with other companies that market medical devices in the global medical device marketplace. We do not know whether these companies, or other potential competitors who may be developing medical devices, may succeed in developing technologies or products that are more efficient than those offered by us, and that would render our technology and existing products obsolete or non-competitive. Potential new competitors may also have substantially greater financial, manufacturing and marketing resources than those possessed by us. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended purpose of our products. Accordingly, the life cycles of our products are difficult to estimate. To compete successfully, we must keep pace with technological advancements, respond to evolving consumer requirements and achieve market acceptance.

We may not continue to receive necessary FDA clearances or approvals, which could hinder our ability to market and sell our products.

If we modify our medical devices and the modifications significantly affect safety or effectiveness, or if we make a change to the intended use, we will be required to submit a new premarket notification, or 510(k), to FDA. We would not be able to market the modified device in the U.S. until FDA issues a clearance for the 510(k).

Additionally, if FDA publishes a regulation requiring a premarket approval (PMA) application for the medical devices we market, we would then need to submit a PMA, and have it filed with the agency, by the date specified by FDA in its regulation. A PMA requires us to prove the safety and effectiveness of a device to the FDA. The process of obtaining PMA approval may require a clinical study and is expensive, time-consuming, and uncertain. If we did obtain PMA approval, any change after approval affecting the safety or effectiveness of the device will require approval of a PMA supplement.

If we offer new products that require 510(k) clearance or PMA approval, we will not be able to commercially distribute those products until we receive such clearance or approval. Regulatory agency approval or clearance for a product may not be received or may entail limitations on the device's indications for use that could limit the potential market for the product. Delays in receipt of, or failure to obtain or maintain, regulatory clearances and approvals, could delay or prevent our ability to market or distribute our products. Such delays could have a material adverse effect on our equipment business.

If we are unable to comply with applicable governmental regulations, we may not be able to continue our operations.

We also must comply with current Good Manufacturing Practice (cGMP) requirements as set forth in the Quality System Regulation (QSR) to receive FDA approval to market new products and to continue to market current products. The QSR imposes certain procedural and documentation requirements on us with respect to manufacturing and quality assurance activities, including packaging, storage, and record keeping. Our products and activities are subject to extensive, ongoing regulation, including regulation of labeling and promotion activities and adverse event reporting. Also, our FDA registered facilities are subject to inspection by the FDA and other governmental authorities. Any failure to comply with regulatory requirements could delay or prevent our ability to market or distribute our products. Violation of FDA statutory or regulatory requirements could result in enforcement actions, such as voluntary or mandatory recalls, suspension or withdrawal of marketing clearances or approvals, seizures, injunctions, fines, civil penalties, and criminal prosecutions, all of which could have a material adverse effect on our business. Most states also have similar post-market regulatory and enforcement authority for devices.

As a sales channel partner, we are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws.

We cannot predict the nature of any future laws, regulations, interpretations, or applications, nor can we predict what effect additional governmental regulations or administrative orders, when and if promulgated, would have on our business in the future. We may be slow to adapt, or we may never adapt to changes in existing requirements or adoption of new requirements or policies. We may incur significant costs to comply with laws and regulations in the future or compliance with laws or regulations may create an unsustainable burden on our business.

We may not receive approvals by foreign regulators that are necessary for international sales.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary from country to country. Premarket approval or clearance in the United States does not ensure regulatory approval by other jurisdictions. If we, or any international distributors, fail to obtain or maintain required pre-market approvals or fail to comply with foreign regulations, foreign regulatory authorities may require us to file revised governmental notifications, cease commercial sales of our products in the applicable countries or otherwise cure the problem. Such enforcement action by regulatory authorities may be costly.

In order to sell our products within the European Union, we must comply with the European Union's Medical Device Directive. The CE marking on our products attests to this compliance. Future regulatory changes may limit our ability to use the CE mark, and any new products we develop may not qualify for the CE mark. If we lose this authorization or fail to obtain authorization on future products, we will not be able to sell our products in the European Union.

We depend on suppliers for the supply of certain products.

We depend on suppliers for parts, components and certain finished goods. While we do not foresee any difficulties in timely receiving products at competitive prices, the inability of not receiving products in timely fashion or at competitive prices would adversely affect our business. In addition, as a GEHC channel partner, we could be negatively impacted by interruptions or delays to equipment installations, production and quality issues, and other customer concerns related to GEHC.

We depend on management and other key personnel.

We are dependent on a limited number of key management and technical personnel. The loss of one or more of our key employees may harm our business if we are unable to identify other individuals to provide us with similar services. We do not maintain "key person" insurance on any of our employees. In addition, our success depends upon

our ability to attract and retain additional highly qualified sales, management, manufacturing and research and development personnel. We face competition in our recruiting activities and may not be able to attract or retain qualified personnel.

We may not have adequate intellectual property protection.

Our patents and proprietary technology may not be able to prevent competition by others. The validity and breadth of claims in medical technology patents involve complex legal and factual questions. Future patent applications may not be issued, the scope of any patent protection may not exclude competitors, and our patents may not provide competitive advantages to us. Our patents may be found to be invalid and other companies may claim rights in or ownership of the patents and other proprietary rights held or licensed by us. Also, our existing patents may not cover products that we develop in the future. Moreover, when our patents expire, the inventions will enter the public domain. There can be no assurance that our patents will not be violated or that any issued patents will provide protection that has commercial significance. Litigation may be necessary to protect our patent position. Such litigation may be costly and time-consuming, and there can be no assurance that we will be successful in such litigation.

The loss or violation of certain of our patents and trademarks could have a material adverse effect upon our business.

Since patent applications in the United States are maintained in secrecy until such patent applications are issued, our current product development may infringe patents that may be issued to others. If our products were found to infringe patents held by competitors, we may have to modify our products to avoid infringement, and it is possible that our modified products would not be commercially successful.

We do not intend to pay dividends in the foreseeable future.

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

Risks Related to Our Industry

Our growth could suffer if the markets into which we sell products decline, do not grow as anticipated or experience cyclicality.

Our growth depends in part on the growth of the healthcare markets which we serve. Our quarterly sales and profits depend substantially on the volume and timing of orders installed during the fiscal quarter, and the installation of such orders is difficult to forecast. Product demand is dependent upon the customer's capital spending budget as well as government funding policies, and matters of public policy as well as product and economic cycles that can affect the spending decisions of these entities. These factors could adversely affect our growth, financial position, and results of operations.

Technological change is difficult to predict and to manage.

We face the challenges that are typically faced by companies in the medical device field. Our product line has required, and any future products will require, substantial development efforts and compliance with governmental clearance or approval requirements. We may encounter unforeseen technological or scientific problems that force abandonment or substantial change in the development of a specific product or process.

We are subject to product liability claims and product recalls that may not be covered by insurance.

The nature of our business exposes us to risks of product liability claims and product recalls. Medical devices as complex as ours frequently experience errors or failures, especially when first introduced or when new versions are released.

We currently maintain product liability insurance at \$5,000,000 per occurrence and \$6,000,000 in the aggregate. Our product liability insurance may not be adequate. In the future, insurance coverage may not be available on commercially reasonable terms, or at all. In addition, product liability claims or product recalls could damage our reputation even if we have adequate insurance coverage.

We do not know the effects of healthcare reform proposals.

The healthcare industry is undergoing fundamental changes resulting from political, economic and regulatory influences. In the United States, comprehensive programs have been suggested seeking to increase access to healthcare for the uninsured, control the escalation of healthcare expenditures within the economy and use healthcare reimbursement policies to balance the federal budget.

We expect that the United States Congress and state legislatures will continue to review and assess various healthcare reform proposals, and public debate of these issues will likely continue. There have been, and we expect that there will continue to be, a number of federal and state proposals to constrain expenditures for medical products and services, which may affect payments for products such as ours. We cannot predict which, if any of such reform proposals will be adopted and when they might be effective, or the effect these proposals may have on our business. Other countries also are considering health reform. Significant changes in healthcare systems could have a substantial impact on the manner in which we conduct our business and could require us to revise our strategies.

#### Risks Related to our Securities

The application of the "penny stock" rules could adversely affect the market price of our common stock and increase your transaction costs to sell those shares.

As long as the trading price of our common shares is below \$5 per share, the open-market trading of our common shares will be subject to the "penny stock" rules. The "penny stock" rules impose additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 together with their spouse). For transactions covered by these rules, the broker-dealer must make a special suitability determination for the purchase of securities and have received the purchaser's written consent to the transaction before the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the broker-dealer must deliver, before the transaction, a disclosure schedule prescribed by the Securities and Exchange Commission relating to the penny stock market. The broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. These additional burdens imposed on broker-dealers may restrict the ability or decrease the willingness of broker-dealers to sell our common shares, and may result in decreased liquidity for our common shares and increased transaction costs for sales and purchases of our common shares as compared to other securities.

Our common stock is subject to price volatility.

The market price of our common stock historically has been and may continue to be highly volatile. Our stock price could be subject to wide fluctuations in response to various factors beyond our control, including, but not limited to:

- medical reimbursement;
- quarterly variations in operating results;
- announcements of technological innovations, new products or pricing by our competitors;
- the rate of adoption by physicians of our technology and products in targeted markets;
  - the timing of patent and regulatory approvals;
  - the timing and extent of technological advancements;
    - results of clinical studies;
- the sales of our common stock by affiliates or other shareholders with large holdings; and
  - general market conditions.

Our future operating results may fall below the expectations of securities industry analysts or investors. Any such shortfall could result in a significant decline in the market price of our common stock. In addition, the stock market has experienced significant price and volume fluctuations that have affected the market price of the stock of many medical device companies and that often have been unrelated to the operating performance of such companies. These broad market fluctuations may directly influence the market price of our common stock.

#### **Additional Information**

We are subject to the reporting requirements under the Securities Exchange Act of 1934 and are required to file reports and information with the Securities and Exchange Commission (SEC), including reports on the following forms: annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports files or furnished pursuant to Section 13(a) or 15(d) of the Securities Act of 1934.

#### ITEM 2 – PROPERTIES

We owned our 18,000 square foot headquarters and manufacturing facility at 180 Linden Avenue, Westbury, New York 11590, until August 15, 2007 when we sold it under a five-year leaseback agreement for \$1.4 million. The net proceeds from the sale was approximately \$425,000, after payment in full of the two secured notes on our facility, brokers fees, closing costs, and the opening of a certificate of deposit in accordance with the provisions of the new lease. The annual rental expense for the lease is approximately \$150,000. We believe that this facility, which houses our Equipment segment and corporate headquarters, is adequate to meet our current needs and should continue to be adequate for the immediately foreseeable future.

Our Sales Representation segment operates from a facility in Greensboro, North Carolina, where we lease 2,600 square feet of office space at an annual rental expense of approximately \$48,000.

#### ITEM 3 – LEGAL PROCEEDINGS

There were no material legal proceedings.

#### **PART II**

# ITEM 5 – MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock currently trades on OTCQB, the middle tier of the OTC marketplace reserved for fully reporting issuers, under the symbol VASO.PK. On May 26, 2006, our common stock ceased trading on the NASDAQ Capital Market tier of the NASDAQ Stock Market and began trading on the NASD Pink Sheets. Effective June 20, 2006, our common stock began trading on the Over-the-Counter Bulletin Board (OTCBB). On February 22, 2011, our common stock was delisted from OTCBB and was quoted solely on OTC Link. The number of record holders of common stock as of August 22, 2011, was approximately 1,000, which does not include approximately 11,000 beneficial owners of shares held in the name of brokers or other nominees. The table below sets forth the range of high and low trade prices of the common stock for the fiscal periods specified.

	Fiscal 2011		Fiscal 2010	1
	High	Low	High	Low
First quarter	\$0.24	\$0.18	\$0.09	\$0.07
Second quarter	\$0.21	\$0.18	\$0.09	\$0.06
Third quarter	\$0.31	\$0.18	\$0.08	\$0.05
Fourth quarter	\$0.74	\$0.34	\$0.31	\$0.05

The last bid price of the Company's common stock on August 22, 2011, was \$0.31 per share.

# **Dividend Policy**

We have never paid any cash dividends on our common stock and do not intend to pay cash dividends in the foreseeable future.

# ITEM 7 –MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

This Management's Discussion and Analysis of Financial Condition and Results of Operations contains descriptions of our expectations regarding future trends affecting our business. These forward looking statements and other forward-looking statements made elsewhere in this document are made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Please read the section titled "Risk Factors" in "Item One – Business" to review certain conditions, among others, which we believe could cause results to differ materially from those contemplated by the forward-looking statements.

Except for historical information contained in this report, the matters discussed are forward-looking statements that involve risks and uncertainties. When used in this report, words such as "anticipates", "believes", "could", "estimates" "expects", "may", "plans", "potential", "intends", and similar expressions, as they relate to the Company or its management identify forward-looking statements. Such forward-looking statements are based on the beliefs of the Company's management, as well as assumptions made by and information currently available to the Company's management. Among the factors that could cause actual results to differ materially are the following: the effect of business and economic conditions; the effect of the dramatic changes taking place in the healthcare environment; the impact of competitive procedures and products and their pricing; medical insurance reimbursement policies; unexpected manufacturing or supplier problems; unforeseen difficulties and delays in the conduct of clinical trials and other product development programs; the actions of regulatory authorities and third-party payers in the United States and overseas; uncertainties about the acceptance of a novel therapeutic modality by the medical community; continuation of the GEHC agreement; and the risk factors reported from time to time in the Company's SEC reports. The Company undertakes no obligation to update forward-looking statements as a result of future events or developments.

The following discussion should be read in conjunction with the financial statements and notes thereto included in this Annual Report on Form 10-K.

#### Overview

Vasomedical, Inc. was incorporated in Delaware in July 1987. Unless the context requires otherwise, all references to "we", "our", "us", "Company", "registrant", "Vasomedical" or "management" refer to Vasomedical, Inc. and its subsidiaries 1995, we have been primarily engaged in designing, manufacturing, marketing and supporting EECP® Enhanced External Counterpulsation systems based on our unique proprietary technology currently indicated by the United States Food & Drug Administration (FDA) for use in cases of stable or unstable angina, congestive heart failure (CHF), acute myocardial infarction (i.e., heart attack, (MI)) and cardiogenic shock. In April 2010, the Company, through its wholly-owned subsidiary Vaso Diagnostics d/b/a VasoHealthcare, organized a group of medical device sales professionals in the anticipation of entering into the sales representation business for other equipment manufacturers. On May 19, 2010, VasoHealthcare signed a sales representative agreement with GE Healthcare (the "GEHC Agreement"), the healthcare business unit of General Electric Company (NYSE: GE), for the sale of select GE Healthcare Diagnostic Imaging products. Under the GEHC Agreement, VasoHealthcare has been appointed the exclusive representative for these products to specific market segments in the 48 contiguous states of the United States and the District of Columbia. The GEHC Agreement has an initial term of three years commencing July 1, 2010, subject to extension and also subject to earlier termination under certain circumstances. We now report VasoHealthcare activities under our Sales Representation reportable segment and EECP® and other medical device

operations under our Equipment reportable segment (see Note C).

During the last several years, the Company has incurred operating losses. We have sought to achieve profitability by launching the VasoHealthcare business, and by expanding our U.S. market product portfolio to include ambulatory monitoring devices (the BIOX series ECG Holter recorders, ambulatory blood pressure monitors and analysis software) and patient management devices (the EZ ECG and EZ O2 products). We also are looking for accretive acquisitions in the medical device market.

In fiscal 2011, the Company's aggregate revenues increased from \$4,205,942 to \$16,373,424 oe 289% from. the prior fiscal year. While the Company incurred operating losses due in large part to the revenue recognition rules associated with its VasoHealthcare business, it generated significant operating cash flows in excess of \$4.1 million.

Results of Operations – Fiscal Years Ended May 31, 2011 and 2010

Net revenues increased by \$12,167,482, or 289%, to \$16,373,424 in fiscal 2011, from \$4,205,942 in fiscal 2010. We reported a net loss applicable to common stockholders of \$4,319,132 in fiscal 2011 as compared to \$1,892,073 in fiscal 2010. Our total net loss was \$0.04 and \$0.02 per basic and diluted common share for the years ended May 31, 2011 and 2010, respectively.

#### Revenues

Revenue in our Equipment segment increased 25% to \$5,260,291 for the fiscal year ended May 31, 2011 from \$4,205,942 for the fiscal year ended May 31, 2010. Equipment segment revenue from equipment sales increased approximately 43% to \$3,029,177 for fiscal 2011 as compared to \$2,119,270 for fiscal 2010. The increase in equipment sales is due primarily to a 55% increase in the number of EECP® units sold internationally, as well as a 33% increase in domestic EECP® units shipped. In addition, revenue from other medical equipment increased 363% in fiscal year 2011 as compared to the prior fiscal year.

Average selling prices for EECP equipment were slightly higher in fiscal 2011. We anticipate that demand for EECP® systems would remain soft domestically unless there is greater clinical acceptance for the use of EECP® therapy in treating patients with angina or angina equivalent symptoms who meet the current reimbursement guidelines, or a favorable change in current reimbursement policies by CMS or third party payors to consider EECP therapy as a first-line treatment option for angina or cover some or all Class II & III heart failure patients. Patients with angina or angina equivalent symptoms eligible for reimbursement under current policies include many with serious comorbidities, such as heart failure, diabetes, peripheral vascular disease and/or others.

Equipment segment revenue from equipment rental and services increased 7% to \$2,231,114 in fiscal 2011 from \$2,086,672 in fiscal year 2010. Revenue from equipment rental and services represented 42% of total Equipment segment revenue in fiscal 2011 and 50% in fiscal 2010. The increase in revenue generated from equipment rentals and services is due primarily to increased on-demand service and equipment rental revenues.

Commission revenues in the Sales Representation segment were \$11,113,133 in fiscal 2011. No revenues were recorded in fiscal 2010 as the GEHC contract had not yet begun. As discussed in Note B, the Company defers recognition of commission revenue until underlying equipment acceptance is complete. As of May 31, 2011, \$10,805,767 in deferred commission revenue was recorded in the Company's consolidated condensed balance sheet, of which \$756,404 is long-term.

#### **Gross Profit**

The Company recorded gross profit of \$10,912,852, or 67% of revenue, in fiscal 2011 compared to \$2,211,512, or 53% of revenue, in fiscal 2010. The increase of \$8,701,340 was due primarily to both higher gross profit rates and higher absolute dollars in the Sales Representation segment.

Equipment segment gross profit increased to \$2,413,344, or 46% of Equipment segment revenues, for fiscal 2011 compared to \$2,211,512, or 53% of Equipment segment revenues, for fiscal 2010 due mainly to higher sales volume. The increase in absolute dollars was partially offset by a decrease in gross profit percentage, which arose primarily from higher manufacturing overhead costs, including personnel and transportation charges. Equipment segment gross profits are dependent on a number of factors, particularly the mix of new and refurbished EECP® systems and the mix

of models sold, their respective average selling prices, the ongoing costs of servicing EECP® systems, and certain fixed period costs, including facilities, payroll and insurance.

Sales Representation segment gross profit was \$8,499,508 for fiscal 2011. Cost of commissions of \$2,613,625 reflects commission expense associated with recognized commission revenues. Commission expense associated with deferred revenue is recorded as deferred commission expense until the related commission revenue is earned.

#### **Operating Loss**

Operating loss was \$3,932,638 for fiscal 2011 as compared to an operating loss of \$1,979,860 for fiscal 2010. The increase in the operating loss was primarily attributable to an operating loss of \$2,961,788 in our Sales Representation segment for fiscal 2011, as compared to an operating loss of \$1,056,982 for fiscal 2010 in that segment. The increased segment loss reflects additional start-up costs and the deferral of commission revenue and expense in fiscal 2011. Equipment segment operating loss in fiscal 2011 was \$525,200, including \$309,054 in share-based expenses, as compared to an operating loss of \$489,532, including \$55,224 in share-based expenses, in fiscal 2010.

Selling, general and administrative ("SG&A") expenses for fiscal 2011 and 2010 were \$14,383,380, or 88% of revenues, and \$3,772,569, or 90% of revenues, respectively, reflecting an increase of \$10,610,811 or approximately 281%. The increase in SG&A expenditures in fiscal 2011 resulted primarily from increased wages, benefits, commissions, and insurance expenses related to the Sales Representation segment, which began operations in the last two months of fiscal 2010 and ramped up in early fiscal 2011.

During fiscal 2011, the Company recorded a provision for doubtful accounts and commission adjustments of \$1,149,986 as compared to fiscal year 2010 when the Company recorded a provision for doubtful accounts and commission adjustments of \$71,277. Of the fiscal 2011 provision, \$1,132 was to reverse the accrual for bad debt expense, \$58,200 were direct write-offs, net of recovery, and \$1,209,318 was to reduce gross deferred revenues for estimated adjustments.

Research and development ("R&D") expenses of \$462,110, or 3% of revenues, for fiscal 2011 increased by \$43,307, or 10%, from \$418,803, or 10% of revenues, for fiscal 2010. The increase is primarily attributable to an increase in product development expenses.

#### **Interest and Financing Costs**

Interest and financing costs for fiscal 2011 was \$32,220 compared to \$5,383 in fiscal 2010. Interest and financing costs consisted of interest on a short-term note to finance the Company's insurance premiums and interest charged on trade payable to related party.

#### Interest and Other Income, Net

Interest and other income for fiscal 2011 and 2010, were \$27,839 and \$79,871, respectively. In fiscal year 2010 other income primarily consisted of a cash settlement of a lawsuit against one of the Company's competitors. Interest income reflects interest earned on the Company's cash balances and financing receivables.

#### Amortization of Deferred Gain on Sale-leaseback of Building

The amortization of deferred gain on sale-leaseback of building for fiscal years 2011 and 2010 was \$53,245. The gain resulted from the Company's sale-leaseback of its facility.

#### Income Tax Benefit/(Expense), Net

During fiscal year 2011, we recorded income tax expense of \$6,755 compared to fiscal year 2010, when the Company recorded an income tax benefit of \$35,952. The fiscal 2010 income tax benefit was primarily a research and development credit associated with the federal stimulus package of 2009.

Ultimate realization of any or all of the deferred tax assets is not assured due to significant uncertainties and material assumptions associated with estimates of future taxable income during the carry-forward period. In the future, such

assessments may change due to the introduction of the distribution and representation business of VasoHealthcare.

#### Liquidity and Capital Resources

#### Cash and Cash Flow

We have financed our operations primarily from working capital, and the issuance of the Company's Series E Preferred Stock. At May 31, 2011, we had cash and cash equivalents of \$8,130,031, short-term investments of \$109,709 and working capital of \$2,836,509 compared to cash and cash equivalents of \$481,679, short-term investments of \$68,850 and working capital of \$1,262,422 at May 31, 2010.

Cash provided by operating activities was \$4,139,840 during fiscal year 2011, which consisted of a net loss after adjustments to reconcile net loss to net cash of \$1,924,066, and cash provided by operating assets and liabilities of \$6,063,906. The changes in the account balances primarily reflect increases in accrued commissions of \$1,934,662, and deferred revenue of \$10,894,867, partially offset by an increase in deferred commission expense of \$2,532,048 and accounts and other receivables of \$4,694,680. These changes in account balances are due mainly to the operations of our Sales Representation segment. Net trade receivables for our Equipment Segment were 18% of revenues for fiscal 2011, as compared to 10% of revenues for fiscal 2010. Trade receivables turnover for our Equipment Segment was 5.71 times for fiscal 2011 as compared to 5.57 times for fiscal 2010. As discussed in Note B, the Company defers recognition of commission revenue until underlying equipment acceptance is complete.

Standard payment terms on our domestic equipment sales are generally net 30 to 90 days from shipment and do not contain "right of return" provisions. We have historically offered a variety of extended payment terms, including sales-type leases, in certain situations and to certain customers in order to expand the market for our EECP® products in the US and internationally. Such extended payment terms were offered in lieu of price concessions, in competitive situations, when opening new markets or geographies and for repeat customers. Extended payment terms cover a variety of negotiated terms, including payment in full - net 120, net 180 days or some fixed or variable monthly payment amount for a six to twelve month period followed by a balloon payment, if applicable. During fiscal 2011 and 2010, there were no revenues generated from sales in which initial payment terms were greater than 90 days. During fiscal year 2011 one sales-type lease with a period of three years generated \$42,000 in Equipment Segment revenue and \$2,958 in interest income. There were no sales-type leases offered during fiscal year 2010. In general, reserves are calculated on a formula basis considering factors such as the aging of the receivables, time past due, and the customer's credit history and their current financial status. In most instances where reserves are required, or accounts are ultimately written-off, customers have been unable to successfully implement their EECP® program. As we are creating a new market for the EECP® therapy and recognizing the challenges that some customers may encounter, we have opted, at times, on a customer-by-customer basis, to recover our equipment instead of pursuing other legal remedies, which has resulted in our recording of a reserve or a write-off.

Investing activities during fiscal 2011 used cash of \$175,097 for purchases of property and equipment and investment in a certificate of deposit.

Financing activities during fiscal 2011 provided cash of \$3,683,609 consisting of net proceeds from issuance of preferred stock. Notes payable of \$250,000 were issued and subsequently repaid during fiscal 2011.

#### Liquidity

During the last several years, the Company has incurred operating losses. We have sought to achieve profitability by launching the VasoHealthcare business, and by expanding our U.S. market product portfolio to include ambulatory monitoring devices (the BIOX series ECG Holter recorders, ambulatory blood pressure monitors and analysis software) and patient management devices (the EZ ECG and EZ O2 products).

In fiscal 2011, the Company issued Series E convertible preferred stock (see Note N) to finance the initial operation of its Sales Representation segment and ultimately generated in excess of \$4.1 in operating cash flow by fiscal year end. While we expect to continue to generate significant operating cash flows in fiscal 2012, as described in Section 1A "Risk Factors", the progressive nature of the GEHC Agreement can cause related cash inflows to vary widely during the fiscal year.

In addition, under the terms of our agreement with GEHC, we are entitled to commissions on certain undelivered sales orders received by GEHC prior to our agreement and transferred to us from GEHC as of September 30, 2010. These transferred orders, though subject to various risks including potential cancellation and changes in credit worthiness and availability, as well as the Company's continued compliance under the GEHC Agreement, generated commission revenue of \$2.4 million from October 2010 to May 2011, and are expected to generate additional commission revenues estimated to range from \$3.4 million to \$4.3 million over approximately one or more years.

Based on our current operations through May 31, 2011, we believe internally generated funds from our Equipment and Sales Representation segments will be sufficient for the Company to continue operations through at least June 1, 2012.

#### Off-Balance Sheet Arrangements

We do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities (SPES), which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of May 31, 2011, we are not involved in any unconsolidated SPES.

## **Related Party Transactions**

On June 21, 2007, we entered into a Securities Purchase Agreement with Kerns Manufacturing Corp. ("Kerns"). Concurrently with our entry into the Securities Purchase Agreement, we also entered into a Distribution Agreement and a Supplier Agreement with Living Data Technology Corporation ("Living Data"), an affiliate of Kerns.

Pursuant to the Distribution Agreement, as amended, we have become the exclusive worldwide distributor of the AngioNew EECP® systems manufactured by Living Data. As additional consideration for such agreement, we agreed to issue a total of 9,990,840 shares of our common stock to Living Data. The Distribution Agreement has an initial term extending through May 31, 2012.

Pursuant to the Supplier Agreement, Living Data became our exclusive supplier of the external counterpulsation therapy systems that we market under the registered trademark EECP®. On February 28, 2010, the Supplier Agreement was terminated and, in connection with the termination, the Company purchased Living Data's remaining inventory at cost (\$469,450), which was paid in 7,824,167 shares of common stock valued at the closing price on the termination date. Prior to termination, the Company purchased in fiscal 2010 additional EECP® therapy systems for \$40,000 from Living Data. Payment terms on certain purchases prior to 2010, plus \$2,260 in commissions for sales of certain BIOX products, leave a balance of \$265,863 and \$240,000 in Trade Payable to Related Party on the accompanying consolidated condensed balance sheets as of May 31, 2011 and May 31, 2010, respectively. The payable balance due Living Data was satisfied through a cash payment in August 2011.

On February 28, 2011, David Lieberman and Edgar Rios were appointed by the Board of Directors as directors of the Company. Mr. Lieberman, a practicing attorney in the State of New York for in excess of 35 years specializing in corporation and securities law, was appointed to serve as the Vice Chairman of the Board. He is currently a senior partner at the law firm of Beckman, Lieberman & Barandes, LLP, which firm performs certain legal services for the Company. Mr. Rios currently is President of Edgary Consultants, LLC, and was appointed in conjunction with the Company's consulting agreement with Edgary Consultants, LLC.

The consulting agreement (the "Agreement") between Vasomedical, Inc. and Edgary Consultants, LLC ("Consultant") commenced on March 1, 2011 and terminates on February 28, 2013. The Agreement provides for the engagement of Consultant to assist the Company in seeking broader reimbursement coverage of EECP® therapy. More specifically, Consultant will be assisting the Company in the following areas:

- 1. Engaging the adoption of EECP® therapy as a first line option for FDA cleared indications as it relates to CCS Class III/IV angina with a major commercial healthcare third-party payer.
- 2. Engaging a major commercial healthcare payer to formally collaborate and co-sponsor a study with Vasomedical for the efficacy, efficiency and/or cost effectiveness of the EECP® therapy for NYHA Class II/III heart failure.
  - 3. Engaging final approval from the Centers for Medicare and Medicaid Services ("CMS") of EECP® therapy as a first line treatment for CCS Class III/IV angina.
- 4. Engaging final approval from CMS to extend coverage and provide for the reimbursement of EECP® therapy for CCS Class II angina; and
- 5. Engaging final approval from CMS to extend coverage and provide for the reimbursement of EECP® therapy for NYHA Class II/III heart failure.

In consideration for the services to be provided by Consultant under the Agreement, the Company has agreed to issue to Consultant or its designees, approximately 10% of the outstanding capital stock of the Company, of which the substantial portion (in excess of 82%) is performance based as referenced above. In conjunction with the Agreement, 3,000,000 shares of restricted common stock valued at \$1,020,000 were issued in March 2011. In connection with this Agreement, Mr. Lieberman received 600,000 of these restricted shares. The Company has recorded the fair value of the shares issued to Consultant as a prepaid expense and is amortizing the cost ratably over the two year agreement. The unamortized value is reported as Due from Related Party in our accompanying consolidated balance sheet as of May 31, 2011.

During fiscal 2011 the Company sold, or issued as dividends, 246,870 shares of Series E Preferred Stock (see Note N) to directors, management, and other related parties of the Company.

#### Effects of Inflation

We believe that inflation and changing prices over the past two years have not had a significant impact on our revenue or on our results of operations.

#### Critical Accounting Policies and Estimates

Note B of the Notes to Consolidated Financial Statements includes a summary of our significant accounting policies and methods used in the preparation of our financial statements. In preparing these financial statements, we have made our best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. Our critical accounting policies are as follows:

#### Revenue Recognition

The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred or service has been rendered, the price is fixed or determinable and collectability is reasonably assured. In the United States, we recognize revenue from the sale of our EECP® systems in the period in which we deliver the system to the customer. Revenue from the sale of our EECP® systems to international markets is recognized upon shipment of the product to a common carrier, as are supplies, accessories and spare parts delivered to both domestic and international customers. Returns are accepted prior to the in-service and training subject to a 10% restocking charge or for normal warranty matters, and we are not obligated for post-sale upgrades to these systems. In addition, we use the installment method to record revenue based on cash receipts in situations where the account receivable is collected over an extended period of time and in our judgment the degree of collectability is uncertain.

In most cases, revenue from domestic EECP® system sales is generated from multiple-element arrangements that require judgment in the areas of customer acceptance, collectability, the separability of units of accounting, and the fair value of individual elements. We follow the FASB Accounting Standards Codification ("ASC") Topic 605 "Revenue Recognized" ("ASC 605") which outlines a framework for recognizing revenue from multi-deliverable arrangements. The principles and guidance outlined in ASC 605 provide a framework to determine (a) how the arrangement consideration should be measured (b) whether the arrangement should be divided into separate units of accounting, and (c) how the arrangement consideration should be allocated among the separate units of accounting. We determined that the domestic sale of our EECP® systems includes a combination of three elements that qualify as separate units of accounting:

#### • EECP® equipment sale;

- provision of in-service and training support consisting of equipment set-up and training provided at the customer's facilities; and
- a service arrangement (usually one year), consisting of: service by factory-trained service representatives, material and labor costs, emergency and remedial service visits, software upgrades, technical phone support and preferred response times.

Each of these elements represent individual units of accounting as the delivered item has value to a customer on a stand-alone basis, objective and reliable evidence of fair value exists for undelivered items, and arrangements normally do not contain a general right of return relative to the delivered item. We determine fair value based on the price of the deliverable when it is sold separately, or based on third-party evidence, or based on estimated selling price. Assuming all other criteria for revenue recognition have been met, we recognize revenue for:

- EECP® equipment sales, when delivery and acceptance occurs based on delivery and acceptance documentation received from independent shipping companies or customers;
  - in-service and training, following documented completion of the training; and
  - service arrangement, ratably over the service period, which is generally one year.

In-service and training generally occurs within a few weeks of shipment and our return policy states that no returns will be accepted after in-service and training has been completed. The amount related to in-service and training is recognized as service revenue at the time the in-service and training is completed and the amount related to service arrangements is recognized ratably as service revenue over the related service period, which is generally one year. Costs associated with the provision of in-service and training and the service arrangement, including salaries, benefits, travel, spare parts and equipment, are recognized in cost of equipment sales as incurred.

The Company also recognizes revenue generated from servicing EECP® systems that are no longer covered by the service arrangement, or by providing sites with additional training, in the period that these services are provided. Revenue related to future commitments under separately priced extended service agreements on our EECP® system are deferred and recognized ratably over the service period, generally ranging from one year to four years. Costs associated with the provision of service and maintenance, including salaries, benefits, travel and spare parts, and equipment, are recognized in cost of sales as incurred. Amounts billed in excess of revenue recognized are included as deferred revenue in the consolidated balance sheets.

Revenues from the sale of EECP® systems through our international distributor network are generally covered by a one-year warranty period. For these customers we accrue a warranty reserve for estimated costs to provide warranty parts when the equipment sale is recognized.

#### Revenue and Expense Recognition for VasoHealthcare

The Company recognizes commission revenue in its Sales Representation segment when persuasive evidence of an arrangement exists, service has been rendered, the price is fixed or determinable and collectability is reasonably assured. These conditions are deemed to be met when the underlying equipment has been accepted at the customer site in accordance with the specific terms of the sales agreement. Consequently, amounts billable under the agreement with GE Healthcare in advance of the customer acceptance of the equipment are recorded as accounts receivable and deferred revenue in the consolidated condensed balance sheet. Similarly, commissions payable to our sales force related to such billings are recorded as deferred commission expense when the associated deferred revenue is recorded. Commission expense is recognized when the corresponding commission revenue is recognized.

#### Accounts Receivable, net

The Company's accounts receivable are due from customers engaged in the provision of medical services and from GEHC. Credit is extended based on evaluation of a customer's financial condition and, generally, collateral is not required. Accounts receivable are generally due 30 to 90 days from shipment and are stated at amounts due from customers net of allowances for doubtful accounts, returns, term discounts and commission adjustments. Accounts that remain outstanding longer than the contractual payment terms are considered past due. Estimates are used in determining the allowance for doubtful accounts based on the Company's historical collections experience, current trends, credit policy and a percentage of its accounts receivable by aging category. In determining these percentages, we look at historical write-offs of our receivables. The Company also looks at the credit quality of their customer base as well as changes in their credit policies. The Company continuously monitors collections and payments from our customers, and writes off receivables when all efforts at collection have been exhausted. While credit losses have historically been within expectations and the provisions established, the Company cannot guarantee that it will continue to experience the same credit loss rates that they have in the past.

## Inventories, net

The Company values inventory at the lower of cost or estimated market, with cost being determined on a first-in, first-out basis. The Company often places EECP® systems at various field locations for demonstration, training, evaluation, and other similar purposes at no charge. The cost of these EECP® systems is transferred to property and equipment and is amortized over the next two to five years. The Company records the cost of refurbished components of EECP® systems and critical components at cost plus the cost of refurbishment. The Company regularly reviews inventory quantities on hand, particularly raw materials and components, and records a provision for excess and obsolete inventory based primarily on existing and anticipated design and engineering changes to its products as well as forecasts of future product demand.

We comply with the provisions of ASC Topic 330, "Inventory". The statement clarifies that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage) should be recognized as current-period charges and requires the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities.

#### **Deferred Revenues**

The Company records revenue on extended service contracts ratably over the term of the related contract period. In accordance with the provisions of ASC Topic 605, we defer revenue related to EECP® system sales for the fair value of installation and in-service training to the period when the services are rendered and for warranty obligations ratably over the service period, which is generally one year.

Amounts billable under the agreement with GE Healthcare in advance of customer acceptance of the equipment are recorded initially as deferred revenue, and commission revenue is subsequently recognized as customer acceptance of such equipment is reported to us by GEHC.

#### Warranty Costs

Equipment sold is generally covered by a warranty period of one year. Under the provisions of ASC Topic 605, for certain arrangements, a portion of the overall system price attributable to the first year service arrangement is deferred and recognized as revenue over the service period. As such, we do not accrue warranty costs upon delivery but rather we recognize warranty and related service costs as incurred.

Equipment sold to international customers through our distributor network is generally covered by a one-year warranty period. For these customers the Company accrues an allowance for estimated warranty costs of providing a parts only warranty when the equipment sale is recognized.

The factors affecting our warranty liability included the number of units sold and historical and anticipated rates of claims and costs per claim.

#### Net Loss per Common Share

Basic loss per share is based on the weighted average number of common shares outstanding without consideration of potential common stock. Diluted loss per share is based on the weighted number of common and potential dilutive common shares outstanding. The calculation takes into account the shares that may be issued upon the exercise of stock options and warrants, reduced by the shares that may be repurchased with the funds received from the exercise, based on the average price during the period. Options and warrants to purchase shares of common stock, as well as convertible preferred stock and unvested common stock grants, are excluded from the computation of diluted earnings per share because the effect of their inclusion would be anti-dilutive.

#### **Income Taxes**

Deferred income taxes are recognized for temporary differences between financial statement and income tax bases of assets and liabilities and loss carry forwards for which income tax benefits are expected to be realized in future years. A valuation allowance is established, when necessary, to reduce deferred tax assets to the amount expected to be realized. In estimating future tax consequences, we generally consider all expected future events other than an enactment of changes in the tax laws or rates. Deferred tax assets are continually evaluated for realizability. To the extent our judgment regarding the realization of the deferred tax assets changes, an adjustment to the allowance is recorded, with an offsetting increase or decrease, as appropriate, in income tax expense. Such adjustments are recorded in the period in which our estimate as to the realizability of the assets changed that it is "more likely than not" that all of the deferred tax assets will be realized. The "more likely than not" standard is subjective and is based upon our estimate of a greater than 50% probability that the deferred tax asset will be realized.

Deferred tax assets and liabilities are classified as current or non-current based on the classification of the related asset or liability for financial reporting. A deferred tax asset or liability that is not related to an asset or liability for financial reporting, including deferred tax assets related to carryforwards, are classified according to the expected reversal date of the temporary difference.

The Company also complies with the provisions of the ASC Topic 740, "Income Taxes", which prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. No amounts were accrued for the payment of interest and penalties at May 31, 2011 and May 31, 2010. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

#### Share-based Employee Compensation

The Company complies with ASC Topic 718 "Compensation – Stock Compensation" ("ASC 718"), which requires all companies to recognize the cost of services received in exchange for equity instruments, to be recognized in the financial statements based on their fair values. For purposes of estimating the fair value of each option on the date of grant, the Company utilized the Black-Scholes option-pricing model.

Vasomedical accounts for share-based compensation in accordance with fair value recognition provisions, under which the Company uses the Black-Scholes option pricing model which requires the input of subjective assumptions. These assumptions include estimating the length of time employees will retain their stock options before exercising them ("expected term"), the estimated volatility of the Company's common stock price over the expected term and the number of options that will ultimately not complete their vesting requirements. The Company estimates the expected term and forfeitures based on the terms set forth in the option agreements and no assumption that any options will not complete their vesting period, which approximates actual historical behavior, and it estimates volatility of the

Company's stock based on the Company's historical stock price performance over the past five years. Changes in the subjective assumptions could materially affect the estimate of fair value of stock-based compensation; however management believes changes in certain assumptions that could be reasonably possible in the near term, would not have a material effect on the expense recognized for fiscal 2011.

Equity instruments issued to non-employees in exchange for goods, fees and services are accounted for under the fair value-based method of ASC Topic 505 "Equity" (ASC 505).

#### **Recently Issued Accounting Pronouncements**

Effective June 1, 2010, the Company adopted Accounting Standards Update No. 2009-13, "Revenue Recognition (Topic 605)", which revised the authoritative guidance for revenue arrangements with multiple deliverables. This revised authoritative guidance requires companies to allocate revenue in arrangements involving multiple deliverables based on the estimated selling price of each deliverable, even though such deliverables are not sold separately either by a company itself or other vendors. This revised authoritative guidance eliminates the requirement that all undelivered elements must have objective and reliable evidence of fair value before a company can recognize the portion of the overall arrangement fee that is attributable to items that already have been delivered. As a result, the new guidance may allow some companies to recognize revenue on transactions that involve multiple deliverables earlier than under previous requirements. This revised authoritative guidance was effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after December 15, 2009. The adoption of this guidance did not have an impact on the Company's consolidated condensed financial statements.

In July 2010, the Company adopted Accounting Standards Update ("ASU") No. 2010-20, "Receivables (Topic 310): Disclosures about the Credit Quality of Financing Receivables and the Allowance for Credit Losses," (ASU 2010-20). ASU 2010-20 requires enhanced disclosures about an entity's credit quality of financing receivables and the related allowance for credit losses. The provisions of ASU 2010-20 will require expansion of the Company's disclosures on the credit quality of its financing receivables and the allowance for credit losses. The adoption of this guidance did not have an impact on the Company's consolidated condensed financial statements.

#### ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements listed in the accompanying Index to Consolidated Financial Statements are filed as part of this report.

ITEM 9 - CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

#### ITEM 9A - CONTROLS AND PROCEDURES

Report on Disclosure Controls and Procedures

Disclosure controls and procedures reporting as promulgated under the Exchange Act is defined as controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms. Disclosure controls and procedures include without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our CEO and our CFO have evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of May 31, 2011 and have concluded that the Company's disclosure controls and procedures were effective as of May 31, 2011.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company as defined in Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control involves maintaining records that accurately represent our business transactions, providing reasonable assurance that receipts and expenditures of company assets are made in accordance with management authorization, and providing reasonable assurance that unauthorized acquisition, use or disposition of company assets that could have a material effect on our financial statements would be detected or prevented on a timely basis.

Because of its innate limitations, internal control over our financial statements is not intended to provide absolute guarantee that a misstatement can be detected or prevented on the statements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in condition, or that the degree of compliance with the policies or procedures may deteriorate.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation and those criteria, the Company's CEO and CFO concluded that the Company's internal control over financial reporting were effective as of May 31, 2011. This annual report does not include an attestation report of the Company's Independent Registered Public Accounting Firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's Independent Registered Public Accounting Firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only Management's report in this Annual Report.

#### ITEM 9B – OTHER INFORMATION

None.

#### **PART III**

The information required by Part III is intended to be included in our definitive Proxy Statement, which will be filed with the Securities and Exchange Commission in connection with our 2011 Annual Meeting of Stockholders and is incorporated herein by reference.

#### **PART IV**

#### ITEM 15 - EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements and Financial Statement Schedules

(1) See Index to Consolidated Financial Statements on page F-1 at beginning of attached financial statements.

#### (a) Exhibits

- (2) (a) Restated Certificate of Incorporation (2)
  - (b) By-Laws (1)
- (3.1) Certificate of Designations of Preferences and Rights of Series E Convertible Preferred Stock (9)
- (4) (a) Specimen Certificate for Common Stock (1)
  - (b) Specimen Certificate for Series E Convertible Preferred Stock
- (10) (a) 1995 Stock Option Plan (3)
  - (b) Outside Director Stock Option Plan (3)
  - (c) 1997 Stock Option Plan, as amended (4)
  - (d) 1999 Stock Option Plan, as amended (5)
  - (e) 2004 Stock Option/Stock Issuance Plan (6)
  - (f) Securities Purchase Agreement dated June 21, 2007 between Registrant and Kerns Manufacturing Corp. (7)
  - (g) Form of Common Stock Purchase Warrant to dated June 21, 2007 (7)

- (h) Registration Rights Agreement dated June 21, 2007 between Registrant, Kerns Manufacturing Corp. and Living Data Technology Corporation. (7)
- (i) Purchase and Sale Agreement dated June 1, 2007 between 180 Linden Avenue Corp and 180 Linden Realty LLC. (8)
- (j) Lease Agreement dated August 15, 2007 between 180 Linden Realty LLC and Registrant (8)
- (k) Form of Stock Purchase Agreement (9)
- (l) Redacted Sales Representative Agreement between GE Healthcare Division of General Electric Company and Vaso Diagnostics, Inc. d/b/a VasoHealthcare, a subsidiary of Vasomedical, Inc. dated as of May 19, 2010 (10)
- (m) 2010 Stock Plan (11)
- (n) Consulting Agreement dated March 1, 2011 between Vasomedical, Inc. and Edgary Consultants, LLC. (12)
- (o) Employment Agreement entered into as of March 21, 2011 between Vasomedical, Inc. and Jun Ma (13)
- (p) Stock Purchase Agreement dated as of August 19, 2011 among Vasomedical, Inc., Fast Growth Enterprises Limited (FGE) and the FGE Shareholders

(21) Subsidiaries of the Registrant

Name State of Incorporation Percentage Owned by

Company

Viromedics, Inc Delaware 61% Vaso Diagnostics, Inc. New York 100% Vasomedical AcquisitionNew York 100%

Corp.

(31) Certification Reports pursuant to Securities Exchange Act Rule 13a - 14

(32) Certification Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to Registration Statement on Form S-18, No. 33-24095.

- (3) Incorporated by reference to Report on Form 8-K dated January 24, 1995.
- (4) Incorporated by reference to Report on Form 10-K for the fiscal year ended May 31, 1999
- (5) Incorporated by reference to Report on Form 10-K for the fiscal year ended May 31, 2000.
- (6) Incorporated by reference to Notice of Annual Meeting of Stockholders dated October 28, 2004.
  - (7) Incorporated by reference to Report on Form 8-K dated June 21, 2007.
- (8) Incorporated by reference to Report on Form 10-KSB for the fiscal year ended May 31, 2007.
  - (9) Incorporated by reference to Report on Form 8-K dated June 21, 2010.
- (10) Incorporated by reference to Report on Form 8-K/A dated May 29, 2010 and filed November 9, 2010.
  - (11) Incorporated by reference to Report on Form 10-K for the fiscal year ended May 31, 2010.
    - (12) Incorporated by reference to Report on Form 8-K dated March 4, 2011.
    - (13) Incorporated by reference to Report on Form 8-K dated March 21, 2011.

<sup>(2)</sup> Incorporated by reference to Registration Statement on Form S-1, No. 33-46377 (effective 7/12/94).

#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, we have duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 29th day of August 2011.

VASOMEDICAL, INC.

By: /s/ Jun Ma Jun Ma President, Chief Executive Officer, and Director (Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on August 29th, 2011, by the following persons in the capacities indicated:

/s/ Jun Ma President, Chief Executive Officer and Director

Jun Ma (Principal Executive Officer)

/s/ Jonathan Newton Chief Financial Officer (Principal Financial Officer) Jonathan Newton

/s/ Simon Srybnik Chairman of the Board

Simon Srybnik

/s/ David Lieberman Vice Chairman of the Board David Lieberman

/s/ Edgar Rios Director Edgar Rios

/ s / B e h n a mDirector Movaseghi

Behnam Movaseghi

Director

William Dempsey

/s/ Peter C. Castle Director

Peter C. Castle

# Vasomedical, Inc. and Subsidiaries

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Vasomedical, Inc.

We have audited the accompanying consolidated balance sheets of Vasomedical, Inc. and Subsidiaries (collectively, the "Company") as of May 31, 2011 and 2010, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Vasomedical, Inc. and Subsidiaries as of May 31, 2011 and 2010, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Rothstein, Kass & Company, P.C.

Roseland, New Jersey August 26, 2011 F-2

# Vasomedical, Inc. and Subsidiaries

# CONSOLIDATED BALANCE SHEETS

	May 31, 2011	May 31, 2010
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$8,130,031	\$481,679
Short-term investments	109,709	68,850
Accounts and other receivables, net of an allowance for doubtful		
accounts and commission adjustments of \$1,296,947 at May 31, 2011,		
and \$146,961 at May 31, 2010	4,018,572	473,878
Inventories, net	1,786,057	2,063,769
Financing receivables, net	18,425	-
Deferred commission expense	2,532,048	-
Deferred related party consulting expense - current portion	510,000	-
Other current assets	267,235	91,848
Total current assets	17,372,077	3,180,024
PROPERTY AND EQUIPMENT, net of accumulated depreciation of		
\$1,633,290 at May 31, 2011, and \$1,612,098 at May 31, 2010	366,199	303,038
DEFERRED DISTRIBUTOR COSTS, net of accumulated amortization of		
\$464,402 at May 31, 2011, and \$338,818 at May 31, 2010	124,474	250,058
FINANCING RECEIVABLES, net	27,133	-
DEFERRED RELATED PARTY CONSULTING EXPENSE	382,500	-
OTHER ASSETS	282,162	130,390
	\$18,554,545	\$3,863,510
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES  CURRENT LIABILITIES		
Accounts payable	\$480,661	\$271,620
Accrued commissions	1,963,826	29,164
Accrued expenses and other liabilities	632,374	240,301
Sales tax payable	160,321	141,884
Deferred revenue - current portion	10,917,732	854,403
Deferred gain on sale-leaseback of building - current portion	53,245	53,245
Accrued professional fees	61,550	86,985
Trade payable due to related party	265,863	240,000
Total current liabilities	14,535,572	1,917,602
Total carrent machines	11,000,072	1,517,002
LONG-TERM LIABILITIES		
Notes payable	-	1,250,000
Deferred revenue	1,004,483	172,945
Accrued rent expense	3,001	16,386
Deferred gain on sale-leaseback of building	8,874	62,121
Other long-term liabilities	94,835	11,900
Total long-term liabilities	1,111,193	1,513,352
	,,	,
COMMITMENTS AND CONTINGENCIES (NOTE Q)		

STOCKHOLDERS' EQUITY		
Preferred stock, \$.01 par value; 1,000,000 shares authorized;		
299,024 issued and outstanding at May 31, 2011	2,990	-
Common stock, \$.001 par value; 250,000,000 shares authorized;		
117,078,704 shares at May 31, 2011 and 110,271,131 at		
May 31, 2010 issued and outstanding	117,079	