

VASOMEDICAL INC
Form 10-K/A
November 05, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K/A
Amendment No. 2

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended May 31, 2010
 TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission File No. 0-18105

VASOMEDICAL, INC.
(Exact name of registrant as specified in Its Charter)

Delaware 11-2871434
(State or other (IRS
jurisdiction of Employer
incorporation or Identification
organization) No.)

180 Linden Avenue, Westbury, New York 11590
(Address of Principal Executive Offices) (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, OTC:BB
\$.001 par value
(Title of Class) 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 file reports pursuant to Section 13 or Section 15(d) of the Act.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 No

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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 \$14,088,479 based on the closing sales price of the common stock as quoted on the OTC-BB on August 23, 2010.

At August 23, 2010, the number of shares outstanding of the issuer's common stock was 110,271,131.

EXPLANATORY NOTE

Vasomedical, Inc. (the “Company,” “we,” “us,” or “our”) is filing this Amendment No. 2 on Form 10-K/A to our Report on Form 10-K for the fiscal year ended May 31, 2010 (the “Report”) for the purpose of including an updated signature page and certifications.

Except as described above, no other amendments are being made to this Report. This Form 10-K/A does not reflect events occurring after the August 30, 2010 filing of our Report or modify or update the disclosure contained in the Report in any way other than as required to reflect the amendments discussed above.

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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; 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. Since 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 US 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. The EECP® therapy is a non-invasive, outpatient treatment of diseases of the cardiovascular system. The therapy serves to increase blood perfusion in the heart muscle and therefore helps restore systemic vascular function. The therapy increases blood flow and oxygen supply to the heart muscle and other organs and decreases the heart’s workload and reduces oxygen demand, while also improving function of the endothelium, the lining of blood vessels throughout the body, lessening resistance to blood flow. We provide hospitals, clinics and physician private practices with EECP® equipment, treatment guidance, and a staff training and equipment maintenance program designed to provide optimal patient outcomes. We also offer accessories and consumables to EECP® therapy providers. EECP® is a registered trademark for Vasomedical’s Enhanced External Counterpulsation therapy and systems. For more information, visit www.vasomedical.com.

During the last several years, we incurred operating losses. We have attempted to achieve profitability by reducing operating costs and halting the trend of declining revenue, and to reduce cash usage through bringing our cost structure more into alignment with current revenues. Excluding the start-up costs related to Vaso Healthcare, the Company has reduced personnel costs by reorganization. The Company has negotiated new terms on professional fees, facility expenses, and shipping and supply costs. The Company is also looking to obtain other sources of funding to help stabilize cash flow and to respond to customers requests for flexible payment terms on our EECP® therapy systems.

In the last couple of years, the Company has been looking to diversify its business, including offering additional medical devices in its product portfolio, and has since introduced patient monitoring devices (the BIOX series Holter and ABP recorders and analysis software) and patient management devices (the EZ ECG and EZ O2 products) into the US market. In April 2010, the Company, through a wholly owned subsidiary Vaso Diagnostics d/b/a Vaso Healthcare, organized a group of medical device sales professionals in the hope of entering into the sales and representation business for other equipment manufacturers. On May 19, 2010, Vaso Healthcare signed a sales

representative agreement with GE Healthcare (the “GEHC Agreement), the healthcare business unit of GE (NYSE: GE), for the sale of select GE Healthcare Diagnostic Imaging products. Under the GEHC Agreement, Vaso Healthcare 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 is for an initial term of three years commencing July 1, 2010, subject to extension and also subject to earlier termination under certain circumstances. These circumstances include failure to materially achieve sales goals, failure to maintain a minimum number of sales representatives, and various legal and GEHC policy requirements. The Company has received financial commitments for up to \$5,000,000 for the purpose of funding this project, of which, \$1,250,000 was received as of May 31, 2010 in the form of promissory notes. Promissory notes were subsequently cancelled in June 2010 through the issuance of the Company’s Series E convertible preferred stock. As of August 29, 2010, the Company had issued an aggregate of \$3,300,000 principal amount of its Series E convertible preferred stock.

Market Overview of EECP® Therapy

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 831 thousand lives in the United States in 2006 and was responsible for 1 of every 3 deaths, according to The American Heart Association (AHA) Heart and Stroke Statistical 2010 Update (2010 Update). An estimated 81.1 million Americans suffer from some form of cardiovascular disease. Among these, 17.6 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). Angina is a symptom of a condition called myocardial ischemia, which occurs when the heart muscle or myocardium doesn't receive sufficient blood, hence as much oxygen, as it needs. This usually happens because one or more of the heart's coronary arteries, the blood vessels that supply blood to the heart muscle, is narrowed or blocked. Insufficient blood supply to meet the need of the organ to function is called ischemia. Angina may happen on exertion, such as during exercise, periods of emotional stress, exposure to extreme cold or heat, after a heavy meals, too much alcohol consumption or cigarette smoking, etc. Some people, such as those with a coronary artery spasm and those with severe coronary arteries occlusion, may have angina even when they are resting.

The number of angina patients in the United States was increased to approximately 10.2 million, according to the 2010 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 over 65% of the patients who receive EECP® therapy are Medicare patient, 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. Please see the heading "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. Causes range from chronic high blood pressure, heart-valve disease, heart attack, coronary artery disease, heartbeat irregularities, severe lung disease such as emphysema, congenital disease, cardiomyopathy, hyperthyroidism, severe anemia and others.

CHF is treated with medication and, sometimes, surgery on heart valves or the coronary arteries 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 2010 Update, in 2006 approximately 3.1 million men and 2.7 million women 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™ (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. Measures of change in peak oxygen consumption were not statistically significant in the overall study population, though a trend favoring EECP® therapy was present in early follow-up. Patients in the trial who had an ischemic etiology (i.e. pre-existing coronary artery disease), demonstrated a greater response to EECP® therapy than those who had an idiopathic (non-ischemic) etiology.

The preliminary results of the PEECH™ trial were presented at the American College of Cardiology scientific sessions in March 2005. The final results of the PEECH™ trial were published online on August 25, 2006 by the Journal of the American College of Cardiology (JACC) and in print 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™ 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 EECPC® 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 EECPC® therapy is angina or angina equivalent symptoms and the patient satisfies other listed criteria. Additionally, we will continue to pursue expansion of coverage for EECPC® therapy with Medicare and other third-party payers as evidence of its clinical utility develops.

Other Potential Applications of EECPC® Therapy

While currently we only have FDA clearance to market EECPC® 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 EECPC® therapy. Results of these studies show that EECPC® 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 EECPC® 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 EECPC® 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 EECPC® therapy in ischemic stroke (*Cerebrovasc Dis*. Vol. 26, p. 97) and another paper in a randomized, crossover study demonstrating the efficacy of EECPC® 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 EECPC® 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 EECPC® therapy and 87% sustained their improvement at 1-year follow up. They concluded that EECPC® 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 EECPC® 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). EECPC® Therapy has been shown to improve endothelial function, increase the release of nitric oxide to dilate vasculature, forming the physiological base of using EECPC® to treat ED. The critical issue to examine is the treatment protocol, how long and how often should EECPC® 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 are needed to confirm the preliminary findings and drive market clearance and reimbursement. The market size for each of the disease listed above is large, and the probability of success is high.

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 researches aiming to fully explain the precise scientific means by which EECP® therapy achieves its long-term beneficial effects continue 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

Early History

Early experiments with counterpulsation at Harvard in the 1950s demonstrated that this technique markedly reduces the workload, and thus oxygen consumption, of the left ventricle. This basic effect has been demonstrated over the past forty years in both animal experiments and in patients. The clinical benefits of external counterpulsation were not consistently achieved in early studies because the equipment used then lacked some of the features found in the current EECP® systems, such as the computerized electrocardiographic signal interpretation for triggering, and the use of pneumatic versus hydraulic actuating media that makes sequential cuff inflation possible. As the technology improved, however, it became apparent that both internal (i.e. intra-aortic balloon pumping) and external forms of counterpulsation were capable of improving survival in patients with cardiogenic shock following myocardial infarction. Later, in the 1980s, physicians in China reported on their extensive experience in treating angina using the newly developed "enhanced" sequentially inflating EECP® device that incorporated three sets of cuffs including the buttocks cuff instead of a single cuff used in the previous system. The Chinese investigators were able to show that a 36-hour course of EECP® treatment reduced the frequency and severity of anginal symptoms during normal daily functions as well as during exercise, and also that the improvements were sustained for years after therapy.

These results prompted a group of investigators at the State University of New York at Stony Brook (Stony Brook) to undertake a number of open label studies with the EECP® system between 1989 and 1996 to reproduce the Chinese results, using both subjective and objective endpoints. These open label and non-randomized studies, showed significant improvement in exercise tolerance by patients as evidenced by an increase in exercise treadmill stress testing, improvement in the perfusion of ischemic regions of the heart muscle by thallium radionuclide imaging stress testing, and partial or complete resolution of coronary perfusion defects. All of these results were reported in medical literature and support the assertion that EECP® therapy is an effective and durable treatment for patients suffering from chronic angina pectoris.

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 confirm the patient benefits observed in the open studies conducted at Stony Brook and to provide definitive scientific evidence of EECP® therapy's effectiveness. MUST-EECP® was completed in July 1997 and the results presented at the annual meetings of the American Heart Association in November 1997 and the American College of Cardiology in March 1998. The results of MUST-EECP® 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™ Study

As part of our program to expand the therapy's indications for use beyond the treatment of angina, we applied for and received FDA approval in April 1998 to study, under an Investigational Device Exemption (IDE) protocol, the application of EECP® therapy in the treatment of CHF. A 32 patient feasibility study was conducted simultaneously at the University of Pittsburgh, the University of California San Francisco and the Grant/Riverside Methodist Hospitals in Columbus, Ohio. The results of this study were presented at the 49th Scientific Sessions of the American College of Cardiology in March 2000 and the Heart Failure Society of America's Annual Meeting in September 2000, and were published in the July/August 2002 issue of Congestive Heart Failure. This study indicated that EECP® therapy could improve exercise capacity, increase functional capacity was beneficial to left ventricular function in patients with NYHA Class II and III (i.e. mild to moderate) heart failure and a reduced left ventricular ejection fraction (i.e. LVEF 35% or less).

In summer 2000, an IDE supplement to proceed with a pivotal study to demonstrate the efficacy of EECP® therapy in the most prevalent types of heart failure patients was approved. This study, known as PEECH™, began patient enrollment in March 2001 in nearly thirty centers including the Cleveland Clinic, Mayo Clinic, the Minnesota Heart Failure Consortium, the University of California at San Diego Medical Center, and the University of Pittsburgh Medical Center. Vasomedical obtained 510(k) clearance for CHF from FDA in June 2002, obviating the need to continue this trial for FDA regulatory reasons. However, we decided to complete the clinical trial in order to use the anticipated clinical outcomes to help establish the clinical validation of EECP® therapy as a treatment for CHF and to provide additional scientific support for Medicare, Medicaid and other third-party payers to expand reimbursement coverage of EECP® therapy to include the CHF indication.

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. Enrollment of patients into the PEECH™ trial was completed in February 2004, with 187 patients, and the six-month follow-up examinations were completed by the end of December 2004. The preliminary results of the PEECH™ trial were presented at the American College of Cardiology scientific sessions in March 2005. On August 25, 2006, the results of the trial were initially published on line by the Journal of the American College of Cardiology (JACC), and in print in its September 19, 2006 issue. JACC is the official journal of the American College of Cardiology.

The PEECH™ 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™ 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™ 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™)

In 1998 we sponsored the International Patient EECP® Registries (IEPR™) 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™ is a voluntary registry recording consecutive patients enrolled in clinical sites undergoing for at least 1 hour of EECP® therapy. The objective of IEPR™ was to document the baseline characteristics, safety and effectiveness of EECP® therapy in the treatment of chronic angina. By the end of recruitment in July 2001, over 5,000 patients had been enrolled from 84 sites, concluding the enrollment of Phase I of the International EECP® Patient Registry (IEPR™-1). Patients in IEPR™-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™-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™-2 also added heart failure specific data (including the Kansas City Cardiomyopathy Questionnaire). After treatment completion data are 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™.

IEPR™-1

The design, methods, baseline characteristics of patients enrolled in IEPR™-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™-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 that 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 adverse clinical event rate was low. Patients also reported

improvement in health status, quality of life and satisfaction with life. At two-year follow-up, 74.9% of patients reported their angina symptom status (CCSC class) was improved compared to before EECP® therapy, and the accompanying improvements in angina frequency and quality of life measures were largely sustained as well. Nine percent (9%) of patients had died over the two-year follow-up and 15% had undergone a revascularization procedure (angioplasty, stenting or coronary bypass surgery). 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™-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™-2

Upon completion of enrollment of IEPR™-1 in July 2001, we had already begun to enroll patients in the PEECH trial for heart failure patients and felt that we should continue the International EECP® Patient Registry to Phase II to capture information on changes in patients with heart failure symptom, occurrence of clinical events due to heart failure and to include a heart failure-specific quality of life questionnaire. IEPR™-2 was initiated in February 2002, collecting additional data on 2,500 patients with 2-year follow-up.

Results of the two-year clinical outcomes from IEPR™-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™-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.

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-month before EECP® therapy were compared with those at 6-month 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 of healthcare costs each year.

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 over 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 that EECP® therapy can provide benefit to appropriate patients in the following ways:

- Enhancement of coronary and peripheral circulation, myocardial perfusion, ventricular function and hemodynamics;
 - Improvement in endothelial function and vascular reactivity;
 - Elimination or reduction of cardiac ischemia;
 - Elimination or reduction in symptoms and improved functional class in angina and heart failure;
 - Resolution of reversible ischemic defects found on quantitative myocardial perfusion studies;
- Increased exercise duration and increased time to ischemic changes during treadmill exercise in angina and increased exercise duration and peak oxygen consumption in heart failure in properly selected patients;
 - Elimination or reduction in use of anti-angina medications;
 - Improved quality of life in patients with angina and heart failure.

Strategic Objectives for the EECP® Business

Our short and long-term plans are to:

- a) Maintain our cost structure alignment with current revenues in the short term by:
 - i) continuing to monitor, reduce, or eliminate spending on all but critical new product development and clinical research projects;
 - ii) focusing on rebuilding our revenue base through supporting our direct sales effort and expanding our use of independent sales representatives; and
 - iii) maintaining tight control on all areas of personnel cost and spending.
 - b) Pursue possible strategic investments and creative partnerships with others who have distinctive competencies or delivery capabilities for serving the cardiovascular and disease management marketplace, as opportunities become available.
 - c) Increase market penetration in the domestic reimbursable user base for EECP® therapy by:
 - i) expanding reimbursement to include coverage for the treatment of ischemic NYHA Class II and III CHF patients;
 - ii) marketing directly to third-party payers to increase third-party reimbursement; and
 - iii) expanding reimbursement coverage in the angina market to include patients with CCS Class II angina.
 - d) Increase the clinical and scientific understanding of EECP® therapy by:
 - i) re-submitting data when available to insurers, including Medicare, for favorable coverage policies;
 - ii) continuing to support on a limited basis academic reference centers in the United States and overseas in order to accelerate the growth and prestige of EECP® therapy.
 - e) Increase awareness of the benefits of the EECP® therapy in the healthcare community by:
 - i)

- developing campaigns to market the benefits of EECP® therapy directly to clinicians, third-party payers and patients;
- ii) engaging in educational campaigns for providers and medical directors of third-party insurers designed to highlight the cost-effectiveness and quality-of-life advantages of EECP® therapy; and
 - iii) continuing the development of EECP® therapy in certain international markets, principally through the expansion of our distribution network and obtaining of reimbursement approvals.
 - f) Maintain development efforts to improve the EECP® system and expand its intellectual property estate.

These 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. To a large extent, limited financial resource availability reduces 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.

Sales and Marketing of EECP® Systems

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 and a national sales manager, 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. Additional marketing activities include promotion of awareness among third-party payers of the benefits of EECP® treatment for patients suffering from CHF as well as angina.

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 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 territory..

Our international marketing activities include, among other things, assisting distributors in obtaining regulatory clearance and national or third-party healthcare insurance reimbursement approval, and participating in trade shows and medical conferences to create greater awareness and acceptance of EECP® therapy by clinicians.

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

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 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). There can be no assurance that other companies will not develop new technologies or enter the market intended for EECP® therapy systems. Such other companies may have substantially greater financial, manufacturing and marketing resources and technological expertise than those possessed by us and may, therefore, succeed in developing technologies or products that are more efficient than those offered by Vasomedical and that would render our technology and existing products obsolete or noncompetitive.

Government Regulations

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. In the following we will mainly discuss regulatory issues related to our EECP® systems, since other products the Company has introduced belong to lower FDA classifications (Class I or Class II) with less stringent regulatory requirement and the Company is selling them as a distributor not a manufacturer.

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). In February 1995, the Company received 510(k) clearance by the US FDA to market the second-generation version of its EECP® therapy system, the MC2, which

incorporated a number of technological improvements over the predicate system. In December 2000, the Company received 510(k) clearance to market its third generation system, the TS3. The FDA's clearance in these cases was for the use of EECP® therapy in the treatment of patients suffering from stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock. In June 2002, the FDA granted 510(k) market clearance for an upgraded TS3, which incorporated the Company's patented CHF treatment and oxygen saturation monitoring technologies, and provided for a new indication for the use of EECP® in CHF, which applied to all then-current models of the Company's EECP® therapy systems. The AngioNew®-V EECP® system, a fully automated mobile and compact device that does not require a dedicated treatment table, was cleared by the US FDA in December 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 EEC[®] 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 the FDA will agree with our conclusions that a new 510(k) was unnecessary on these occasions or in other similar instances, or that our products will not be subject to a regulation requiring a PMA for preamendments Class III external counterpulsation devices.

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.

Foreign Regulation

In most countries to which we seek to export our EECPC[®] systems, a local regulatory clearance must be obtained. The regulatory review process varies from country to country and can be complex, markings costly, uncertain, and time-consuming. Current Vasomedical EECPC[®] systems are all CE marking certified for European Union countries as well as 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. The HIPAA privacy rule governs the use and disclosure of protected health information by "Covered Entities," which are (1) health plans, (2) health care clearinghouses, and (3) health care providers that transmit health information in electronic form in connection with certain health care transactions such as benefit claims. 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.”

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 evaluations of the use of EECP® therapy in patients with chronic angina and heart failure continue to appear in presentations at major scientific meetings and in peer-reviewed publications each year, there continues to be reluctance in the cardiology community about its broader use until reimbursement situation becomes more favorable. Additional evidence regarding the efficacy of EECP® therapy and its long lasting effect continues to appear, however the evidence may not be sufficient to warrant a modification of practice guidelines to a more favorable recommendation and increased acceptance by the medical community.

Reimbursement

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. Even if successful, 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. Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payers for our products could have a material adverse effect on our financial condition and operating results.

Our reimbursement strategies are currently focused in the following primary areas: expanding Medicare coverage to include congestive heart failure and mild angina, expanding coverage with other third-party payers, expanding Medicare coverage for angina, increasing 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 EEC[®] 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 EEC[®] 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 2010 national average payment rate per hourly EEC[®] therapy session in the physician office setting and the hospital outpatient facility is \$145.42 and \$104.23, respectively. Actual reimbursement rates vary throughout the country and range from \$105 to \$215 per hourly EEC[®] 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

If there were any material change in the availability of Medicare coverage, or if the reimbursement level for treatment procedures using the EEC[®] 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 June 23, 2005, CMS also received a separate application from a competing manufacturer of external counterpulsation equipment, to request expansion of coverage to include 1) treatment of congestive heart failure, to include NYHA Class II, III with a left ventricular ejection fraction (LVEF) less than or equal to 40%, and acute heart failure; 2) treatment of stable angina to include CCSC II angina; 3) treatment of acute myocardial infarction; 4) treatment of cardiogenic shock. On September 15, 2005, they amended their request to include NYHA Class IV heart failure.

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™ study but 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 will continue to pursue expansion of coverage for EECP® therapy with Medicare and other third-party payers as evidence of its clinical utility develops.

Expanding 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. If there were any material change 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; as a consequence, a mix of available private and public healthcare providers may not yet be aware of coverage of this therapy. Our reimbursement strategy has been opportunistic and responsive to the selling opportunities presented through our distribution partners. During the past fiscal years our efforts on behalf of EECP® therapy in both the private and public healthcare sectors of selected international markets have been initiated by our distributors, in support of the therapy, in their designated territory. However, we do not anticipate a significant impact on financial performance in the next fiscal year, given the long lead times from submission to approval of international dossiers for each reimbursement authority.

Patents and Trademarks

We own thirteen US patents including eight utility and three design patents that expire at various times between 2009 and 2023. In addition, more than 20 foreign patents have been issued that expire at various times from 2009 to 2023. We will from time to time file other patent applications regarding specific enhancements to the current EECF® models, future generation products, and methods of treatment in the future. Moreover, trademarks have been registered for the names “EECF” “AngioNew” and “Natural Bypass”.

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 EECF® patents and trademarks could have a material adverse effect upon our business.

Employees

As of May 31, 2010, we employed 84 full-time persons including 61 in Vaso Diagnostics d/b/a Vaso Healthcare, a wholly owned subsidiary in the sales and representation business. The number is expected to increase in the next few months as the Company strengthens its marketing and sales effort for its EECF® and related business as well as placing more representatives in the field for its sales representative agreement with GE Healthcare. None of our employees are represented by a labor union. We believe that our employee relations are good.

The Company also has several part-time employees in the engineering and technical fields.

Manufacturing

Vasomedical maintains its manufacturing capacity in the Westbury NY location to satisfy domestic and international needs for the TS3, TS4 and Lumenair EECF® systems, and contracts Life Enhancement Technology Co. Ltd. for the manufacture of AngioNew® and Lumenair EECF® systems. Life Enhancement Technology was, until 2009, the manufacturing facility of AngioNew® systems for Living Data Technology Corp., a stockholder of Vasomedical, all EECF® 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). 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 EECF® systems.

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, which could result in a further decline in the value of our common stock.

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 largely dependent on our ability to reduce operating costs sufficiently, as well as halting the current trend of declining revenue. Our ability to maintain our current base of revenue and increase revenue is largely dependent upon restructuring our sales and marketing efforts for the EECP® systems in the angina market, where reimbursement is currently available and operating in a more efficient manner, as well as our capability in introducing new products and developing new business.

We have entered into a new business through our subsidiary, Vaso Healthcare and are initially incurring substantial operating losses.

In May 2010, our subsidiary, Vaso Healthcare signed a Sales Representative Agreement with GE Healthcare (“GEHC Agreement”) for the sale of GE healthcare diagnostic imaging products. While the GEHC Agreement commenced July 1, 2010, we have employed since April, 2010 approximately 60 full time employees to perform services under the GEHC Agreement which has resulted in expenses of approximately \$1,062,000 through May 31, 2010. We are continuing to incur substantial additional expenses under this Agreement. While we believe that revenues under the GEHC Agreement should exceed expenses, resulting in profitability to the Company, there are no representations that we will succeed in our efforts under the GEHC Agreement.

Risks Related to Our Business

We are materially dependent on medical reimbursement for treatment procedures using EECP® therapy on patients with congestive heart failure in order to achieve growth.

We are currently dependent on a single product platform which, based on current medical reimbursement policies, provides coverage for a restricted class of heart patients. On May 31, 2005, we submitted an application to CMS to expand the national coverage policy for external counterpulsation treatment to patients with Canadian Cardiovascular Class II stable angina and to patients with New York Heart Association (NYHA) Class II and III stable heart failure symptoms with an ejection fraction less than 35%. The application was accepted by CMS effective June 20, 2005, and CMS announced their decision to maintain the existing coverage as stated prior to the application and not to expand it to include Class II Angina and Class II/III CHF on March 20, 2006. Results of the PEECH™ trial have been published in the Journal of the American College of Cardiology in September 2006, and the subgroup analysis of CHF patients age 65 and over has also been published in the November-December 2006 issue of the Journal of Congestive Heart Failure. These two papers have been submitted to CMS for reconsideration of our application. We had met with representatives from CMS in February 2007 and presented our case. CMS has requested additional data from us. We will continue our dialogue with CMS to obtain coverage for heart failure patients. However, there is no assurance that the Company will have sufficient resources to gather the necessary data to be sufficient to support expansion of the Medicare National Coverage Policy for EECP® treatment for NYHA class II and III heart failure patients.

If we do not receive medical coverage for treatment procedures using EECP® therapy on patients with CHF, it will adversely affect our future business prospects.

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

Health care providers, such as hospitals and physician private practices, 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 material change 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 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 to realize an appropriate return on the purchase of our products.

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Increased acceptance by the medical community is important for growth.

While many abstracts and publications are presented each year at major scientific meetings worldwide with respect to EECP® treatment efficacy, there is continued 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 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 at least three other companies that are marketing external counterpulsation devices. We do not know whether these companies or other potential competitors who may be developing external counterpulsation 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 external counterpulsation 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 be unable to market the modified device until FDA issues a clearance for the 510(k).

Additionally, if FDA publishes a regulation requiring a premarket approval application or PMA for external counterpulsation devices, we would then need to submit a PMA, and have it filed by 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 is expensive, time-consuming, and uncertain. If FDA were to require a PMA application, we may be required to undertake a clinical study, which likely will be expensive and require lengthy follow-up, to demonstrate the effectiveness of the device. 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 any such 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 business.

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If we are unable to comply with applicable governmental regulation, 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 postmarket regulatory and enforcement authority for devices.

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 distributor, 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.

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

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 \$7,000,000 per occurrence and \$7,000,000 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 \$149,000. We believe that our current facility is adequate to meet our current needs and should continue to be adequate for the immediately foreseeable future.

ITEM 3 – LEGAL PROCEEDINGS

There were no material legal proceedings.

ITEM 4 – SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

There were no matters submitted to a vote of security holders during the fourth quarter of the fiscal year.

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 the Over-the-Counter Bulletin Board under the symbol VASO.OB. 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). The number of record holders of common stock as of August 23, 2010, was approximately 1,040, which does not include approximately 15,000 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 High	2010 Low	Fiscal High	2009 Low
First Quarter	\$ 0.09	\$ 0.07	\$ 0.10	\$ 0.06
Second Quarter	\$ 0.09	\$ 0.06	\$ 0.08	\$ 0.02
Third Quarter	\$ 0.08	\$ 0.05	\$ 0.03	\$ 0.02
Fourth Quarter	\$ 0.31	\$ 0.05	\$ 0.09	\$ 0.02

The last bid price of the Company's common stock on August 23, 2010, was \$0.23 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 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF
7 – 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; 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. Since 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 US 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. The EECP® therapy is a non-invasive, outpatient treatment of diseases of the cardiovascular system. The therapy serves to increase blood perfusion in the heart muscle and therefore helps restore systemic vascular function. The therapy increases blood flow and oxygen supply to the heart muscle and other organs and decreases the heart’s workload and reduces oxygen demand, while also improving function of the endothelium, the lining of blood vessels throughout the body, lessening resistance to blood flow. We provide hospitals, clinics and physician private practices with EECP® equipment, treatment guidance, and a staff training and equipment maintenance program designed to provide optimal patient outcomes. We also offer accessories and consumables to EECP® therapy providers. EECP® is a registered trademark for Vasomedical's Enhanced External Counterpulsation therapy and systems. For more information, visit www.vasomedical.com.

During the last several years, we incurred operating losses. We have attempted to achieve profitability by reducing operating costs and halting the trend of declining revenue, and to reduce cash usage through bringing our cost structure more into alignment with current revenues. Excluding the start-up costs related to Vaso Healthcare, the Company has reduced personnel costs through reorganization. The Company has negotiated new terms on professional fees, facility expenses, and shipping and supply costs. The Company is also looking to obtain other sources of funding to help stabilize cash flow and to respond to customers requests for flexible payment terms on our EECP® therapy systems.

In the last couple of years, the Company has been looking to diversify its business, including offering additional medical devices in its product portfolio, and has since introduced patient monitoring devices (the BIOX series Holter and ABP recorders and analysis software) and patient management devices (the EZ ECG and EZ O2 products) into the US market. In April 2010, the Company, through a wholly owned subsidiary Vaso Diagnostics d/b/a Vaso Healthcare, organized a group of medical device sales professionals in the hope of entering into the sales and representation business for other equipment manufacturers. On May 19, 2010, Vaso Healthcare signed a sales representative agreement with GE Healthcare, the healthcare business unit of GE (NYSE: GE), for the sale of select GE Healthcare Diagnostic Imaging products. Under the GEHC Agreement, Vaso Healthcare 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 is for an initial term of three years commencing July 1, 2010, subject to extension and also subject to earlier termination under certain circumstances. These circumstances include failure to materially achieve sales goals, failure to maintain a minimum number of sales representatives, and various legal and GEHC policy requirements. The Company has received financial commitments for up to \$5,000,000 for the purpose of funding this project, of which, \$1,250,000 was received as of May 31, 2010 in the form of promissory notes. These promissory notes were subsequently settled in June 2010 through the issuance of Series E preferred stock (see Note R).

Results of Operations – Fiscal Years Ended May 31, 2010 and 2009

Net revenue from sales, leases and service of our EECP® systems for the fiscal years ended May 31, 2010 and 2009, was \$4,205,942 and \$4,471,186, respectively, which represented a decline of \$265,244, or 6%. We reported a net loss attributable to common stockholders of \$1,892,073 and \$1,524,711 for fiscal 2010 and 2009, respectively. Excluding the loss of \$1,062,256 for Vaso Healthcare, the net loss applicable to common stockholders would be \$829,817, a

decrease of 46% from prior fiscal year, primarily due to a reduction of operating expenses. Our total net loss was \$0.02 per basic and diluted common share for the fiscal years ended May 31, 2010 and May 31, 2009.

Revenues

Revenue from equipment sales decreased approximately 5% to \$2,119,270 for the fiscal year ended May 31, 2010 as compared to \$2,219,729 for the prior year. The decrease in equipment sales is due primarily to a decrease in the total number of units sold, offset by an increase in the average sales price of EEC[®] systems.

We believe the decline in sales reflects weakened demand in the refractory angina market as existing capacity is more fully utilized, coupled with increased direct and indirect competition. We anticipate that demand for EEC[®] systems will remain soft unless there is greater clinical acceptance for the use of EEC[®] therapy in treating patients with angina or angina equivalent symptoms who meet the current reimbursement guidelines or an expansion of the current CMS national reimbursement policy to include 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. Despite this, many cardiology clinicians appear to be waiting for approval of reimbursement coverage for heart failure as a primary indication before they will move forward with the treatment of ischemic heart failure patients with angina equivalent symptoms. Reluctance to bill for ischemic heart failure patients under the current coverage guidelines, and failure to get or maintain adequate reimbursement coverage for angina and heart failure would adversely affect our business prospects.

Our revenue from equipment rental and services decreased 7% to \$2,086,672 in fiscal 2010 from \$2,251,457 in fiscal year 2009. Revenue from equipment rental and services represented approximately 50% of total revenue in fiscal 2010 and 2009. The decrease in revenue generated from equipment rentals and services is due to a decrease in the service business and a decrease in recognition of revenue for service agreements from the prior fiscal year ended May 31, 2009.

Gross Profit

Gross profit in total increased to 2,211,512, or 53% of revenues, for fiscal 2010 compared to \$1,905,370, or 43% of revenues, for fiscal 2009, representing an increase of 16% in total dollar amount. The increase in total gross profit, when compared to prior year in absolute dollars, is principally due to lower cost of equipment sales as compared to fiscal year 2009. For equipment sales in fiscal year 2010 there is an increase in gross profit in absolute dollars of \$423,708 or 67% when compared to fiscal year 2009. This is due mainly to decreased manufacturing overhead costs.

Gross profits are dependent on a number of factors, particularly the mix of EEC[®] models sold domestically and internationally and their respective average selling prices, the mix of EEC[®] units sold, rented or placed during the period, service contract sales, and the ongoing costs of service, and certain fixed period costs, including facilities, payroll and insurance. Gross profit margins are generally less on non-domestic business due to the use of distributors resulting in lower selling prices. Consequently, the gross profit realized during the current period may not be indicative of future margins. In addition, at the end of the third quarter ended February 28, 2010, the Company identified alternate uses for certain items in inventory that had previously been written down to the lower of cost or market by approximately \$96,000. As these items are incorporated into future products sold, this allowance would be credited to cost of goods sold.

Selling, General and Administrative

Selling, general and administrative (“SG&A”) expenses for fiscal 2010 and 2009 were \$3,772,569, or 90% of revenues, and \$3,013,276, or 67% of revenues, respectively, reflecting an increase of \$759,293 or approximately 25%. Excluding the start-up costs of Vaso Healthcare, SG&A expenditures for operations in fiscal year 2010 was \$2,644,310, representing a decrease \$368,966, or 12%, compared to prior fiscal year. Administration expenses decreased \$355,549, mainly due to decreases in personnel, insurance and professional fee costs. Marketing expenses

decreased \$30,935 due to decreased expenditures in consultants used to complete marketing projects. Sales expenses increased \$17,518 as a result of increased expenditures in personnel and their associated costs.

During fiscal 2010 the Company recorded a provision for doubtful accounts of \$71,277 compared to fiscal 2009 when the Company recorded a provision for doubtful accounts of \$537. The recording of the provision is primarily a result of specific allowance for accounts the Company has placed into collections during fiscal 2010. The Company will continue efforts to ensure collection of accounts receivable.

Research and Development

Research and development (“R&D”) expenses of \$418,803 or 10% of revenues for fiscal 2010, decreased by \$100,706, or 19%, from \$519,509 or 12% of revenues for fiscal 2009. The decrease is primarily attributable to less personnel and associated costs, engineering consulting and associated expenditures, and new product spending.

Interest Expense and Financing Costs

Interest expense and financing costs increased to \$5,383 for fiscal 2010 from zero for the prior year. Interest expense primarily reflects interest on notes payable issued to finance the start-up costs of Vaso Healthcare.

Interest and Other Income, Net

Interest and other income for fiscal 2010 and 2009 was \$79,871 and \$55,334, respectively.

Amortization of Deferred Gain on Sale-leaseback of Building

The amortization of deferred gain on sale-leaseback of building for fiscal 2010 and 2009 was \$53,245 and \$53,245, respectively. The gain resulted from the Company’s sale-leaseback of its facility.

Income Tax Expense, Net

During fiscal year 2010, the Company reversed the provision for income taxes by \$9,862, received cash refunds and credits of approximately \$17,400, mostly in the form of refunds for credits for research and development costs as part of the federal stimulus package of 2009, and incurred an additional expense of \$29. During fiscal year 2009, we recorded a provision for income taxes of \$7,500 and the Company incurred an additional expense of \$197.

As of May 31, 2010, the recorded deferred tax assets were \$20,966,375, reflecting an increase of \$629,723 during the fiscal year ended May 31, 2010, which was offset by a valuation allowance of the same amount.

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 Vaso Healthcare.

Liquidity and Capital Resources

Cash and Cash Flow

We have financed our operations primarily from working capital, from a private equity financing and the sale of our facility under a leaseback agreement during fiscal year 2008. We also issued promissory notes in April and May 2010 in the aggregate sum of \$1,250,000 to raise capital for the start-up of the Vaso Healthcare business, with the intent of converting the notes into equity. On May 31, 2010, we had cash and cash equivalents and short-term investments in the form of certificates of deposit of \$550,529 and working capital of \$1,263,691 compared to cash and cash equivalents of \$914,580 and working capital of \$1,300,647 on May 31, 2009.

Cash used in operating activities was \$1,588,387 during fiscal 2010, which consisted of a net cash loss after adjustments to reconcile net loss to net cash of \$1,350,140 and cash used by changes in operating assets and liabilities

of \$238,247. The changes in operating assets and liabilities primarily reflect decreases in accounts receivable of \$166,626 and other assets of \$50,722, and increases in accounts payable of \$158,036, accrued rent expense of \$1,615, and accrued professional fee of \$77,235, offset by an increase in inventory of \$287,320, and decreases in accrued expenses and other liabilities of \$122,993, sales tax payable of \$1,809, deferred revenue of \$260,359, and trade payable due to related party of \$20,000. Net accounts receivable were 10% of revenues for the period ended May 31, 2010, as compared to 15% for the period ended May 31, 2009, and accounts receivable turnover increased to 5.6 times as of May 31, 2010, as compared to 4.7 times as of May 31, 2009.

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 2010 and 2009, there were no revenues generated from sales in which initial payment terms were greater than 90 days and we offered no sales-type leases during either period. 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 provided cash of \$276,009 during the fiscal year ended May 31, 2010, which consisted of the redemption of nine-month certificates of deposit in the amount of \$370,523 offset by the purchase of a twelve-month certificate of deposit for \$68,850 and purchases of property and equipment of \$25,664. Investing activities during the fiscal year ended May 31, 2009 used cash of \$393,082, which consisted of investments in equipment of \$22,559 and the redemption of short-term investments of \$370,523.

In June, July, and August 2010, the Company received an aggregate of \$3,300,000 through the sale of its Series E convertible preferred stock. Proceeds from the issuance were used, in part, to pay notes payable held as of May 31, 2010.

The following is a summary of the powers, designations, preferences and other rights of the Series E convertible preferred stock.

- i. Face Amount. The face amount per share of the Series E Preferred Stock is \$16.00.
- ii. Dividends. Cumulative dividends will accrue at a rate of 5% per annum, payable semi-annually in additional shares of the Series E Preferred. Dividends on the Series E Preferred will be paid in preference to any dividends paid to the holders of the Company's Common Stock or any other series of the Company's preferred stock made junior to the Series E Preferred.
- iii. Liquidation Preference. On any liquidation, dissolution or winding-up of the Corporation, the holders of the Series E Preferred will receive payment of twice the aggregate face amount thereof, plus all accrued and unpaid dividends, before any payments or distributions are paid or provided for the Company's Common Stock or any other series of the Company's preferred stock made junior to the Series E Preferred. In the event of a sale of all or substantially all the Company's stock or assets, the holders of the Series E Preferred will receive payment of 1.2 times the aggregate face amount thereof, plus all accrued and unpaid dividends, before any payments or distributions are paid or provided for the Company's Common Stock or any other series of the Company's preferred stock made junior to the Series E Preferred.
- iv. Conversion Rights. Each share of the Series E Preferred will be convertible at any time or from time to time at the holder's option commencing six months from the issuance date into 100 shares of Common Stock (an exercise price of \$.16 per share of Common Stock, the "Conversion Price"), subject to anti-dilution adjustment as set forth below. Commencing at any time one year from the issuance date, one-half 50% of the Series E Preferred will be automatically converted into 100 shares of Common Stock for each share of Series E Preferred if the closing market price of the Common Stock is 3 times the Conversion Price for 30 consecutive trading days and the average daily trading volume during those 30 days is 250,000 shares or greater. Notwithstanding the foregoing, the Series E Preferred shall be automatically converted into Common Stock on June 1, 2015.
- v. Voting Rights. Investors in the Series E Preferred will have voting rights in the ratio of 100 votes for each share of Series E Preferred and shall vote together with the Common Stock as a single class.
- vi. Anti-Dilution Adjustments. The 100-to-1 conversion ratio of the Series E Preferred will be subject to proportional adjustment for stock dividends, stock splits and other similar changes in capitalization. If the Company issues or sells shares of its capital stock for consideration of a price of less than the lesser of its then current market price or the applicable Conversion Price, the Conversion Price shall be adjusted to be such lower price at which the Company issued or sold shares of its capital stock; provided, however, that the Company shall have the right to issue shares and options under its option plans.

Liquidity

During the last several years, we incurred operating losses. We have attempted to achieve profitability by reducing operating costs and halting the trend of declining revenue, and to reduce cash usage through bringing our cost structure more into alignment with current revenues. Excluding the start-up costs related to Vaso Healthcare, the Company has reduced personnel costs through reorganization. The Company has negotiated new terms on

professional fees, facility expenses, and shipping and supply costs. The Company is also looking to obtain other sources of funding to help stabilize cash flow and to respond to customers requests for flexible payment terms on our EECP® therapy systems.

In the last couple of years, the Company has been looking to diversify its business, including offering additional medical devices in its product portfolio, and has since introduced patient monitoring devices (the BIOX series Holter and ABP recorders and analysis software) and patient management devices (the EZ ECG and EZ O2 products) into the US market. In April 2010, the Company, through a wholly owned subsidiary Vaso Diagnostics d/b/a Vaso Healthcare, organized a group of medical device sales professionals in the hope of entering into the sales and representation business for other equipment manufacturers. On May 19, 2010, Vaso Healthcare signed a sales representative agreement with GE Healthcare, the healthcare business unit of GE (NYSE: GE), for the sale of select GE Healthcare Diagnostic Imaging products. Under the GEHC Agreement, Vaso Healthcare 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 is for an initial term of three years commencing July 1, 2010, subject to extension and also subject to earlier termination under certain circumstances. These circumstances include failure to materially achieve sales goals, failure to maintain a minimum number of sales representatives, and various legal and GEHC policy requirements. The Company has received financial commitments for up to \$5,000,000 for the purpose of funding this project. As of August 29, 2010, the Company had issued an aggregate of \$3,300,000 principal amount of its Series E convertible preferred stock as part of its \$5,000,000 financial commitment.

Based on our current operations, including anticipated internally generated funds from its Vaso Healthcare subsidiary and the receipt of funds through the issuance of its Series E convertible preferred stock, we believe that we have sufficient working capital to continue our operations through at least June 1, 2011.

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, 2010, 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, an affiliate of Kerns (Living Data).

We sold to Kerns, pursuant to the Securities Purchase Agreement, 21,428,572 shares of our common stock at \$.07 per share for a total purchase price of \$1,500,000, as well a five-year warrant to purchase 4,285,714 shares of our common stock at an initial exercise price of \$.08 per share (the Warrant). The agreement further provided for the appointment to our Board of Directors of two representatives from Kerns. In furtherance thereof, Dr. Jun Ma and Mr. Simon Srybnik, Chairman of both Kerns and Living Data, have been appointed members of our Board of Directors. On October 15, 2008, Dr. Jun Ma was appointed Chief Executive Officer. Pursuant to the Distribution Agreement, we have become the exclusive distributor in the United States of the AngioNew® ECP systems manufactured by Living Data. As additional consideration for such agreement, we agreed to issue an additional 6,990,840 shares of our common stock to Living Data. Pursuant to the Supplier Agreement, Living Data became the exclusive supplier to us of the ECP therapy systems that we market under the registered trademark EECP®. The Distribution Agreement and the Supplier Agreement each have an initial term extending through May 31, 2012.

On November 20, 2008, the Company entered into an Amendment to the Distribution Agreement with Living Data to expand the territory covered in the Distribution Agreement to provide for exclusive distribution rights of AngioNew® ECP systems worldwide. In consideration for these rights, the Company agreed to issue Living Data 3,000,000 restricted shares of its common stock having a fair market value of \$60,000 at time of issue.

On February 28, 2010, the Company entered into an Amendment to the Supplier Agreement with Living Data to terminate the Supplier Agreement and permit Vasomedical to manufacture or cause to be manufactured EECP® systems at its will. In connection with this termination, Vasomedical purchased Living Data's remaining inventory at cost (\$469,450), which was paid in common stock valued at the closing price on the contract date.

Pursuant to a Registration Rights Agreement, we granted to Kerns and Living Data, subject to certain restrictions, "piggyback registration rights" covering the shares sold to Kerns as well as the shares issuable upon exercise of the Warrant and the shares issued to Living Data.

On July 10, 2007, the Board of Directors appointed Mr. Behnam Movaseghi, Treasurer and Chief Financial Officer of Kerns Manufacturing Corporation, to our Board of Directors.

As affiliates of Living Data and Kerns, Dr. Ma, Mr. Movaseghi and Mr. Srybnik have each been directly involved in the transactions between Living Data and Kerns, and the Company, with respect to the Securities Purchase

Agreement, the Distribution Agreement and the Supplier Agreement, as well as consulting services to the Company with no compensation.

During fiscal 2009, the Company purchased EECP® therapy systems under the Supplier Agreement for \$595,000 from Living Data. During fiscal 2010, the Company purchased additional EECP® therapy systems under the Supplier Agreement for \$509,450 from Living Data, including \$469,450 purchased in February 2010, as per an Amendment to the Supplier Agreement Dated February 28, 2010. Payment terms on certain purchases leave a balance of \$240,000 in Trade Payable to Related Party on the accompanying consolidated balance sheet as of May 31, 2010. In addition, during fiscal 2009, Living Data purchased \$3,118, worth of EECP® therapy system components from the Company.

During fiscal 2009 Living Data assigned to Vasomedical, Inc. all of its rights and interests under its Distributorship Agreement with a corporation organized and existing under the laws of the People's Republic of China, that manufactures Ambulatory Blood Pressure Monitors, Ambulatory ECG Recorders and Holter & ABPM Combiner Recorders, for \$20,000 payable to Living Data based on certain terms and conditions. Vasomedical also must pay to Living Data 5% of the selling price or 5% of the cost of all goods sold (whichever is higher), and 5% of the cost of all goods transferred but not sold under the Assignment Agreement to Living Data based on sales of this equipment. The Company now sells these systems in the United States and some other countries now that regulatory clearance had been obtained.

During fiscal 2009 Living Data assigned to Vasomedical, Inc. all of its rights and interests under its Distributorship Agreement with a corporation organized and existing under the laws of the People's Republic of China that manufactures Ultrasound Scanners, for \$20,000 payable to Living Data based on certain terms and conditions. Vasomedical also must pay to Living Data 5% of the selling price or 5% of the cost of all goods sold (whichever is higher), and 5% of the cost of all goods transferred but not sold under the Assignment Agreement to Living Data based on sales of this equipment. The Company has elected not to sell these systems in the United States and other countries.

Further, Kerns provides the Company, free of charge, part-time use of one of its Information Technology (IT) employees as well one of their IT consultants to provide the Company with IT and database support services. In addition, a clinical applications support specialist and a service engineer from Living Data were used by the Company during fiscal 2009 to provide customers with clinical training and technical service. The Company was charged \$3,900 for the services of the clinical applications support specialist and \$2,700 for the services of the service engineer during fiscal 2009.

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

Financial Reporting Release No. 60, which was released by the Securities and Exchange Commission, or SEC, in December 2001, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Note B of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended May 31, 2010 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. In accordance with the guidance in ASC Topic 605, we use the residual method to allocate the arrangement consideration when it does not have fair value of the EECP® system sale. Under the residual method, the amount of consideration allocated to the delivered item equals the total arrangement consideration less the aggregate fair value of the undelivered items. 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.

The Company has also entered into lease agreements for our EEC[®] systems, generally for terms of one year or less, that are classified as operating leases. Revenues from operating leases are generally recognized, in accordance with the terms of the lease agreements, on a straight-line basis over the life of the respective leases. For certain operating leases in which payment terms are determined on a “fee-per-use” basis, revenues are recognized as incurred (i.e., as actual usage occurs). The cost of the EEC[®] system utilized under operating leases is recorded as a component of property and equipment and is amortized to cost of sales over the estimated useful life of the equipment, not to exceed five years. There were no significant minimum rental commitments on these operating leases at May 31, 2010.

Accounts Receivable, net

The Company’s accounts receivable are due from customers engaged in the provision of medical services. 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 other allowances. 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 EEC[®] systems at various field locations for demonstration, training, evaluation, and other similar purposes at no charge. The cost of these EEC[®] 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 EEC[®] 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 EEC[®] 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.

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 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, 2010 and May 31, 2009. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

Stock-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 stock-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 2010.

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

The Company continually assesses any new accounting pronouncements to determine their applicability to the Company. Where it is determined that a new accounting pronouncement affects the Company’s financial reporting, the Company undertakes a study to determine the consequence of the change to its financial statements and assures that there are proper controls in place to ascertain that the Company’s financials properly reflect the change. New pronouncements assessed by the Company recently are discussed below:

In June 2009, FASB approved SFAS No. 168, the FASB Accounting Standards Codification (“the Codification”) as the single official source of authoritative U.S. GAAP (other than guidance issued by the SEC), superseding existing FASB, American Institute of Certified Public Accountants, Emerging Issues Task Force (“EITF”), and related literature. After that date, only one level of authoritative U.S. GAAP exists. All other literature is considered non-authoritative. The Codification did not change U.S. GAAP; instead, it introduced a new structure that is organized in an easily accessible, user-friendly online research system. The Codification, which changed the referencing of financial standards, is effective for interim and annual periods ending on or after September 15, 2009.

Fair Value Measurements and Disclosures

In January 2010, the FASB issued an update to ASC Topic 820, “Fair Value Measurements and Disclosures”, amending the disclosure requirements under Topic 820. The update requires additional disclosures for transfers in and out of Levels 1 and 2 fair value measurements, as well as enhanced disclosures for activity in Level 3 fair value measurements. In addition, the update also clarifies existing requirements regarding the level of disaggregation for assets and liabilities and disclosure of inputs and valuation techniques used to measure fair value. The additional disclosure requirements under ASC Topic 820 were effective for the Company beginning January 1, 2010 and did not have an impact on the Company’s consolidated financial statements.

In August 2009, the FASB issued an update to ASC Topic 820 that provides additional guidance on the fair value measurement of liabilities. Specifically, this update provides clarification in circumstances in which a quoted price in an active market is not available. The update to ASC Topic 820 was effective for the Company beginning July 1, 2009 and did not have an impact on the Company’s consolidated financial statements.

In June 2008, the FASB issued an update to ASC Topic 260, “Earnings Per Share”, that addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and, therefore, need to be included in the earnings allocation in computing earnings per share under the two-class method. The update to ASC Topic 260 requires unvested share-based payment awards that contain non-forfeitable rights to dividends or dividend equivalents (whether paid or unpaid) to be treated as participating securities and to be included in the computation of earnings per share pursuant to the two-class method. The revisions to ASC Topic 260 were effective for the Company beginning July 1, 2009 and did not have an impact on the Company’s consolidated financial statements.

In December 2007, the FASB issued an update to ASC Topic 805, “Business Combinations”, which significantly changed the accounting for business combinations in a number of areas, including the treatment of contingent consideration, pre-acquisition contingencies, transaction costs, restructuring costs and income taxes. The revisions to ASC Topic 805 were effective for acquisitions that occur after July 1, 2009 and did not have an impact on the Company’s consolidated financial statements.

In April 2008, the FASB issued an update to ASC Topic 350, “Intangibles — Goodwill and Other”, which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset. This amendment is effective on a prospective basis to all intangible assets acquired and for disclosures on all intangible assets recognized on or after the beginning of the first annual period subsequent to December 15, 2008. The amendment to ASC Topic 350 was effective for the Company beginning July 1, 2009 and did not have a material impact on the Company’s consolidated financial statements.

In October 2009, the FASB issued an update to ASC Topic 605, “Revenue Recognition”, 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 current requirements. This revised authoritative guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after December 15, 2009. Early adoption is permitted at the beginning of a company’s fiscal year. We adopted this guidance on June 1, 2010, and are evaluating the effect of the adoption on our consolidated 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, 2010 and have concluded that the Company’s disclosure controls and procedures were not effective as of May 31, 2010.

ITEM 9A(T) – CONTROLS AND PROCEDURES

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.

The Company believes it currently has a lack of adequate accounting resources to address non-routine transactions and certain financial reporting matters on a timely basis. Controls over the application of accounting policies are within the scope of internal controls. As a consequence, management has concluded that this lack of adequate accounting resources to address these issues is a material weakness in the Company's internal controls, as defined by the Public Company Accounting Oversight Board. The Company believes that this material weakness is in the process of being remedied.

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 not effective as of May 31, 2010. 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

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors of the Registrant

As of September 24, 2010, the members of our Board of Directors are:

Name of Director	Age	Principal Occupation	Director Since
Simon Srybnik (3)(4)	94	Chairman of the Board and Director	June, 2007
Derek Enlander (1)(2)	62	Director	July, 2007
Jun Ma	47	President and Chief Executive Officer	June, 2007
Behnam Movaseghi (2)	57	Director	July, 2007
William Dempsey (2)	56	Director	June, 2010
Peter C. Castle (1)	42	Director	August, 2010

(1) Member of the Audit Committee

(2) Member of Compensation Committee

(3) Member of the Corporate Governance Committee

(4)

Ex-officio member of all committees

The following is a brief account of the business experience for at least the past five years of our directors:

Simon Srybnik has been a director since June 2007 and Chairman of the Board since June 2010. He is the Chairman of the Board of Kerns Manufacturing Corp. and Living Data Technology Corp. A lifetime entrepreneur and industrialist, Mr. Srybnik has founded and managed many companies in various industries including machinery and process equipment, aerospace and defense, biology and healthcare.

Derek Enlander M.D. has been a director since July 2007. He is an attending physician at the Mount Sinai Medical Center New York, and a clinical instructor at the Mount Sinai Medical School. He is in private practice in Internal Medicine in Manhattan. He is the author of six books on medicine and over twenty research papers. He has invented a new drug to treat immune dysfunction and is the President of Computer Medica Inc., where he invented a Medical History card to store a patient's medical files including X-rays, MRIs, etc. on a credit card size computer readable card.

Jun Ma, PhD has been a director since June 2007 and was appointed President and Chief Executive Officer of the Company on October 16, 2008. Dr. Jun Ma has been an associate professor in engineering at New York Institute of Technology since 1997 and an assistant professor from 1993 to 1997. Previously Dr. Ma provided technology and business consulting services to several companies in aerospace, automotive, biomedical, medical device, and other industries, including Kerns Manufacturing Corp. and Living Data Technology Corp., both of which are stockholders of our Company.

Behnam Movaseghi has been a director since July 2007. Mr. Movaseghi has been treasurer of Kerns Manufacturing Corporation since 2000, and controller from 1990 to 2000. For approximately ten years prior thereto Mr. Movaseghi was a tax and financial consultant. Mr. Movaseghi is a Certified Public Accountant.

William Dempsey has been a director since June 2010. Mr. Dempsey is the former owner and Managing Director of Cardiac Services Ireland, Ltd., a healthcare and distribution company in Ireland and the United Kingdom. He has over 30 years experience in the healthcare and distribution market in Ireland. Mr. Dempsey successfully built and grew Cardiac Services Ireland Ltd. into one of the country's leading suppliers of cardiology, anesthesia, imaging, fetal and obstetrical patient monitoring and resuscitation products.

Peter Castle has been a director since August 2010. Mr. Castle is currently the President and Chief Operating Officer of NetWolves Corporation, where he has been employed since 1998. Mr. Castle also held the position of Chief Financial Officer from 2001 until October 2009, Vice President of Finance since January 2000, Controller from August 1998 until December 1999 and Treasurer and Secretary from August 1999. NetWolves is a global telecommunications and Internet managed services provider offering single-source network solutions that provides multi-carrier and multi-vendor implementation to over 1,000 customers worldwide.

Committees of the Board of Directors

Audit Committee and Audit Committee Financial Expert

The Board has a standing Audit Committee. The Board has affirmatively determined that each director who serves on the Audit Committee is independent, as the term is defined by applicable Securities and Exchange Commission ("SEC") rules. During the fiscal year ended May 31, 2010, ("fiscal 2010") the Audit Committee consisted of Photios T. Paulson, who served as the committee chair during fiscal 2010, Derek Enlander and Martin Zeiger until his resignation in April 2010. The members of the Audit Committee have substantial experience in assessing the performance of companies, gained as members of the Company's Board of Directors and Audit Committee, as well as by serving in various capacities in other companies or governmental agencies. As a result, they each have an understanding of financial statements. The Board believes that the addition of Peter Castle in August 2010 fulfills the role of the financial expert on this committee.

The Audit Committee regularly meets with our independent registered public accounting firm outside the presence of management.

The Audit Committee operates under a charter approved by the Board of Directors. The Audit Committee charter is available on our website.

Compensation Committee

Our Compensation Committee annually establishes, subject to the approval of the Board of Directors and any applicable employment agreements, the salaries that will be paid to our executive officers during the coming year, as well as administers our stock-based benefit plans. During fiscal 2010, the Compensation Committee consisted of Martin Zeiger, who served as the committee chair, until his resignation in April 2010, Derek Enlander, and Photios T. Paulson. None of these persons were our officers or employees during fiscal 2010 or, except as otherwise disclosed, had any relationship requiring disclosure in this Form 10-K/A.

The Compensation Committee operates under a charter approved by the Board of Directors. The Compensation Committee charter is available on our website.

Corporate Governance Committee

The Board of Directors has established a Corporate Governance Committee. During fiscal 2010, the Corporate Governance Committee consisted of John C.K. Hui, who served as committee chair until his resignation in June 2010, Simon Srybnik and Martin Zeiger until his resignation in April 2010. The Corporate Governance Committee monitors developments in corporate governance principles and other corporate governance matters and makes recommendations to the Board of Directors regarding the adoption of additional corporate governance principles.

The Corporate Governance Committee operates under a charter approved by the Board of Directors. The Corporate Governance Committee charter is available on our website.

MEETINGS OF THE BOARD OF DIRECTORS AND COMMITTEES

During the fiscal year ended May 31, 2010 there were:

- 7 meetings of the Board of Directors
- 4 meetings of the Audit Committee
- 1 meeting of the Compensation Committee

The Corporate Governance Committee did not hold any meetings during the fiscal year ended May 31, 2010.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires directors, executive officers and persons who beneficially own more than 10% of our common stock (collectively, "Reporting Persons") to file initial reports of ownership and reports of changes in ownership of our common stock with the SEC. Reporting Persons are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file. To our knowledge, based solely on our review of the copies of such reports received or written representations from certain Reporting Persons that no other reports were required, we believe that during fiscal 2010, all Reporting Persons timely complied with all applicable filing requirements.

Corporate Governance - Code of Ethics

We have adopted a Corporate Code of Business Ethics (the "Code") that applies to all employees, including our principal executive officer, principal financial officer, and directors of the Company. A copy of the Code can be found on our website, www.vasomedical.com. The Code is broad in scope and is intended to foster honest and ethical conduct, including accurate financial reporting, compliance with laws and the like. If any substantive amendments are made to the Code or if there is any grant of waiver, including any implicit waiver, from a provision of the Code to our Chief Executive Officer or Chief Financial Officer, we will disclose the nature of such amendment or waiver in a Current Report on Form 8-K.

Executive Officers of the Registrant

As of September 24, 2010 our executive officers are:

Name of Officer	Age	Position held with the Company
Jun Ma, PhD	47	President, Chief Executive Officer and Director
Jonathan Newton	49	Chief Financial Officer
John C.K. Hui, PhD	64	Senior Vice-President and Chief Technology Officer

Jonathan P. Newton was appointed Chief Financial Officer of the Company effective September 1, 2010. From June 2006 to August 2010, Mr. Newton was Director of Budgets and Financial Analysis for Curtiss-Wright Flow Control. His responsibilities included the development of sophisticated financial forecasting models, preparing the annual budget, long-term strategic planning, cost analysis and SOX compliance. From August 2001 to June 2006, Mr. Newton was Vasomedical's Director of Budgets and Analysis. In that capacity, his responsibilities included preparing annual budgets and forecasts, revenue, margin and cost analyses for management and the Company's outside auditors, Board of Directors presentations, and preparation of the Company's quarterly and annual SEC filings. Prior positions included Controller of North American Telecommunications Corp., Accounting Manager for Luitpold Pharmaceuticals, positions of increasing responsibility within the internal audit function of the Northrop Grumman

Corporation and approximately three and one half years as an accountant for Deloitte Haskins & Sells, during which time Mr. Newton became a certified public accountant . Mr. Newton holds a B.S. in Accounting from SUNY at Albany, and a B.S. in Mechanical Engineering from Hofstra University.

John C. K. Hui, Ph.D. has been our Senior Vice President and Chief Technology Officer since October 16, 2008, our President, Chief Executive Officer and Chief Technology Officer from April 1, 2007 through October 15, 2008, as well as a director since February 1995. From February 1995 until April 2007, he was a Senior Vice President. Dr. Hui has been an Assistant Professor in the Department of Surgery and Division of Cardiology at the State University of Stony Brook, New York since 1978. He has also been a scientist in the medical department of Brookhaven National Laboratories. Dr. Hui was CEO and President of and a principal stockholder in Vasogenics, Inc. at the time of its acquisition by us in January 1995.

ITEM 11 - EXECUTIVE COMPENSATION

The following table sets forth the annual and long-term compensation of our Chief Executive Officer and each of our most highly compensated officers who were serving as executive officers at the end of the last completed fiscal year, and certain former executive officers as required under SEC rules (collectively, the “Named Executive Officers”) for services rendered for fiscal 2010 and the year ended May 31, 2009 (“fiscal 2009”).

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards (\$)	Option Awards (\$)(2)	Non-Equity	Nonqualified	All	Total (\$)
						Incentive Compensation (\$)	Deferred Earnings (\$)	Other Compensation (\$)(1)	
Jun Ma, PhD Chief Executive Officer (3)	2010	\$ 148,471	-	\$ 25,000	\$ 20,000	-	-	\$ 1,195	\$ 194,666
John C. K. Hui Senior Vice President and Chief Technology Officer (Chief Executive Officer) (4)	2009	\$ 97,817	-	\$ 10,000	-	-	-	\$ 583	\$ 108,400
Tarachand Singh (Chief Financial Officer) (5)	2010	\$ 157,151	-	\$ 20,000	-	-	-	\$ 22,286	\$ 199,437
Tricia Efstathiou (Chief Financial Officer) (6)	2009	\$ 178,525	-	-	-	-	-	\$ 19,049	\$ 197,574
	2009	\$ 120,000	-	-	-	-	-	\$ 11,368	\$ 131,368
	2009	\$ 26,630	-	\$ 4,000	-	-	-	\$ 2,858	\$ 33,488
	2009	\$ 78,953	-	-	-	-	-	\$ 8,405	\$ 87,358

(1) Represents premiums paid on medical, dental, life and disability group benefit plans, as well as amounts matched in the Company’s 401(k) Plan.

(2) Option awards are valued at the fair market value times the number of shares (which represent the fair market value of the underlying common stock at the time of the respective grants).

(3) Dr. Ma has served as President and Chief Executive Officer since October 16, 2008; Dr. Ma received common stock valued at \$5,000 for service as a director prior to being named President and Chief Executive Officer.

(4) Dr. Hui was President and Chief Executive Officer from April 30, 2007 to October 15, 2008.

(5) Mr. Singh was Chief Financial Officer from March 11, 2009 to August 26, 2010.

(6)