VASOMEDICAL INC
Form 10-K
August 28, 2006

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

[X] ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended May 31, 2006

[ ] 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 jurisdiction of incorporation or organization)	(IRS Employer Identification 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, $.001 par value
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [ ] No [X]

Indicate by a 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 preceding 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 [X] No [ ]

Indicate by a check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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, or a non-accelerated filer. Large Accelerated Filer [ ] Accelerated Filer [ ] Non-Accelerated Filer [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 the voting and non-voting common equity held by non-affiliates of the registrant (based on the closing sale price of $0.42 as of November 30, 2005, was approximately $23,831,000. Shares of common stock held by each officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. The determination of affiliates status is not necessarily a conclusive determination for other purposes.

At August 16, 2006, the number of shares outstanding of the issuer's common stock was 65,198,592.

DOCUMENTS INCORPORATED BY REFERENCE

Part III - (Items 10, 11, 12, 13 and 14) Registrant's definitive proxy statement to be filed pursuant to Regulation 14A of the Securities Exchange Act of 1934.

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PART I

PART II

PART III

PART I

ITEM 1 - BUSINESS

Except for historical information contained herein, the matters discussed are forward looking statements that involve risks and uncertainties. When used herein, words such as "anticipates", "believes", "estimates", "expects", "feels", "plans", "projects" and "intends" and similar expressions, as they relate to us, identify forward-looking statements In addition, any statements that refer to our plans, expectations, strategies or other characterizations of future events or circumstances are forward-looking statements. Such forward-looking statements are based on our beliefs, as well as assumptions made by and information currently available to us. Among the factors that could cause actual results to differ materially are the following: 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 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 our SEC reports. We undertake 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(R) enhanced external counterpulsation systems based on our unique proprietary technology currently indicated for use in cases of stable or unstable angina (i.e., chest pain), congestive heart failure (CHF), acute myocardial infarction (i.e., heart attack, (MI)) and cardiogenic shock. The EECP therapy system is a non-invasive, outpatient therapy for the treatment of diseases of the cardiovascular system. The therapy serves to increase circulation in areas of the heart with less than

adequate blood supply and helps to restore systemic vascular function. 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. EECP is a registered trademark for Vasomedical's enhanced external counterpulsation systems.

We have incurred declines in revenue and significant operating losses during the last three fiscal years and our ability to continue operating as a going concern is dependent upon achieving profitability or through additional debt or equity financing. Achieving 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 is largely dependent upon restructuring our sales and marketing efforts in the angina market where reimbursement is currently available and operating in a more efficient manner. If we are not able to reverse the trend of declining revenue and sufficiently reduce operating costs to generate an adequate cash flow, or raise additional capital, we will not be able to continue as a going concern.

In order to reduce the cash burn and bring our cost structure more into alignment with current revenue, we initiated a company restructuring in January 2006, to reduce personnel and spending on marketing and development projects. We anticipate that the restructuring will reduce manufacturing and operating cost by approximately $3 million per year compared to prior levels. In addition, in April 2006, the board of directors elected to defer meeting fees and certain senior executives elected to defer approximately $0.4 million in annual salary compensation. We believe that these steps to conserve cash will provide the Company with the opportunity to rebuild sales to a profitable level and/or explore strategic opportunities.

Based on the continuation of current revenue levels and the implementation of our restructuring plan initiated in January 2006, we believe that we will be able to fund our minimum projected capital requirements through at least the end of the calendar year.

In the event that additional capital is required, we may seek to raise such capital through public or private equity or debt financings or other means. We may not be able to obtain additional financing on favorable terms or at all. If we are unable to raise additional funds when we need them, we may be required to further scale back our operations, research, marketing or sales efforts or obtain funds through arrangements with collaborative partners or others that may require us to license or relinquish rights to technologies or products. Future capital funding, if available, may result in dilution to current shareholders, and new investors could have rights superior to existing stockholders.

Market Overview

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 2.4 million lives in the United States in 2003 and was responsible for 1 of every 2.7 deaths, according to The American Heart Association (AHA) Heart and Stroke Statistical 2006 Update (2006 Update). Approximately 71.3 million Americans suffer from some form of cardiovascular disease. Among these, 12.0 million have coronary heart disease (CHD).

We have Food and Drug Administration (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 limited to the treatment of stable angina and congestive heart failure indications. Within the stable angina and CHF indications,

Medicare and other third-party payers currently reimburse for stable angina patients with moderate to severe symptoms who do not adequately respond or are not amenable to medications and not candidates for invasive procedures. Ischemic heart failure patients are also reimbursed under the same criteria provided they have documented history of coronary artery disease (CAD) and they are being treated for angina or angina equivalent symptoms as outlined in the American College of Cardiology/American Heart Association 2002 Guideline Update for the Management of Patients With Chronic Stable Angina.

We have actively engaged in research to establish the potential benefits of EECP therapy in the management of CHF and sponsored a pivotal study to demonstrate the efficacy of EECP therapy in the most prevalent types of heart failure patients. This study, known as PEECH (Prospective Evaluation of EECP in Congestive Heart Failure), provided additional clinical data in order to support the use of EECP therapy in the treatment of CHF. The preliminary results of the trial were presented at the American College of Cardiology scientific sessions in March 2005, and we expect the results of the PEECH clinical trial to be published in a peer-reviewed journal. In June 2005 we submitted an application to the Centers for Medicare and Medicaid Services (CMS) for expanded coverage of EECP therapy to include CHF as a primary indication, plus expanded coverage for patients with milder angina. In March 2006, CMS issued a final decision not to expand coverage and keep the existing coverage as stated prior to our application. CMS has advised us that in order for them to fully consider the results of the PEECH clinical study it must be published in a peer-reviewed medical journal, therefore we intend to submit a revised application to CMS to again consider expanding coverage for heart failure patients once the study is published.

However, there can be no assurance that our revised application will be accepted by CMS for review or that reimbursement coverage will be expanded even if the application is accepted for review. If we are unable to obtain an adequate national Medicare coverage policy for treatment procedures using EECP therapy on patients with CHF, it would adversely affect our future business prospects.

Angina

Angina pectoris is the medical term for a recurring pain or discomfort in the chest due to coronary heart disease. Angina is a symptom of a condition called myocardial ischemia, which occurs when the heart muscle or myocardium doesn't receive as much blood, hence as much oxygen, as it needs. This usually happens because one or more of the heart's arteries, the blood vessels that supply blood to the heart muscle, is narrow or blocked. Insufficient blood supply to meet the need of the organ to function is called ischemia.

The cardinal symptom of stable CAD is anginal chest pain or equivalent symptoms, such as exertional dyspnea. Angina is uncomfortable pressure, fullness, squeezing or pain usually occurring in the center of the chest under the breastbone. The discomfort also may be felt in the neck, jaw, shoulder, back or arm. Often the patient suffers not only from the discomfort of the symptom itself but also from the accompanying limitations on activities and the associated anxiety that the symptoms may produce. Uncertainty about prognosis may be an additional source of anxiety. For some patients, the predominant symptoms may be palpitations or syncope that is caused by arrhythmias or fatigue, edema, or orthopnea caused by heart failure. Episodes of angina occur when the heart's need for oxygen increases beyond the oxygen available from the blood nourishing the heart. Physical exertion is the most common though not only trigger for angina. For example, running to catch a bus could trigger an attack of angina while walking might not. Angina may happen during exercise, periods of emotional stress, exposure to extreme cold or heat, heavy meals, alcohol consumption or cigarette smoking. Some people, such as those with a coronary artery spasm, may have angina when they are resting.

There are approximately 6.4 million angina patients in the United States and our EECP therapy currently competes with other technologies in the market for approximately 130,000 new angina patients annually who do not adequately respond to or are not amenable to medical and surgical therapy and have the potential to meet the guidelines for reimbursement of EECP therapy. Most angina patients are treated with medications, including beta blockers to slow and

protect the heart and vasodilators, which are often prescribed to increase blood flow to the coronary arteries. When drugs fail or inadequately correct the problem the patients are considered unresponsive to medical therapy. If the patient is readily amenable, invasive revascularization procedures such as angioplasty and coronary stent placement, as well as coronary artery bypass grafting (CABG) are often employed.

In February 1999, the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers the Medicare program for more than 39 million beneficiaries, issued a national coverage policy for the use of external counterpulsation therapy in the treatment of angina. Medicare reimbursement guidelines have a significant impact in determining the available market for EECP therapy. We believe that over 65% of the patients that receive EECP therapy are Medicare patients and many of the third-party payers follow Medicare guidelines, which limits reimbursement for EECP therapy to patients who do not adequately respond to or are not amenable to medical therapy and are not readily amenable to surgical 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 enabling EECP therapy to compete more with other therapies for ischemic heart disease. Please see the heading "Reimbursement" in the "Item-1 Business" section of this Form 10-K for a more detailed discussion of reimbursement issues.

Congestive Heart Failure

CHF is a condition in which the heart loses its full 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 2006 Update, in 2003 approximately 2.4 million men and 2.6 million women in the US had CHF and about 550,000 new cases of the disease occur each year. Deaths caused by the disease increased 20.5% from 1993 to 2003. 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 CHF. The economic burden of congestive heart failure is enormous with an estimated 2005 cost to the health care system in the United States of $29.6 billion. 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(TM) (IEPR) at the University of Pittsburgh Graduate School of Public Health shows that approximately one-third of angina patients treated also have a history of CHF and have demonstrated positive outcomes from EECP therapy.

The PEECH clinical trial provided additional clinical evidence to demonstrate the potential benefits of EECP therapy in the management of CHF, and we included a summary of the results of the PEECH trial in our application to CMS to expand reimbursement coverage to include CHF. The application was accepted by CMS on June 20, 2005, and CMS announced their final decision not to expand coverage on March 20, 2006. Since the PEECH trial had not been published in a peer-reviewed journal prior to CMS issuing a final decision, we intend to resubmit a new application to CMS requesting additional coverage to include heart failure patients once the PEECH manuscript is published. However, there can be no assurance that the results of the PEECH trial or other clinical evidence will be sufficient to support expansion of the Medicare national coverage policy for EECP treatment.

The EECP Therapy Systems

The EECP therapy systems are advanced 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 due to 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 counterpulse in the arterial system, forcing freshly oxygenated blood towards the heart and coronary arteries at a time when resistance to coronary blood flow is at its lowest level. The counter pulse also simultaneously increases the volume of venous blood return to the heart when the heart is filling up for ejection in the contracting phase. Just prior to the next heartbeat when the heart begins to eject blood by contracting (systole), all three cuffs simultaneously deflate, 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 a computerized console 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. The end result of this sequential "squeezing" of the legs is to create a pressure wave that significantly increases peak diastolic pressure benefiting circulation to the heart muscle and other organs, increases venous return so that the heart has more blood volume to

eject out, and increases cardiac output. The release of external pressure produces reduction of systolic pressure, thereby reducing the workload of the heart. This reduction of vascular resistance insures that the heart does not have to work as hard to pump large amounts of blood through the body to help supply its metabolic needs.

While the precise scientific means by which EECP therapy achieves its long-term beneficial effects are only partially explained, 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 are 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 insure 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 required 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 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, Dr. Zheng and colleagues 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 treatment with the EECP system reduced the frequency and severity of anginal symptoms during normal daily functions and also 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 studies, though open label and non-randomized, showed significant improvement in exercise tolerance by patients as evidenced by 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 have been 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 New York Heart Association (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 (Prospective Evaluation of EECP in Congestive Heart Failure), began patient enrollment in March 2001. The PEECH clinical trial involved nearly thirty centers including: the Cleveland Clinic, Mayo Clinic, Scripps Clinic, Thomas Jefferson University Hospital, the University of North Carolina at Chapel Hill, the Minnesota Heart Failure Consortium, Advocate Christ Hospital, Hull Infirmary (UK), the University of California at San Diego Medical Center, the University of Pittsburgh Medical Center, the Lindner Clinical Trial Center and the Cardiovascular Research Institute. 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) medical 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.

On March 8, 2005, the preliminary PEECH clinical trial results were presented by Arthur M. Feldman, MD, PhD, Principal Investigator, in a Late Breaking Clinical Trials session of the American College of Cardiology ("ACC") Annual Scientific Session. Simultaneously, the Company announced the positive results of the trial to the public in a Press Release.

In designing the PEECH trial, success was demonstrated if the difference between EECP therapy combined with optimal medical therapy compared to optimal medical therapy alone achieved a p-value less than 0.025 in at least one of two pre-defined co-primary endpoints:

1. percentage of subjects with greater than or equal to 60 seconds improvement in exercise duration from baseline to six months, or

2. percentage of subjects with at least 1.25 mL/kg/min increase in peak oxygen consumption from baseline to six months.

Additional secondary endpoints were actual changes in exercise duration and peak oxygen consumption, changes in New York Heart Association ("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 (35.4% vs. 25.3%, p=0.016). 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.

Consistent with the results on the primary endpoint of exercise duration, statistically significant differences favoring the EECP-treated group were seen in changes in average exercise duration, symptom status and quality of life during follow-up. Average peak oxygen consumption showed a trend favoring the EECP group at 1 week, but there were no differences detected at later follow-up. Results in patients with heart failure of ischemic etiology were noted to be clearly superior to those patients of idiopathic etiology though the benefit in these later patients could not be ruled out statistically. 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.

Moreover, results of a predefined subgroup analysis showed that patients 65 years of age or older not only had a significantly greater response rate (co-primary endpoint) and average change in exercise duration favoring EECP-treated patients, but the response rate (co-primary endpoint) and average change in peak oxygen consumption were also significantly better out to completion of the study at six months follow-up.

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. There can be no assurance that the results of the PEECH clinical trial will be sufficient to expand reimbursement coverage or the adoption by the medical community of EECP therapy for use in the treatment of congestive heart failure.

The International EECP Patient Registry (IEPR(TM))

The International EECP Patient Registry at the University of Pittsburgh Graduate School of Public Health was established in January 1998 to track the outcomes of angina patients who have undergone EECP therapy. More than one hundred centers have participated in the registry and data from more than 5,000 patients from an initial cohort enrolled between 1998 and 2001 (IEPR-1) have been tabulated and reported in several peer-reviewed publications.

The American Journal of Cardiology published a report in February of 2004 on the two-year outcomes after EECP therapy observed in 1,097 patients with two-year follow-up enrolled in IEPR-1. The authors noted that 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. They characterized this improvement as a "significant and dramatic reduction in CCSC" and stated that the adverse clinical event rate was low. (CCSC, or Canadian Cardiovascular Society Classification, is a rating scale used by physicians to assess the limitations imposed on patients' lives by angina.) Patients also reported improvement in health status, quality of life and satisfaction with life.

At two-years 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 per cent 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 summarize 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."

In a separate report that appeared in The American Journal of Cardiology in 2005, physician investigators participating in the IEPR(TM) reported on the results of EECP therapy in patients with angina who also had severe left ventricular dysfunction (LVD, a reduced pumping capacity of the heart). Previously it was thought that such patients, and those with a diagnosis of heart failure, would be put at risk if treated with EECP therapy, due to the increase in venous return to the heart caused by compression of the leg veins by enhanced external counterpulsation.

The 363 patients in this cohort had long-standing and extensive coronary artery disease, had a high prevalence of cardiovascular disease risk factors, were not amenable to invasive revascularization procedures, and suffered from severe angina. Following completion of EECP treatment, 77% decreased their CCSC angina class by at least one severity rating. The average number of angina episodes per week was greatly reduced and many were able to discontinue the use of nitroglycerin pills designed to relieve angina. As in the overall IEPR population, measures of quality of life were significantly improved after treatment.

The rate of major adverse clinical events, while somewhat more frequent in this group of patients with significant comorbid disease, was characterized as low over the course of EECP therapy. Exacerbation of heart failure was significantly more frequent in patients who did not complete therapy compared to

those who did (16% vs. 0%) in patients with a previous history of heart failure.

At two-years of follow-up, 83% remained alive and 70% were free of death, heart attack or invasive revascularization procedures (coronary artery bypass surgery, angioplasty and/or stenting) during that period. The majority of patients experienced sustained relief of their angina and improved quality of life. Twenty per cent of the group underwent repeat EECP therapy during the two-year follow-up, mostly due to failure to complete the original course of therapy.

A second phase of enrollment into the registry (IEPR-2) enrolled approximately 2,500 patients between 2002 and 2004 and these patients are currently being followed to 2-year follow-up. IEPR-2 incorporates sub-studies regarding treatment beyond 35 hours, possible predictors of response, effects on certain aspects of peripheral vascular disease and sexual dysfunction in men. Notably, the data set was modified in February 2003 to capture information on changes in heart failure symptom status, occurrence of clinical events due to heart failure and to include a heart failure-specific quality of life questionnaire in IEPR-2 patients with concomitant heart failure.

Vasomedical considers the IEPR(TM) to be a vital source of information about the effectiveness and safety of EECP(R) therapy in a real-world environment for the medical community at large. To date, eighteen full-length articles reporting data from the IEPR(TM) have been published in peer-review medical journals and more than seventy-five abstracts have been presented at a variety of major cardiovascular scientific conferences. For this reason, we continue to provide an ongoing grant to fund the registry to publicize data that assists clinicians in delivering optimal care to patients.

Registry data, while considered a valuable source of complementary clinical data, is deemed by scientific cardiologists and others to be less convincing than data from randomized, 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 upon results observed in patients enrolled in registries.

Other studies and publications

A search on the term "external counterpulsation" of the PubMed database available through the National Library of Medicine conducted on August 21, 2006, identified one-hundred-ninety-eight (198) citations of articles published in the medical scientific literature, including 28 review articles. The vast majority of these publications have reported results in patients with chronic stable angina and/or heart failure treated with EECP therapy, while others have reported use of the device in other cardiovascular or non-cardiovascular indications. The vast majority of these reports are generated using Vasomedical EECP therapy systems and equipment. 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 Initiatives

Our short- and long-term plans are to:

a) reduce the cash burn and bring our cost structure into alignment with current revenue in the short term by:
   i) reducing or eliminating spending on all but critical new product development and clinical research projects,
   ii) focusing on rebuilding our revenue base supporting our direct sales effort and expanding our use of independent sales representatives, and
   iii) maintaining tight cost 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) completing the analysis of the PEECH clinical trial, publishing the results in a major peer-reviewed medical journal and resubmitting data 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 and

e) Increase awareness of the benefits of the EECP therapy in the medical 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 establishment of a distribution network and the seeking of reimbursement approvals.

f) Maintain development efforts to improve the EECP system and expand its intellectual property estate by filing for additional patents in the United States and other countries.

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 resources available reduce our ability to achieve these strategic objectives. Please see the section of this Form 10-K entitled "Risk Factors" for a description of certain risks among others that may cause our actual results to vary from the forward-looking statements.

Sales and Marketing

Domestic Operations

We sell EECP therapy systems to treatment providers such as hospitals, clinics and physician private practices in the United States through a direct and indirect sales force. Our sales force is a combination of employees and independent sales representatives managed by a vice president of sales plus in-house administrative support.

The efforts of our sales organization are further supported by a staff of clinical educators who are responsible for the onsite training of physicians and therapists as new centers are established. This clinical applications group is also engaged in training and certification of new personnel at each site, as well as for 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 creating awareness among third-party payers to 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, preventative maintenance, 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 product internationally through a network of independent distributors. It has generally been our policy to appoint distributors exclusive marketing rights to EECP therapy systems in their respective countries, 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. In most cases, distributors must assist us either to obtain an FDA-equivalent marketing clearance, country registration or to establish confirmatory clinical trials, conducted by local key opinion leaders in cardiology, required to obtain Ministry of Health approval, certification or reimbursement. Each distributor is responsible for registering the product and obtaining any required regulatory or clinical approvals, supporting local reimbursement efforts for EECP therapy and maintaining an infrastructure to

provide post-sales support.

To date, revenues from international operations have not been significant. Revenues from non-domestic markets were 8%, 9% and 4% for the fiscal years ended May 21, 2006, 2005, and 2004, respectively. Our international marketing activities include, among other things, assisting in obtaining national or third-party healthcare insurance reimbursement approval and participating in 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, other trade regulations and local medical regulations. Tariff and trade policies, domestic and foreign tax and economic policies, 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 four direct competitors with an external counterpulsation device on the market, namely Cardiomedics, Inc., ACS, Scottcare and Living Data Technologies Corporation. In addition, other companies have 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, biotechnology and 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), cardiac recovery systems, total artificial hearts, cardiac resynchronization devices, ranolazine and nesiritide (Natrecor(R)); as well as newer technologies currently in FDA-approved clinical trials such as 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.

Device Classification

FDA regulates medical devices, including the requirements for premarket

review, according to their classification. Class I devices are generally lower risk products for which general regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness. Most Class I devices are exempt from the requirement of 510(k) premarket notification clearance; however, 510(k) clearance is necessary prior to marketing a non-510(k) exempt Class I device in the United States. Class II devices are devices for which general regulatory controls are insufficient, but for which there is sufficient information to establish special controls, such as guidance documents or standards, to provide reasonable assurance of safety and effectiveness. A premarket notification clearance is necessary prior to marketing a non-510(k) exempt Class II device in the United States. Class III devices are 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 approve a premarket approval or PMA application prior to marketing a Class III device in the United States.

A medical device is considered by FDA to be a preamendments device, and generally not subject to premarket review, if it was commercially distributed before May 28, 1976, the date the Medical Device Amendments of 1976 became law. A postamendments device is one that was first distributed commercially on or after May 28, 1976. Postamendments device versions of preamendments Class III devices are subject to the same requirements as those preamendments devices. FDA may require a PMA for a preamendments Class III device only after it publishes a regulation calling for such PMA submissions. Persons who market preamendments devices must submit a PMA, and have it filed by FDA, by a date specified by FDA in order to continue marketing the device. Prior to the effective date of a regulation requiring a PMA, devices must have a cleared premarket notification or 510(k) for marketing.

Certain external counterpulsation devices were commercially distributed prior to May 28, 1976. Our external counterpulsation devices were marketed after 1976; however, they were found to be substantially equivalent to a preamendments Class III device and therefore are subject to the same requirements as the preamendments external counterpulsation devices.

Premarket Review

The 510(k) premarket notification process requires an applicant to give notice to FDA of its intent to introduce its device into commerce. In its premarket notification, the applicant must demonstrate that its new or modified medical device is substantially equivalent to a legally marketed or predicate device. Prior to beginning commercialization of the new or modified product it must receive an order from the FDA classifying the device under section 510(k) in the same classification as the predicate device, and as a result, the new device will be cleared for marketing. 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). In February 1995, the Company received 510(k) clearance to market the second-generation version of its EECP therapy system, the MC2, which incorporated a number of technological improvements over the original system. In addition, 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.

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). FDA publishes guidance for medical device manufacturers on the types of changes that meet the requirements for a new 510(k) prior to introduction of a device for marketing distribution. Vasomedical followed FDA's guidance on when to submit a new 510(k) for changes to a device and concluded that the changes incorporated into its Model TS4 did not require a new 510(k) prior to its introduction to market. Vasomedical subsequently obtained a 510(k) that applied to the Model TS4 and all of its models in March 2004, when it made changes to the labeling of all of its EECP therapy systems. In November 2004, the Company introduced its Model Lumenair, and again concluded that the changes did not require a new 510(k) at that time. There can be no assurance that the FDA will agree with Vasomedical's 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.

If a device does not receive a clearance order because the FDA determines that the device is not substantially equivalent to a predicate device and thus the device automatically is considered a Class III device, the applicant may ask the FDA to make a risk-based classification to place the device in Class I or II. However, if a timely request for risk-based classification is not made, or if the FDA determines that a Class III designation is appropriate, an approved PMA will be required before the device may be marketed.

The more rigorous premarket review process is the PMA process. The FDA approves a PMA if the applicant has provided sufficient valid scientific evidence to prove that the device is safe and effective for its intended use(s). Applications for premarket approval generally contain human clinical data. This process is usually much more complex, time-consuming and expensive than the 510(k) process, and is uncertain. Both 510(k)s and PMAs now require the submission of user fees in most circumstances.

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 FDA before the trial may begin. A significant risk device is a device that presents a potential for serious risk to the subject and is an implant; is life-sustaining or life-supporting; or is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health. For all clinical testing, the sponsor must obtain informed consent from the patients participating in each trial. 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 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 postmarket 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 the EECP system, we must first obtain approval from the local medical device regulatory authority. The regulatory review process varies from country to country and can be complex, costly, uncertain, and time-consuming.

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 last 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 were 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 several oral or poster presentations at major scientific meetings and in peer-reviewed publications each year, there continues to be skepticism in the cardiology community about its broader use. Additional evidence regarding the efficacy of EECP therapy 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 for commercialization by government agencies, 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 coverage 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 authorization from the FDA or a foreign authority to begin commercial distribution, there may be limited demand for the device until reimbursement approval has been obtained from 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 and obtaining coverage in selected international markets.

Current Medicare Coverage in Angina

In February 1999, the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers the Medicare program for more than 39 million

beneficiaries, issued a national coverage policy under HCPCS code G0166 for the use of the EECP therapy system. Key excerpts from the coverage read as follows:

> "Although ECP devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered, since only that use has developed sufficient evidence to demonstrate its medical effectiveness."
>
> "for patients who have been diagnosed with disabling angina (class III or class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical interventions such as balloon angioplasty and cardiac bypass because:
>
> 1. their condition is inoperable, or at high risk of operative complications or post-operative failure;
> 2. their coronary anatomy is not readily amenable to such procedures; or
> 3. they have co-morbid states, which create excessive risk."

The 2006 national average payment rate per hourly session in the physician office setting and the hospital outpatient facility is approximately $138 and $104, respectively. Reimbursement rates vary throughout the country and range from $113 to $231 per hourly session. Under the Medicare program, physician reimbursement of the provision of EECP therapy is higher if the therapy is performed in a physician office setting as compared to a hospital outpatient facility in order to reflect higher costs associated with the physician office. Since January 2000, the national average payment rate has varied considerably.

The initial national average payment rate for the physician office setting and the hospital outpatient facility in 2000 was approximately $130 and $112, respectively per hourly session. The average payment rate for the physician office setting climbed to $208 per treatment session in 2003 before being reduced approximately 37% in 2004 to $132 per treatment session. In 2005 the physician rate increased approximately 5% and remained unchanged in 2006. The average payment rate for the hospital outpatient facility declined steadily to 2005 before increasing approximately 2% in 2006.

In order to bill and receive payment from Medicare, an individual or entity must be enrolled in the Medicare program for EECP therapy. The physician office setting and the hospital outpatient facility are the only entities currently authorized to receive reimbursement for the EECP therapy under the Medicare program and reimbursement is not permitted to other individuals or entity types, which include, but are not limited to, nurse practitioners, physical therapists, ambulatory surgery centers, nursing homes, comprehensive outpatient rehabilitation facilities, outpatient dialysis facilities, and independent diagnostic testing facilities. For each of these provider types there is statutory authorization and accompanying regulations that govern the terms and conditions of Medicare program participation.

If there were any material change in the availability of Medicare coverage, or if the reimbursement level for treatment procedures using the EECP therapy system is determined to be inadequate, it would adversely affect our business, financial condition and results of operations. Moreover, we are unable to forecast what additional legislation or regulation, if any, relating to the health care industry or Medicare coverage and payment level may be enacted in the future, or what effect such legislation or regulation would have on us.

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

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.

The application was supported by clinical evidence from several of the more than 50 peer-reviewed journal articles, as well as the results from the recently concluded PEECH clinical trial in order to demonstrate that EECP therapy provides relief of stable angina and congestive heart failure in selected patients in the form of:

- improvement in symptoms
- improvement in functional capacity, i.e. ability to perform exertional tasks
- improvement in quality of life and health status

One of the criteria established by CMS to provide coverage, is to assess the effectiveness of the therapy by reviewing the scientific evidence published in peer-review scientific journals. Since the PEECH trial has yet to be published, CMS indicated it had to limit the weight of evidence provided from the PEECH trial for congestive heart failure in making its final decision on March 20, 2006. We intend to resubmit our application once the PEECH trial manuscript does get published so that CMS can provide sufficient weight on the evidence provided in the study.

Although the scientific evidence proving the safety, efficacy and cost effectiveness of EECP treatment has continued to accumulate since the original coverage policy was implemented, there can be no assurance that the existing evidence is sufficient to support an expansion of EECP therapy and CMS may require additional clinical and scientific evidence to support expanded reimbursement coverage. We are unable to predict when or if CMS will approve an expansion of reimbursement coverage for EECP therapy.

If we are unable to obtain an adequate national Medicare coverage policy for treatment procedures using EECP therapy on patients with CHF, it will adversely affect our future business prospects. 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 us.

Expanding Coverage with Other Third-Party Payers

Some private insurance carriers continue to adjudicate EECP treatment claims on a case-by-case basis. Since the establishment of reimbursement by the federal government, however, an increasing number of these private carriers now routinely pay for 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 reimbursing 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, we are aware of two third-party payers that

have begun limited coverage of EECP therapy for the treatment of CHF.

We intend 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 mix of available private and public healthcare providers may not yet be aware of nor cover this therapy. Our reimbursement strategy has been opportunistic and responsive to the selling opportunities presented through our distribution partners. During this fiscal year 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. Additionally, efforts have been initiated to obtain coverage in the public sector in certain overseas markets; however, we do not anticipate an 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 eleven US patents including eight utility and three design patents that expire at various times between 2006 and 2021. In addition, more than 20 foreign patents have been issued that expire at various times from 2007 to 2022. There are six major U.S. applications pending for approval, relating to aspects of the Lumenair system, potential improvements, and new methods of treatment and a notice of allowance in one of the applications has recently been granted. We are pursuing these applications in other countries, including members of the European Union. We are also planning to file other patent applications regarding specific enhancements to the current EECP models, future generation products, and methods of treatment. Moreover, trademarks have been registered for the names "EECP" 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 EECP patents and trademarks could have a material adverse effect upon our business.

Employees

As of May 31, 2006, we employed 46 full-time and 2 part-time persons with 12 in direct sales, sales and clinical applications support, 18 in manufacturing, quality control and technical service, 4 in marketing and customer support, 5 in engineering, regulatory and clinical research and 9 in administration. None of our employees are represented by a labor union. We believe that our employee relations are good.

Manufacturing

We manufacture our EECP therapy systems in a single facility located in Westbury, New York. Manufacturing operations are conducted under the Current Good Manufacturing Practice (CGMP) requirements as set forth in the FDA Quality System Regulation. These regulations subject us to inspections to verify compliance and require us to maintain documentation and controls for the manufacturing and quality activities. ISO 13485 is the international quality standard for medical device manufacturers, based upon the ISO 9001 quality

standard with specific requirements consistent with the FDA Quality System Regulation. While previously we were certified to comply with ISO 9001 requirements, we have applied and received ISO 13485 certification in February 2003. We are also certified to conform with the full quality assurance system requirements of the EU Medical Device Directive and can apply the CE mark to certain of our products. Lastly, we are certified to comply with the requirements of the Canadian Medical Device Regulations (CMDR).

We believe our manufacturing facility, in addition to the other warehouse facilities presently under lease, are adequate to meet the current and immediately foreseeable future demand for the production of these 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 Report. 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.

Risks Related to Our Business

We may not be able to continue as a going concern.

As set forth in our independent auditors report for the fiscal year ended May 31, 2006, we have suffered recurring losses from operations and have a net capital deficiency that raises substantial doubt about our ability to continue as a going concern. We currently anticipate that we will continue to sustain operating losses. Our ability to continue operating, as a going concern is dependent upon achieving profitability or through additional debt or equity financing. Achieving 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 is largely dependent upon restructuring our sales and marketing efforts in the angina market where reimbursement is currently available and operating in a more efficient manner. If we are not able to reverse the trend of declining revenue and sufficiently reduce operating costs to generate an adequate cash flow, or raise additional capital, we will not be able to continue as a going concern.

We are materially dependent on medical reimbursement for treatment procedures using EECP therapy on patients with congestive heart failure in order to achieve continued 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. Since the PEECH trial had not been published in a peer-reviewed journal prior to CMS issuing a final decision, we intend to resubmit a new application to CMS requesting additional coverage to include heart failure patients once the PEECH manuscript is published; however, there can be no assurance that the results of the PEECH trial or other clinical evidence will be sufficient to support expansion of the Medicare national coverage policy for EECP treatment.

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.

Increased acceptance by the medical community is important for continued 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 intervention or revascularization. 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 continued growth.

We face competition from other companies and technologies.

We compete with at least four 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 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 hurt 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 patents are issued, our patent applications 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 Stock Exchange and SEC Regulation

We were de-listed from Nasdaq and may be subject to regulations that could reduce our ability to raise funds.

By letter dated May 2, 2005, we received written notification from Nasdaq that the bid price of our common stock for the last 30 consecutive business days had closed below the minimum $1.00 per share required for continued inclusion under Marketplace Rule 4310(c) (4) (the Rule). In accordance with Marketplace Rule 4310 (c) (d), we were provided an initial period of 180 calendar days to regain compliance plus an automatic extension for additional period of 180 calendar days since we met the Nasdaq Capital Markets initial listing criteria

except for the bid price requirement. During this period our common stock did not rise above the $1.00 per share minimum and on May 26, 2006, our common stock was delisted and our stock is currently traded on the Over-the-Counter Bulletin Board.

As a result of our de-listing from the Nasdaq Capital Market due to low stock price, we may become subject to special rules, called "penny stock" rules that impose additional sales practice requirements on broker-dealers who sell our common stock. Penny stocks generally are equity securities that are not registered on certain national securities exchanges or quoted by Nasdaq and have a price per share of less than $5.00. The rules require, among other things, the delivery, prior to the transaction, of a disclosure schedule required by the Securities and Exchange Commission relating to the market for penny stocks. The broker-dealer also must disclose the commissions payable both to the broker-dealer and the registered representative and current quotations for the securities, and monthly statements must be sent disclosing recent price information.

In the event that our common stock becomes characterized as a penny stock, our market liquidity could be severely affected. The regulations relating to penny stocks could limit the ability of broker-dealers to sell our common stock and thus the ability of purchasers of our common stock to sell their common stock in the secondary market.

Additionally, Nasdaq's delisting of our common stock could have an adverse effect on our ability to raise additional equity capital.

We are subject to stock exchange and SEC regulation.

Recent Sarbanes-Oxley legislation and stock exchange regulations have increased disclosure control, financial reporting, corporate governance and internal control requirements that will increase the administrative costs of documenting and auditing internal processes, gathering data, and reporting information. Our inability to comply with the requirements would significantly

impact our market valuation.

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:

- 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 own our 18,000 square foot headquarters and manufacturing facility at 180 Linden Avenue, Westbury, New York 11590. We currently lease approximately 3,500 square feet of additional warehouse space under an operating lease with a

non-affiliated landlord that expires in September 2006, which we do not intend to renew. 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 under applicable rules.

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 1, 2006, was approximately 1,100, which does not include approximately 27,600 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 2006		Fiscal 2005	
	High	Low	High	Low
First Quarter	$0.88	$0.53	$1.27	$0.83
Second Quarter	$0.65	$0.38	$1.25	$0.90
Third Quarter	$0.53	$0.16	$1.52	$0.90
Fourth Quarter	$0.35	$0.10	$1.98	$0.57

The last bid price of the Company's common stock on August 14, 2006, was $0.10 per share.

De-listing from the Nasdaq Capital Market

By letter dated May 2, 2005, we received written notification from Nasdaq that the bid price of our common stock for the last 30 consecutive business days had closed below the minimum $1.00 per share required for continued inclusion under Marketplace Rule 4310(c) (4) (the Rule). In accordance with Marketplace Rule 4310 (c) (d), we were provided an initial period of 180 calendar days to regain compliance plus an automatic extension for additional period of 180 calendar days since we met the Nasdaq Capital Markets initial listing criteria except for the bid price requirement. During this period our common stock did not rise above the $1.00 per share minimum and on May 26, 2006, our common stock was delisted and our stock is currently traded over-the-counter.

As a result of our de-listing from the Nasdaq Capital Market due to low stock price, we may become subject to special rules, called penny stock rules that impose additional sales practice requirements on broker-dealers who sell our common stock. The rules require, among other things, the delivery, prior to the transaction, of a disclosure schedule required by the Securities and Exchange Commission relating to the market for penny stocks. The broker-dealer also must disclose the commissions payable both to the broker-dealer and the registered representative and current quotations for the securities, and monthly statements must be sent disclosing recent price information.

The regulations relating to penny stocks could limit the ability of broker-dealers to sell our common stock and thus the ability of purchasers of our common stock to sell their common stock in the secondary market.

Additionally, Nasdaq's delisting of our common stock could have an adverse effect our ability to raise additional equity capital..

Dividend Policy

We have never paid any cash dividends on our common stock. While we do not intend to pay cash dividends in the foreseeable future, payment of cash dividends, if any, will be dependent upon our earnings and financial position,

investment opportunities and such other factors as the Board of Directors deems pertinent. Stock dividends, if any, also will be dependent on such factors as the Board of Directors deems pertinent.

Sale of Convertible Preferred Securities.

On July 19, 2005, we entered into a Securities Purchase Agreement that provided us with gross proceeds of $2.5 million through a private placement of preferred stock with M.A.G. Capital, LLC through its designated funds, Monarch Pointe Fund Ltd., Mercator Momentum Fund III, LP, and Mercator Momentum Fund, LP (the "Investors"). The agreement provided for a private placement of 25,000 shares of our Series D Preferred Stock at $100 per share plus warrants. As of February 7, 2006, all of the preferred shares had been converted into common shares and there are no preferred shares currently outstanding.

ITEM 6 -

SELECTED FINANCIAL DATA

The following table summarizes selected financial data for each of the five years ended May 31 as derived from our audited consolidated financial statements. These data should be read in conjunction with our consolidated financial statements, related notes and other financial information.

	Fiscal Year Ended May 31			
	2006	2005	2004	
Statements of Earnings				
Revenues	$10,942,997	$15,095,778	$22,207,037	$
Cost of sales and services	4,774,329	5,504,535	7,590,103	
Gross profit	6,168,668	9,591,243	14,616,934	
Selling, general & administrative expenses	7,865,533	12,006,774	12,910,997	
Research and development expenses	1,805,667	3,064,683	3,748,389	
Provision for doubtful accounts	110,317	11,084	1,296,759	
Interest and financing costs	81,662	105,232	132,062	
Interest and other income, net	(75,508)	(74,153)	(99,393)	
	9,787,671	15,113,620	17,988,814	
Earnings (loss) before income taxes	(3,619,003)	(5,522,377)	(3,371,880)	(
Income tax (expense) benefit, net	(7,082,138)	(39,661)	(50,640)	
Net earnings (loss)	(10,701,141)	(5,562,038)	(3,422,520)	(
Preferred stock dividend	(877,870)	--	--	
Net loss attributable to common shareholders	$(11,579,011)	$(5,562,038)	$(3,422,520)	$(
Net earnings (loss) per common share				
- basic	$(0.19)	$(0.10)	$(0.06)	
- diluted	$(0.19)	$(0.10)	$(0.06)	
Weighted average common shares				

outstanding - basic	61,351,323	58,547,574	57,981,963	
- diluted	61,351,323	58,547,574	57,981,963	
Balance Sheet Data				
Cash, cash equivalents, and certificates of deposit	$2,385,778	$2,747,967	$7,545,589	
Working capital	$2,867,288	$3,932,769	$9,771,870	$
Total assets	$7,912,040	$25,361,470	$33,023,615	$
Long-term debt	$853,189	$947,597	$1,092,837	
Stockholders' equity (1)	$3,166,156	$19,162,797	$24,594,169	$

Summary of quarterly financial data (unaudited)

The following is a summary of the Company's unaudited quarterly operating results for the years ended May 31, 2006 and 2005.

	Three months ended					
(in 000s except earnings (loss) per share data)	May 31, 2006	Feb. 28, 2006	Nov. 30, 2005	Aug. 31, 2005	May 31, 2005	Feb. 28, 2005
Revenues	$1,885	$2,842	$2,680	$3,536	$3,848	$2,964
Gross profit	$859	$1,614	$1,582	$2,113	$2,344	$1,800
Net loss attributable to common shareholders	$(504)	$(695)	$(8,682)	$(1,698)	$(1,001)	$(2,027)
Loss per share - basic	$(0.01)	$(0.01)	$(0.15)	$(0.03)	$(0.02)	$(0.03)
- diluted	$(0.01)	$(0.01)	$(0.15)	$(0.03)	$(0.02)	$(0.03)
Weighted average common shares outstanding -						
- basic	65,173	62,162	59,421	58,616	58,553	58,553
- diluted	65,173	62,162	59,421	58,616	58,553	58,553

ITEM 7 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Forward-looking statements are identified by words such as "anticipates", "believes", "could", "estimates", "expects", "feels", "intends", "may", "plans", "potential", and "projects" and similar expressions. In addition, any statements that refer to our plans, business plan, expectations, strategies or other characterizations of future events or circumstances are forward-looking statements. Such forward-looking statements are based on our beliefs, as well as assumptions made by and information currently available to us. 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 medical insurance reimbursement policies including the continued inability to obtain Medicare reimbursement for heart failure patients; competitive procedures and products and their pricing; unexpected manufacturing 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 our SEC