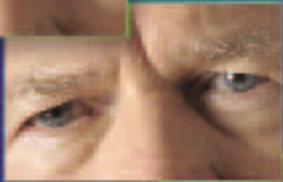


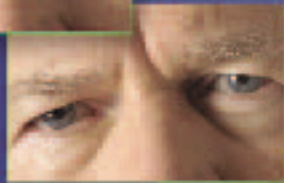
Documented results. Supported by science.



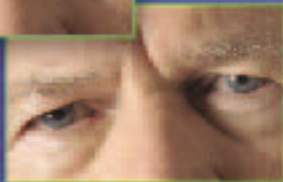
**APRIL 1995**  
*Beta-blocker and  
statin therapy*



**NOVEMBER 1997**  
*Angioplasty*



**AUGUST 2001**  
*Bypass surgery*



**MARCH 2003**  
*Vasomedical EECP<sup>®</sup> treatment*



**MAY 2003...**  
*Significant symptom reduction*

*The positive effects of EECP<sup>®</sup> therapy continue to grow.*

# DEAR SHAREHOLDERS

During fiscal year 2004 the Company maintained its focus and executed many of the plans put in place during late FY03. We were able to increase awareness and adoption of EECP therapy, despite a significant unexpected 34% drop in physician practice reimbursement from the prior year. An estimated 19,000 patients are now being treated annually with enhanced external counterpulsation, up approximately 33% from the prior year.

While the Company revenues declined approximately 15% from the prior year, the cash balance has continued to increase from \$5.5 million at the beginning of the year to \$7.5 on May 31st. Average selling prices declined approximately 12% compared to the previous fiscal year, reflecting competitive price competition and price pressure resulting from the reduction in Medicare reimbursement rates. However, total EECP system volume remained virtually unchanged. Equipment rental and services revenues grew 47%, compared with the previous fiscal year and now represents approximately 13% of total Company revenues compared with 8% last year. We intend to continue our efforts to increase this portion of our business, which is a growing source of high-margin recurring revenue.



## SALES AND MARKETING

The Company strengthened its selling organization over the past fiscal year. Some positive results of these changes were seen during the second half of the fiscal year. The Company placed the second largest number of machines in a quarter during the fourth quarter of fiscal 2004.

We continued to invest in growing the awareness and clinical benefits of the EECP therapy among the cardiology community. A journal advertising campaign was launched during the second quarter to augment the peer-to-peer direct mail campaigns initiated in the prior fiscal year. We also continued to have a strong presence at select domestic and international cardiovascular scientific conferences as well as several local symposia. EECP therapy also gained national media attention during the past year having been featured on the *CBS Morning Show*, *TIME* magazine, *Investor's Business Daily* and several local news channels.

## REIMBURSEMENT

Reimbursement continues to play a critical role in the adoption of the EECP therapy. At the beginning of calendar year 2004, Medicare dropped the physician payment rate from \$208 per hour to \$137 per hour. This reduction had a negative impact on sales throughout the fiscal year, resulting in lower than anticipated unit sales. We also continued to support our customers in gaining positive reimbursement coverage from other third-party payers. EECP therapy is now reimbursed by the majority of private insurers for treating refractory angina patients.

## CLINICAL

We achieved one of the most significant clinical milestones for EECP therapy in January with the enrollment of the last patient into our PEECH (Prospective Evaluation of EECP in Congestive Heart Failure) trial to reach our target of 180 patients.

Every year, the number of clinical studies demonstrating positive effects of EECP therapy continues to grow. This past year was no exception, with

twelve peer reviewed journal articles, and approximately twenty abstract presentations delivered at cardiovascular related conferences.

## PRODUCT DEVELOPMENT

During this past fiscal year the Company introduced the TS4 product line that is an upgrade of the previous model TS3. The Company will no longer offer new MC2 or TS3 models once the inventories are depleted in early fiscal 2005. The Company also received clearance for marketing all of its currently available systems with fewer contraindications than it had previously. These changes in labeling now more accurately reflect common procedures followed by our providers.

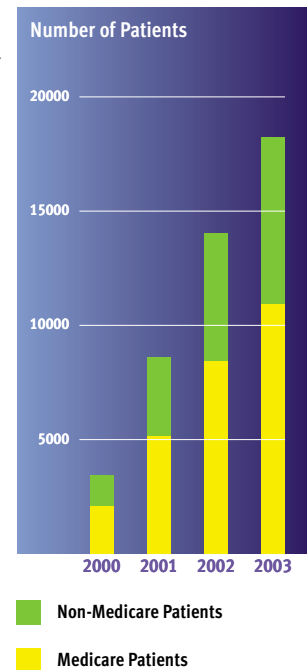
## FUTURE

The next fiscal year will be an exciting time for us, as the data from the PEECH trial will become available. To the extent the results are favorable, the results of the trial will be submitted to the Centers of Medicare and Medicaid (CMS) to support the adoption of a Medicare national coverage policy. We expect to be able to submit the results to CMS by early 2005 and release the results to the public by March 2005 at the annual American College of Cardiology Scientific session. Based on this timetable, we anticipate a CHF coverage decision by CMS in late 2005 to early 2006. This has been a major project for the Company and we are all happy to see it near completion. CHF is a substantially larger market than the refractory angina market, in which we currently participate. We are excited over the commercial opportunity this may represent.

Developing the scientific and clinical evidence to support the growth of EECP therapy in the medical community and expand the markets available to our product is essential to the growth our company. While our current focus is on the completion of the PEECH trial, we intend to continue to invest in other clinical trials and sponsor research. We also plan to continue investing in product development, our direct sales and distribution network along with our marketing programs while supporting our customers in growing awareness of the therapy.

The introduction of a new medical therapy is always a lengthy and difficult task. EECP therapy has come a long way over the past four years from being virtually unknown to becoming one of the fastest growing medical device therapies in the US. We would like to thank our dedicated employees and shareholders along with the physicians and patients who put their trust in EECP therapy. Thank you.

PHOTIOS T. PAULSON  
INTERIM CEO



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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

**FORM 10-K**

- ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
*For the fiscal year ended May 31, 2004*
- 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.**

*(Name of registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**11-2871434**

*(IRS Employer  
Identification No.)*

**180 Linden Avenue, Westbury, New York**

*(Address of Principal Executive Offices)*

**11590**

*(Zip Code)*

**Registrant's telephone number, including area code: (516) 997-4600**

**Securities registered under Section 12(b) of the Act: None**

**Securities registered under Section 12(g) of the Act:**

*Common Stock, \$.001 par value*

*(Title of Class)*

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  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.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act).

Yes  No

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant (based on the closing sale price of \$1.06 as of November 30, 2003 was approximately \$ 57,931,000. Shares of common stock held by each officer and director and by each person who owns 5% of 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 10, 2004, the number of shares outstanding of the issuer's common stock was 58,552,688.

**DOCUMENTS INCORPORATED BY REFERENCE**

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

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## INDEX TO FORM 10-K

	<u>Page</u>
<b>PART I</b>	
Item 1. Business .....	1
Risk Factors.....	12
Item 2. Properties .....	17
Item 3. Legal Proceedings.....	17
Item 4. Submission of Matters to a Vote of Security Holders.....	17
<b>PART II</b>	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities.....	18
Item 6. Selected Financial Data.....	19
Item 7. Management’s Discussion and Analysis of Financial Condition and results of Operation.....	20
Item 7A. Quantitative and Qualitative Disclosures about Market Risk .....	30
Item 8. Financial Statements and Supplementary Data.....	30
Item 9. Changes in and Disagreements with Accountants and Accounting and Financial Disclosure .....	30
Item 9A. Controls and Procedures .....	31
<b>PART III</b>	
Item 10. Directors and Executive Officers of the Registrant .....	32
Item 11. Executive Compensation.....	32
Item 12. Security Ownership of Certain Beneficial Owners and Management.....	32
Item 13. Certain Relationships and Related Transactions .....	32
Item 14. Principal Accountant Fees and Services .....	32
<b>PART IV</b>	
Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.....	32
Signatures .....	34

## 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” or “Vasomedical” refer to Vasomedical Inc. and its subsidiaries. Since 1995, we have been primarily engaged in designing, manufacturing, marketing and supporting EECP® external counterpulsation systems based on our proprietary technology currently indicated for use in cases of stable or unstable angina (i.e., chest pain), cardiogenic shock, acute myocardial infarction (i.e., heart attack, (MI)) and congestive heart failure (CHF). The EECP 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 may restore systemic vascular function. We provide hospitals and physician private practices with EECP equipment, treatment guidance, and a staff training and maintenance program designed to provide optimal patient outcomes. EECP is a registered trademark for Vasomedical's enhanced external counterpulsation systems.

#### *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 931,000 lives in the United States in 2001 and was responsible for 1 of every 2.6 deaths, according to The American Heart Association (AHA) *Heart and Stroke Statistical 2004 Update (2004 Update)*. If high blood pressure is included, approximately 64 million Americans suffer from some form of cardiovascular disease. Among these, 13.2 million have coronary artery disease (CAD).

We have Food and Drug Administration (FDA) clearance to market the EECP therapy for use in the treatment of angina pectoris (angina), cardiogenic shock, acute myocardial infarction and CHF, however our current marketing efforts are limited to the treatment of refractory angina, where reimbursement for the EECP treatment is available. Medicare and numerous other commercial third-party payers currently provide reimbursement for the treatment of refractory angina using the EECP therapy.

We are also actively engaged in research to establish the potential benefits of EECP therapy in the management of CHF and are sponsoring a pivotal study to demonstrate the efficacy of EECP therapy in most types of heart failure patients. This study, known as PEECH (Prospective Evaluation of EECP in Congestive Heart Failure), is intended to provide additional clinical data in order to support a Medicare national coverage policy for the use of the EECP therapy in the treatment of CHF. We expect to be able to release the results of the PEECH trial by early 2005.

#### *Angina*

Angina pectoris is the medical term for a recurring pain or discomfort in the chest due to coronary heart disease (CHD). 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 is called ischemia.

Typical 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. 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 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 6.5 million angina patients in the United States and the EEC therapy currently competes with other technologies in the market for approximately 150,000 angina patients annually who are considered refractory to medical and/or surgical therapy and have the potential to meet the Medicare guidelines for reimbursement of the EEC therapy. Most angina patients are treated with medications, including vasodilators, which are often prescribed to increase blood flow to the coronary arteries. When drugs fail or cease to correct the problem they are considered refractory to medical therapy. Invasive revascularization procedures such as angioplasty and coronary stent placement, as well as coronary artery bypass grafting (CABG) are often employed in both refractory and non-refractory angina patients.

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 the EEC system. Medicare reimbursement guidelines have a significant impact in determining the available market for EEC therapy. We believe that over 65% of the patients that receive EEC therapy are Medicare patients and many of the third-party payers follow Medicare guidelines, which limits reimbursement for the EEC therapy to patients who are refractory to medical and/or surgical therapy. As a result, an important element of our strategy is to grow the market for EEC therapy by expanding reimbursement coverage to include a broader range of angina patients than the current coverage policy provides and enabling the EEC therapy to compete more with other technologies. Please see the heading "Reimbursement" in the "Item-1 Business of this Form 10-K" section for a more detailed discussion of reimbursement issues.

#### *Congestive Heart Failure*

CHF is a complication of many serious diseases in which the heart loses its full pumping capacity, causing blood to back up into other organs, especially the lungs and liver. The condition affects both sexes and is most common in people over age 50. Symptoms include shortness of breath, fatigue, swelling of the abdomen, legs and ankles, rapid or irregular heartbeat, low blood pressure and enlargement of the liver. Causes range from high blood pressure, heart-valve disease, heart attack, coronary artery disease, heartbeat irregularities, severe lung disease such as emphysema, congenital heart disease, cardiomyopathy, hyperthyroidism and severe anemia.

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 continue to advance. 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 2004 Update, in 2001 approximately 2.5 million men and 2.5 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 155% from 1979 to 2001. The prevalence of the disease is growing rapidly as a result of the aging of the population and the improved survival rate of people after heart attacks. At age forty the lifetime risk of developing CHF for both men and women was 1 in 5. Also, 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. In addition to careful outpatient care and monitoring, the economic burden of congestive heart failure is enormous with an estimated 2004 cost to the health care system in the United States of \$28.8 billion. In 1999, \$3.6 billion (an average of \$5,456 per discharge) was paid to Medicare beneficiaries for CHF.

Given the pressing need to identify new and effective methods to treat CHF, we have been actively focusing clinical development resources on CHF. Congestive heart failure offers a good strategic fit with our current angina business and offers a new market opportunity for EEC 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 EEC Patient Registry™ (IEPR) at the University of Pittsburgh Graduate School of Public Health currently shows that approximately one-third of patients treated also have a history of CHF and have demonstrated positive outcomes from EEC therapy.

The PEECH trial is intended to provide additional clinical evidence to demonstrate the potential benefits of the EEC therapy in the management of CHF and we plan to submit the results of the PEECH trial to Centers for Medicare and Medicaid Services (CMS) to support the adoption of a Medicare national coverage policy. We expect to be able to submit the results of the PEECH trial to CMS and release the results of the PEECH trial to the public by early 2005. We anticipate a coverage decision in late 2005 or early 2006; however, there can be no assurance that the results of the PEECH trial will be sufficient to support expansion of the Medicare national coverage policy for the EEC treatment.

## **The EECP Therapy Systems**

The EECP therapy systems marketed by us 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, 5 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. 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 bed while wearing three sets of inflatable pressure cuffs, resembling oversized blood pressure cuffs, on the calves, the lower and upper thighs, including the buttocks. The cuffs inflate rapidly and sequentially -- via computer-interpreted ECG signals -- starting from the calves and proceeding upward to the buttocks during the resting phase of each heartbeat (diastole). This has the effect of creating a strong retrograde counter pulse in the arterial system, forcing freshly oxygenated blood towards the heart and coronary arteries, while simultaneously increasing the volume of venous blood return to the heart under increased pressure. 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 to 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 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, while also reducing systolic pressure, to the general benefit of the vascular system. This surge of circulation insures that the heart does not have to work as hard to pump large amounts of blood through the body, and that more blood is forced into the coronary arteries which supply energy to the heart muscle or myocardium.

While the precise mechanism of action remains unknown, there is evidence to suggest that the EECP therapy triggers a neurohormonal response that induces the production of growth factors and dilates existing blood vessels. This in turn fosters the recruitment of collateral blood vessels, which bypass blocked or narrowed vessels and increase blood flow to restore ischemic areas of the heart muscle that are receiving an inadequate supply of blood. The myocardium itself may also develop new vasculature. There is also evidence to support a mechanism related to improved function of the endothelium (the inner lining of the blood vessels), reducing constriction of blood vessels that supply oxygenated blood to the body's organs and tissues and 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 gating, 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 a third cuff for the buttocks. Not only did a course of treatment with the EECP system reduce the frequency and severity of anginal symptoms during normal daily functions and also during exercise, but also 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 studies with the EECP system between 1989 and 1996 to reproduce the Chinese results, using both subjective and objective endpoints. These studies, though open and non-randomized, showed statistical improvement in exercise tolerance by patients as evidenced by thallium-stress testing and partial or complete resolution of coronary perfusion defects as evidenced by radionuclide imaging studies. All of these results have been reported in the 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 large randomized, controlled and double-blinded multicenter clinical study (MUST-EECP) at four 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, showed that EECP therapy was a safe and effective treatment option for patients suffering from angina pectoris, including those on maximal medication and for whom invasive revascularization procedures were no longer an option. The results of the MUST-EECP study confirmed the clinical benefits described in earlier open trials, namely a decline in anginal frequency, an increase in the ability to exercise and a decrease in exercise-induced signs of myocardial ischemia. Data collected by the IEPR closely mirror the results seen in the MUST-EECP trial.

In fiscal 1999, we completed a quality-of-life study with the EECP system in the same institutions and with 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 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 its 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 49<sup>th</sup> 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 concluded that EECP therapy increased functional capacity of the patients, was beneficial to left ventricular function and portends to be a useful adjunct to current medical therapy in heart failure patients.

In summer 2000, an IDE supplement to proceed with a pivotal study to demonstrate the efficacy of EECP therapy in most types of heart failure patients was approved. This study, known as PEECH (Prospective Evaluation of EECP in Congestive HearFailure), began patient enrollment in March 2001. The PEECH trial involves 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 and the Cardiovascular Research Institute. The 510(k) clearance for CHF granted in June 2002 obviated the need to continue this trial for FDA regulatory reasons. However, we intend to complete the clinical trial and use the anticipated positive clinical outcomes to establish the clinical validation of EECP therapy as a treatment for CHF and to obtain Medicare and other third-party reimbursement for this indication.

The PEECH trial enrollment was completed in February 2004 with 187 patients. The protocol for the study requires patient examinations six months following treatment and will evaluate improvements in exercise capacity and quality of life, as well as the reduction in the need for certain medications that CHF patients are typically prescribed. We anticipate that the six-month follow-up examinations will be completed by the end of October 2004. We expect to be able to release the results of the PEECH trial in March 2005 and, provided results of the trial are positive, submit a request to CMS to provide reimbursement for use of the EECP therapy in treatment of CHF in early 2005. Based on the above timetable we anticipate a coverage decision by CMS in late 2005 or early 2006.

We are blinded to the results of the PEECH trial until after the study is completed and there can be no assurance that the results of the PEECH trial will be sufficient to demonstrate the efficacy of the EECP therapy in the treatment of congestive heart failure or that the results will provide sufficient evidence to expand insurance coverage or the adoption of the EECP therapy for use in the treatment of congestive heart failure by the medical community.

### *The IEPR Registry*

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 patients who have undergone EECP therapy. More than one

hundred centers have participated in the registry and data from 5,000 patient records has been entered. Phase 2 of the IEPR, planned for an additional 2,500 patients, began enrollment in January 2002 and incorporates sub-studies that are examining treatment beyond 35 hours of treatment, where needed, the presence of protein in the urine of type 2 diabetic patients as a predictor of response to EECP therapy, the effects on peripheral vascular disease, and the effects of sexual function in men. The IEPR is a vital source of information about the effectiveness of EECP therapy in a real-world environment for the medical community at large. For this reason, we will continue to provide an ongoing grant to fund the registry to publicize data that assists clinicians in delivering optimal care to patients. Data from the IEPR show that patients continue to receive dramatic benefit at six, twelve, twenty-four and thirty-six months following completion of their course of EECP therapy. Data on 1,097 patients in the IEPR reported early in 2004 showed 92% of patients remained alive (including 41% free of cardiac events during that period) and sustained reduction in anginal status and nitrate medication use at 2 years following EECP therapy.

The following tables illustrate the results:

	Pre-EECP (N=5,019)	Post EECP (N=3,982)	At 1 year (N=2,374)	At 2 years (N=1,022)	At 3 years (N=238)
	%	%	%	%	%
No Angina	--	20.7	29.1	33.3	34.9
Class I	3.5	26.2	21.2	20.7	19.3
Class II	14.7	36.4	29.4	26.7	24.8
Class III	58.4	14.0	16.2	15.0	16.0
Class IV	23.4	2.6	4.1	4.3	5.0
prn Nitro Use	68.8	31.5	43.4	40.8	44.4

Patient Demographics		Medical History		Angina Improvement Post EECP	
Mean age	66.8 years	Duration of CAD	10.8 years	> 1 CCSC	82.3%
Age > 65	59.7%	Prior PCI/CABG	85.8%	> 2 CCSC	45.4%
Male gender	75.5%	Prior MI	67.6%		
		CHF	31.7%		
		Diabetes	41.3%		

*N = number of patients reporting at these points*

CCSA = Canadian Cardiovascular Society Classification

#### *Other studies and publications*

Over the last several years, our clinical bibliography has expanded to include over 50 publications in peer-review journals, as well as other publications and abstracts presented at major medical conferences. Notable among these studies are several discussing the neurohumoral effects of EECP therapy including increases in the levels of nitric oxide, a potent vasodilator and decreases in levels of endothelin a vasoconstrictor as well as the release of certain growth factors.

#### **Strategic Initiatives**

Our short- and long-term plans are to:

- a) Increase the domestic reimbursable user base for the EECP therapy by:
  - i) obtaining reimbursement for the treatment of CHF,
  - ii) marketing directly to third-party payers to increase third-party reimbursement, and
  - iii) reducing reimbursement limitations in the refractory angina market.
- b) Increase the clinical and scientific understanding of the EECP therapy by:
  - i) completing the PEECH clinical trial, publishing the results in a major peer-review medical journal and submitting data to insurers, including Medicare, for favorable coverage policies;
  - ii) continuing to establish and support academic reference centers in the United States and overseas in order to accelerate the growth and prestige of EECP therapy and to increase the number and diversity of clinical and mode-of-action studies, as well as the number of presentations, publications, speakers and advocates; and

- iii) providing an ongoing grant to fund the International EECF Patient Registry at the University of Pittsburgh Graduate School of Public Health to publicize key information relating to patient outcomes.
- c) Increase awareness of the benefits of the EECF therapy in the medical community by:
  - i) developing campaigns to market the benefits of EECF 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 EECF therapy; and
  - iii) continuing the development of the EECF therapy in certain international markets, principally through the establishment of a distribution network.
- d) Maintain development efforts to improve the EECF system and expand its intellectual property estate by filing for additional patents in the United States and other countries.
- e) 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.

These strategic objectives above 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. 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 EECF systems to treatment providers in the United States through a direct sales force directly to hospitals and physician private practices. Our sales force is currently comprised of over twenty sales representatives, as well as one independent sales organization and is supported by a management team consisting of a vice president of domestic sales, three regional sales managers plus in-house administrative support.

The efforts of our sales organization are further supported by a field-based staff of seven clinical educators who are responsible for the onsite training of physicians and therapists as new centers are established. Training generally takes approximately two and a half days. 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 EECF therapy.

Our marketing activities include medical journal advertising, direct mail promotions aimed at the cardiology medical community, publication of EECF-related newsletters to EECF therapy centers and participants in the IEPR study, support of 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 the EECF therapy in the medical community. Additional marketing activities include creating awareness among third-party payers to the benefits of the EECF treatment for patients suffering from CHF as well as angina.

We employ six field service technicians responsible for the repair and maintenance of EECF systems and, in some instances, on-site training of a customer's biomedical engineering personnel as required. We provide a one-year product warranty that includes parts and labor and we offer post-warranty service to our customers under 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 in exchange for exclusive marketing rights to EECF systems in their respective countries. 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 or to establish confirmation clinical evaluations conducted by local opinion leaders in cardiology. Each distributor is responsible for obtaining any required regulatory approvals, supporting local reimbursement efforts for the EECF therapy and maintaining an infrastructure to provide post-sales support, including clinical training and product maintenance services.

To date, revenues from international operations have not been significant (fiscal 2004 revenues were less than 4% of total revenues) but we anticipate international revenues to increase in future years. 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 EEC 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 that our international distributors will be successful in marketing the EEC therapy.

### **Competition**

Presently, we are aware of at least two competitors with an external counterpulsation device on the market, namely Cardiomedics, Inc. and Nicore, Inc. In addition, at least eight other companies have received FDA 510K clearance for external counterpulsation systems, 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 such as the intra-aortic balloon pump (IANP), ventricular assist devices (VAD), coronary artery bypass graft (CABG), coronary angioplasty, mechanical circulatory support (MCS), transmyocardial laser revascularization (TMR), cardiac recovery systems, total artificial hearts; as well as newer technologies currently in FDA clinical trials such as spinal cord stimulation (SCS) and partial fatty acid oxidation (pFOX inhibitor). We are unaware of any other biotech or pharmaceutical technologies that may impact our ability to market and distribute EEC systems in the near term.

There can be no assurance that other companies will not develop new technologies or enter the market intended for EEC 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, 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. 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 patent-pending CHF treatment and oxygen saturation monitoring technologies, and provided for a new indication for the use of EECP in CHF, which applied to all present models of the Company's EECP systems. In March 2004, the Company obtained 510(k) market clearance for revisions to the labeling of all its products, including the new Model TS4, which eliminated certain contraindications and changed other precautions. There can be no assurance that our products will not be subject to a regulation requiring a PMA for preamendments Class III external counterpulsation devices.

#### *Premarket Review.*

The 510(k) premarket notification process requires an applicant to give 90 days 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 we 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). 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 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 Practices or GMP requirements set forth in FDA's Quality System Regulation or QSR that require manufacturers to have a quality system for the design and production 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 current good manufacturing practice 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 EEC system, it 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 its 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 Conformity Assessment System (CMDCAS).

There can be no assurance that we will obtain desired foreign authorizations to commercially distribute its products in those markets or that we will comply with all laws, regulations and standards that pertain to its 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 impacts of the HIPAA privacy rule to be material to our business.

#### **Reimbursement**

Sales of our products depend in part on the availability of reimbursement by government programs such as Medicare, Medicaid, private health care insurance and managed-care plans. Whether a product receives coverage depends upon 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 accepted standards of medical practice, the product's cost effectiveness, whether the product is experimental or investigational, and whether the product is not otherwise excluded from coverage by law or regulation. 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 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 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, 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: obtaining Medicare coverage for congestive heart failure, expanding coverage with other third-party payers, reducing the limitations in 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 G1066 for the use of the EECF 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.”*

Additionally, a physician must be present in the office suite and immediately available to provide assistance and directions throughout the time that personnel are performing the procedure.

The 2004 national average payment rate per hourly session in the physician office setting and the hospital outpatient facility is approximately \$137 and \$113, respectively. Under the Medicare program, physician reimbursement of the provision of the EECF 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 cost 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 steadily to \$208 per treatment session in 2003 before being reduced approximately 34% to the 2004 rate, while the average payment rate for the hospital outpatient facility declined steadily to the 2004 rate.

In order to bill and receive payment from Medicare, an individual or entity must be enrolled in the Medicare program for EECF therapy. The physician office setting and the hospital outpatient facility are the only entities currently authorized to receive reimbursement for the EECF therapy under the Medicare program and reimbursement is not permitted to other individuals or entities types, which include, but are not limited to, nurse practitioners, physical therapists, ambulatory surgery centers nursing homes, comprehensive outpatient rehabilitation facilities, out patient 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 the reimbursement level for treatment procedures using the EECF 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.

#### *Reducing the Limitations in Medicare Coverage for Angina*

We have initiated discussions with CMS to broaden the national coverage policy for the EECP treatment to include all classes of stable angina and eliminate the language from current policy that limits coverage to those patients who are not readily amenable to surgical interventions, such as balloon angioplasty and cardiac bypass. Although the scientific evidence proving the safety, efficacy and cost effectiveness of the EECP treatment has continued to accumulate since the original coverage policy was implemented, additional clinical and scientific evidence may be required by CMS to support expanded coverage and we are unable to predict when or if we will be able to reduce the current limitations for Medicare coverage in angina. We do not anticipate any changes to the coverage language in fiscal 2005.

#### *Obtaining Medicare Coverage for Congestive Heart Failure*

In June 2002, we announced that all three of our models of the EECP system had been granted a 510(k) market clearance from the FDA for a new indication for the treatment of congestive heart failure. We intend to apply to CMS for a national coverage policy for EECP therapy specific to CHF when we have completed and analyzed the results of the ongoing PEECH trial, a randomized, controlled clinical study on the use of EECP in CHF patients.

We expect to be able to submit the results of the PEECH trial to CMS and release the results of the trial by early 2005. We anticipate a coverage decision in late 2005 or early 2006; however, there can be no assurance that the results of the PEECH trial will be sufficient to support expansion of the Medicare national coverage policy for the EECP treatment. If we were unable to obtain an adequate national Medicare coverage policy for treatment procedures using the EECP system in CHF, it would 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 the 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 the 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 treatments 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 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. The results in fiscal 2004 included limited coverage for EECP therapy by major private health insurance companies in England, Spain, Saudi Arabia, India and Venezuela. Additionally, efforts have been initiated to obtain coverage in the public sector, in Canada, England, Ireland, Israel, Italy, Malaysia, Thailand and Sweden; 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 seven US 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 four major U.S. applications pending for approval, relating to aspects of the TS3 system, potential improvements, and new methods of treatment. 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 EECF models, future generation products, and methods of treatment. Moreover, trademarks have been registered for the names “EECF” and “Natural Bypass”, as well as for its widely-recognized man-like figure representing the application of EECF therapy.

We pursue a policy of seeking patent protection, both in the US and abroad, for our proprietary technology. There can be no assurance that our patents will not be violated or that any issued patents will provide protection that has commercial significance. As with any patented technology, litigation could be necessary to protect our patent position. Such litigation can be costly and time-consuming, and there can be no assurance that we will be successful. The loss or violation of our EECF patents and trademarks could have a material adverse effect upon our business.

## **Employees**

As of August 1, 2004, we employed 94 full-time and 2 part-time persons with 27 in direct sales and sales support, 7 in clinical applications, 29 in manufacturing, quality control and technical service, 7 in marketing and customer support, 14 in engineering, regulatory and clinical research and 12 in administration. None of our employees are represented by a labor union. We believe that our employee relations are good.

In March 2004 the then current Chief Executive Officer (CEO) of the Company resigned from the Company and Photios T. Paulson, who served as CEO of the Company from October 2002 to June 2003, accepted the position as acting CEO. The Company has engaged a search firm to retain a new CEO. The search is currently ongoing.

## **Manufacturing**

We manufacture our EECF therapy systems in a single facility located in Westbury, New York. Manufacturing operations are conducted under the FDA Quality System Regulations. 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. We received ISO 13485 certification in February 2003.

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.

## **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**

#### **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 EECF 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 EECF 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 cost-effective, is experimental or is used for an unapproved

indication. In addition, reimbursement may not be at or remain at price levels adequate to allow medical professionals to realize an appropriate return on the purchase of our products.

**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 likely would 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.

**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 Practices (GMP) requirements as set forth in the Quality System Regulation or 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 recordkeeping. 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 be dependent on the outcome of certain clinical trials to obtain broader reimbursement coverage and to achieve substantial future 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. While we have been engaged in discussions with the Centers for Medicare and Medicaid Services to expand the class of heart patients for medical coverage, we are uncertain as to the outcome of these meetings. We also have been engaged in certain clinical trials for the purpose of expanding this coverage, most notable being our PEECH trial. We expect that the PEECH trial, which has been evaluating the effectiveness of EECF therapy for congestive heart failure patients, will be concluded at the end of 2004 and it is anticipated that the results will be available in early 2005. Favorable results from the PEECH trial, whose protocol has been designed in cooperation with the FDA, could substantially expand the number of patients available for medical reimbursement. Successful clinical trials are important for substantial future revenue growth.

**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 EECF treatment efficacy, there is continued skepticism concerning EECF therapy methodology. Certain cardiologists, in cases where the EECF 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. We are dependent on consistency of favorable research findings about the EECF therapy and increasing acceptance of the EECF 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 two 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 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 may not be able to manage growth.**

If our short and long-term plans are successful, including our clinical trials, we will experience a period of growth that could place a significant strain upon our managerial, financial and operational resources. Our infrastructure, procedures, controls and information systems may not be adequate to support our operations and to achieve the rapid execution necessary to successfully market our products. Our future operating results will also depend on our ability to successfully upgrade our information systems, expand our direct sales force and our internal sales, marketing and support staff. If we are unable to manage future expansion effectively, our business, results of operations and financial condition will suffer, our senior management will be less effective, and our revenues and product development efforts may decrease.

**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 \$2,000,000 per occurrence and \$5,000,000 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 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 has been and is likely to continue to be highly volatile. Our stock price could be subject to wide fluctuations in response to various factors beyond our control, including:

- 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.

### **A low stock price could result in our being de-listed from the Nasdaq and subject us to regulations that could reduce our ability to raise funds.**

If our stock price, which currently is below \$1.00 per share remains below \$1.00 per share for an extended period of time, or if we fail to maintain other Nasdaq criteria, Nasdaq may de-list our common stock from the Nasdaq SmallCap Market. In such an event, our shares could only be traded on over-the-counter bulletin board system. This method of trading could significantly impair our ability to raise new capital.

In the event that our common stock was de-listed from the Nasdaq SmallCap 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.

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.

### **Recent corporate scandals involving alleged accounting irregularities have resulted in unavailability of, or significantly higher premiums for, director and officer liability insurance.**

As a result of recent well-publicized corporate business failures alleged to have involved improper acts by executives and accounting irregularities, director and officer liability insurance has become more difficult to obtain and the premiums for such insurance have increased significantly. If we are unable to obtain director and officer liability insurance at rates that are reasonable or at all, we may not be able to retain our current officers and directors or attract qualified directors and officers in the future.

**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 lease approximately 7,100 square feet of additional warehouse space under two operating leases with non-affiliated landlords, of which one expires in October 2004 and the other in September 2006, plus additional parking locations in the area at an annual cost of approximately \$92,000. We believe that we can renegotiate the lease that will expire in October 2004 or lease other available space under reasonable terms and that these combined facilities are 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 THE COMPANY'S COMMON STOCK AND RELATED SECURITY HOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock trades on the Nasdaq SmallCap Market tier of The Nasdaq Stock Market<sup>SM</sup> under the symbol VASO. The number of record holders of Common Stock as of August 1, 2004 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 as reported by the Nasdaq SmallCap Market tier of The Nasdaq Stock Market<sup>SM</sup> for the fiscal periods specified.

	Fiscal 2004		Fiscal 2003	
	High	Low	High	Low
First Quarter	\$1.55	\$0.84	\$3.00	\$1.25
Second Quarter	\$1.59	\$0.86	\$1.85	\$0.52
Third Quarter	\$2.34	\$1.00	\$1.20	\$0.70
Fourth Quarter	\$1.94	\$1.10	\$1.60	\$0.63

The last bid price of the Company's Common Stock on August 10, 2004, was \$0.88 per share.

#### 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.

## 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.

	<b>Fiscal Year Ended May 31,</b>				
	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
<b>Statements of Earnings</b>					
Revenues	\$22,207,037	\$24,823,619	\$34,830,471	\$27,508,338	\$13,673,632
Cost of sales and services	7,590,103	9,251,221	10,538,731	7,910,359	3,277,700
Gross profit	14,616,934	15,572,398	24,291,740	19,597,979	10,395,932
Selling, general & administrative expenses	12,910,997	13,714,913	13,686,958	11,634,965	7,383,567
Research and development expenses	3,748,389	4,544,822	5,112,258	2,554,470	1,413,464
Provision for doubtful accounts	1,296,759	3,728,484	1,304,000	325,000	400,000
Interest and financing costs	132,062	186,574	98,140	48,294	7,302
Interest and other income, net	(99,393)	(176,724)	(249,722)	(201,992)	(99,317)
	17,988,814	21,998,069	19,951,634	14,360,737	9,105,016
Earnings (loss) before income taxes	(3,371,880)	(6,425,671)	4,340,106	5,237,242	1,290,916
Income tax (expense) benefit, net	(50,640)	1,634,688	(1,554,000)	6,457,108	400,000
Net earnings (loss)	(3,422,520)	(4,790,983)	2,786,106	11,694,350	1,690,916
Preferred stock dividend requirement	--	--	--	--	(94,122)
Net earnings (loss) applicable to common stockholders	\$(3,422,520)	\$(4,790,983)	\$2,786,106	\$11,694,350	\$1,596,794
Net earnings (loss) per common share					
- basic	\$(0.06)	\$(0.08)	\$0.05	\$0.21	\$0.03
- diluted	\$(0.06)	\$(0.08)	\$0.05	\$0.20	\$0.03
Weighted average common shares outstanding - basic	57,981,963	57,647,032	57,251,035	56,571,402	52,580,623
- diluted	57,981,963	57,647,032	59,468,092	59,927,199	57,141,949

### Balance Sheet Data

Cash, cash equivalents and certificates of deposit	\$7,545,589	\$5,222,847	\$2,967,627	\$3,785,456	\$3,058,367
Working capital	\$9,771,870	\$11,478,092	\$17,225,434	\$16,214,655	\$7,380,236
Total assets	\$33,023,615	\$35,327,550	\$41,418,258	\$36,518,974	\$10,588,962
Long-term debt	\$1,092,837	\$1,177,804	\$1,072,716	\$1,108,593	\$--
Stockholders' equity (1)	\$24,594,169	\$27,319,302	\$31,602,604	\$28,508,729	\$7,943,770

(1) No cash dividends on common stock were declared during any of the above periods.



## **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", "estimates", "expects", "feels", "plans", "projects" and "intends" and similar expressions. 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.*

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

### **Overview**

Vasomedical, Inc. incorporated in Delaware in July 1987 is primarily engaged in designing, manufacturing, marketing and supporting EECP® external counterpulsation systems based on our proprietary technology. EECP therapy 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 may restore systemic vascular function. We provide hospitals and physician private practices with EECP equipment, treatment guidance, and a staff training and maintenance program designed to provide optimal patient outcomes. EECP is a registered trademark for Vasomedical's enhanced external counterpulsation systems.

We have Food and Drug Administration (FDA) approval to market the EECP therapy for use in the treatment of angina pectoris (i.e., chest pain), cardiogenic shock, acute myocardial infarction (i.e., heart attack, (MI)) and congestive heart failure (CHF), however our current marketing efforts are limited to the treatment of refractory angina, where reimbursement for the EECP treatment is available. Medicare and numerous other commercial third-party payers currently provide reimbursement for the treatment of refractory angina using the EECP therapy.

We are also actively engaged in research to establish the potential benefits of EECP therapy in the management of CHF and are sponsoring a pivotal study to demonstrate the efficacy of EECP therapy in most types of heart failure patients. This study, known as PEECH (Prospective Evaluation of EECP in Congestive Heart Failure), is intended to provide additional clinical data in order to support a Medicare national coverage policy for the use of the EECP therapy in the treatment of CHF. We expect to be able to release the results of the PEECH trial by early 2005.

### **Results of Operations**

#### **Fiscal Years Ended May 31, 2004 and 2003**

##### *Summary*

We generated revenues from the sale, lease and service of our EECP systems of \$22,207,037 and \$24,823,619 for the years ended May 31, 2004 and 2003, respectively, reflecting a decrease of \$2,616,582 or 11%. Our loss before income taxes was \$3,371,880 and \$6,425,671 for the years ended May 31, 2004 and 2003, respectively. We reported a net loss of \$3,422,520 and \$4,790,983 for the years ended May 31, 2004 and 2003, respectively.

##### *Revenues*

The decline in revenues in fiscal year 2004 compared to fiscal year 2003 is due primarily to lower revenue from the sale of EECP systems in the domestic market. Domestic equipment revenue for fiscal 2004 declined

approximately 15% compared to prior year due to: a reduction in the average sales price for EECP systems of approximately 12%; a higher proportion of used equipment compared to new equipment sold during fiscal year 2004 compared to 2003, plus adoption of the provisions of EITF 00-21. Average domestic selling prices have been declining for several years reflecting the impact in the market of lower priced competitive products. We believe that the EECP systems currently sell at a significant price premium to competitive products reflecting the clinical efficacy and superior quality of the EECP system plus the many value added services offered by us, however we anticipate that this current trend of declining prices will continue in the immediate future as our competition attempts to capture greater market share through pricing discounts. Revenue in fiscal year 2004 reflects a 115% increase in the sale of used equipment to the domestic market. This increase in used equipment sales reflects primarily an increase in used equipment available for sale following the completion of the PEECH trial and the repossession of EECP systems from previous sales-type lease customers. We sell used equipment as available to help lessen the impact of price sensitive situations. In September 2003, we adopted "Revenue Arrangements with Multiple Deliverables", ("EITF 00-21"). During the nine months following adoption of the provisions of EITF 00-21, as a result of the adoption of the new policy, we deferred \$92,500 of revenue related to the fair value of installation and in-service training and \$658,333 of revenue related to the warranty service for EECP system sales, which would have previously been recognized as revenue during the period. International shipments of EECP systems declined approximately 24% to \$850,333 due to a higher sales rate in the previous year following receipt of the CE Mark. This was partially offset by a 47% increase in revenue from equipment rental and services reflecting an increase of approximately 94% in service related revenue. The higher service revenue reflects an increase in service, spare parts and consumables as a result of the continued growth of the installed base of EECP systems and greater marketing focus on the sale of extended service contracts. Rental revenue declined approximately 27% during the period reflecting fewer outstanding rental agreements and lower average rental prices.

Reimbursement continues to play a critical role in the adoption of the EECP therapy. Medicare dropped the payment rates 34% from \$208 per hour to \$137 per hour for physicians at the beginning of calendar year 2004. The current reimbursement rate is now set at the rates near when the product first received Medicare coverage in 2000, which makes it more difficult for a private physician practice to financially justify an investment to provide the EECP therapy. It is difficult for us to determine the exact impact this decline has had on the market for the EECP therapy. Additionally, the impact from the drop in reimbursement has been partially offset by the decline in average selling prices and we believe that the EECP therapy continues to offer an attractive addition to the physician private practice, plus the company has continued to support its customers in gaining positive reimbursement coverage from other third-party payers during the past year. EECP therapy is now covered by the majority of private insurers for treating angina patients, including many of the leading Blue Cross Blue Shield plans, who typically are the most difficult payers to adopt coverage for new technologies.

#### *Gross Profit*

Gross profit was \$14,616,934 or 66% of revenues for the year ended May 31, 2004, compared to \$15,572,398 or 63% of revenues for the year ended May 31, 2003. Gross profit margin as a percentage of revenue for the twelve-month period ended May 31, 2004, improved compared to the same year of the prior fiscal year despite the lower revenue and the impact from the reduction in average selling prices. The improvement in gross profit as a percentage of sales reflects the decline in expenditures for service related parts, travel and personnel for the year ended May 31, 2004, when compared to same period of the prior year. In addition, the gross profit margin benefited from the sale of an unusually high percentage of used equipment when compared to the prior year. These systems carried lower book values since they were partially amortized and as a result generated above average margins. We have limited quantities of the lower cost systems and do not anticipate a significant volume of used equipment will be sold in the future. The decline in gross profit when compared to the prior year in absolute dollars is a direct result of the lower sales volume.

Gross profits are dependent on a number of factors, particularly the mix of EECP models sold and their respective average selling prices, the mix of EECP units sold, rented or placed during the period, the ongoing costs of servicing such units, and certain fixed period costs, including facilities, payroll and insurance. Gross profit margins are generally less on non-domestic business due to the use of distributors resulting in lower selling prices. Consequently, the gross profit realized during the current period may not be indicative of future margins.

#### *Selling, General and Administrative*

Selling, general and administrative ("SG&A") expenses for the year ended May 31, 2004 and 2003 were \$12,910,997 or 58% of revenues as compared to \$13,714,913 or 55% of revenues, respectively. The decrease of SG&A resulted primarily from a one-time \$600,000 charge arising from the settlement of litigation in the prior year plus a severance charge for approximately \$300,000 in the prior year, as well as lower marketing expenditures,

primarily for outside services and promotional spending for print and electronic media during fiscal year 2004, as compared to fiscal year 2003. The above decreases were partially offset by higher administrative and selling expenses, which reflected increased insurance costs and continued investment in our direct sales force, consisting of additional personnel and higher incentive and travel costs.

#### *Research and Development*

Research and development (“R&D”) expenses of \$3,748,389 or 17% of revenues for fiscal year 2004, decreased by \$796,433, or 18%, from fiscal year 2003 expenses of \$4,544,822, or 18% of revenues. The decrease is due primarily to reduced clinical study expenditures related to the completion of several smaller clinical studies and, at several sites, the patient treatment phase of the PEECH study. This decrease was partially offset by increased product development costs related to new EECF system models and improvements.

We expect to continue our investments in product development and clinical trials in fiscal 2005 and beyond to further validate and expand the clinical applications of the EECF therapy.

#### *Provision for Doubtful Accounts*

During the year ended May 31, 2004, we charged \$1,296,759 to our provision for doubtful accounts as compared to \$3,728,484 during the year ended May 31, 2003. In fiscal 2004, these charges reflect management decision in the second quarter of fiscal 2004 to record a \$680,000 provision to the allowance for doubtful accounts, which represents all funds due from a sales-type lease customer. We sold our EECF systems to a major customer engaged in establishing independent networks of EECF treatment centers under a sales-type lease aggregating revenues of \$1,271,888. No additional equipment was sold to this customer during fiscal 2003 or 2004. This customer became delinquent in its scheduled monthly payments during the fourth quarter of fiscal 2003. During the first and second quarters of fiscal 2004 the customer attempted to remedy the situation and made payments to us totaling \$70,000. In December 2003, the customer ceased operations. Additional provisions for all other accounts totals approximately \$616,759. In fiscal 2003, these charges primarily resulted from approximately a \$3.0 million write-off of receivables with respect to another major customer, comprised of \$2.5 million for the capital lease and \$500,000 in notes receivable, as well as specific reserves against certain international accounts for which extended credit terms were offered. We no longer offer sales-type leases.

#### *Interest Expense and Financing Costs*

Interest expense and financing costs decreased to \$132,062 in the year ended May 31, 2004, from \$186,574 for the same period in the prior year due to repayment of our revolving secured credit facility in May 2003, which resulted in lower average outstanding borrowings during the fiscal year.

#### *Interest and Other Income, Net*

Interest income and other income for the years ended May 31, 2004, and May 31 2003, was \$99,393 and \$176,724, respectively. The decrease in interest income from the prior year is the direct result of the absence of interest income related to certain equipment sold under sales-type leases incurred in fiscal 2003, as well as declining interest rates this year over last year earned on the average cash balances. Higher average cash balances invested during the year ended May 31, 2004, compared to the prior period partially offset the above.

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

During the fiscal year ended May 31, 2004, we recorded a provision for state income taxes of \$50,640. This is in contrast to an income tax benefit of \$1,634,688 reported during the fiscal year ended May 31, 2003.

As of May 31, 2004, we had recorded deferred tax assets of \$14,582,000 net of a \$1,908,000 valuation allowance related to the anticipated recovery of tax loss carryforwards. The amount of the deferred tax assets considered realizable could be reduced in the future if estimates of future taxable income during the carryforward period are reduced. Ultimate realization of the deferred tax assets is dependent upon our generating sufficient taxable income prior to the expiration of the tax loss carryforwards. We believe that the Company is positioned for long-term growth despite the financial results achieved during fiscal years 2004 and 2003, and that based upon the weight of available evidence, that it is “more likely than not” that net deferred tax assets will be realized. The “more likely than not” standard is subjective, and is based upon management’s estimate of a greater than 50% probability that its long range business plan can be realized.

Ultimate realization of any or all of the deferred tax assets is not assured, due to significant uncertainties associated with estimates of future taxable income during the carryforward period. Our estimates are largely dependent upon achieving considerable growth resulting from the successful commercialization of the EECF therapy into the congestive heart failure indication. Such future estimates of future taxable income are based on our beliefs, as well as

assumptions made by and information currently available to us. Certain critical assumptions associated with our estimates include:

- that the results from the PEECH clinical trial will be sufficiently positive to enable the EECP therapy to obtain approval for a national Medicare reimbursement coverage policy plus other third-party payer reimbursement policies specific to the congestive heart failure indication;
- that the reimbursement coverage will be both broad enough in terms of coverage language and at an amount adequate to enable successful commercialization of the EECP therapy into the congestive heart failure indication.

Additional 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;
- other 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.

The amount of the deferred tax assets considered realizable could be reduced in the future if estimates of future taxable income during the carryforward period are reduced or if the accounting standards are changed to reflect a more stringent standard for evaluation of deferred tax assets.

The recorded deferred tax asset and increase to the valuation allowance during the fiscal year ended May 31, 2004 was \$1,286,000.

## **Fiscal Years Ended May 31, 2003 and 2002**

### *Summary*

We generated revenues from the sale, lease and service of EECP systems of \$24,824,000 and \$34,830,000 for fiscal 2003 and fiscal 2002, respectively, representing a 29% decrease. We generated earnings (loss) before income taxes of \$(6,426,000) and \$4,340,000 for fiscal 2003 and fiscal 2002, respectively. We reported net earnings (loss) of \$(4,791,000) and \$2,786,000 for fiscal 2003 and fiscal 2002, respectively, after recognition of an income tax provision (benefit) of \$(1,635,000) and \$1,554,000, respectively.

### *Revenue*

The decrease in revenues in fiscal 2003 as compared to fiscal 2002 is a result of the following:

- Revenues in fiscal 2002 were favorably impacted by \$4,187,000 resulting from the shipment of EECP systems under sales-type leases and there was no equipment sold under sales-type leases in fiscal 2003.
- Revenues in fiscal 2003 were affected by several factors including, an increase in the duration of the selling cycle of our EECP systems and reduced average unit selling prices. Factors that have caused a longer selling cycle for EECP systems include, among other things, (a) a change in the mix of prospective customers toward larger medical practices and hospitals which have longer decision-making processes; (b) inconsistent or inadequate reimbursement coverage policies among certain third-party insurers; and (c) general economic conditions. Factors that have contributed to reduced average selling prices include increased competition and general economic conditions. Fiscal 2003 revenues from equipment sales were adversely impacted by reductions in average selling prices aggregating approximately \$5,100,000.
- Revenues from non-domestic business were \$1,122,000, accounting for nearly 5% of total revenues compared to \$2,725,000, or 8%, in fiscal 2002.

Our revenue growth over the previous fiscal year periods through 2002 resulted primarily from the increase in cardiology practices and hospitals who became providers of EECP therapy following the announcement by the Centers for Medicare and Medicaid Services (CMS) in February 1999 of its decision to extend Medicare coverage nationally to the Company's noninvasive, outpatient treatment for coronary artery disease. CMS is the federal agency that administers the Medicare program for approximately 39 million beneficiaries. In addition, the results of our multicenter, prospective, randomized, blinded, controlled clinical study of EECP (MUST-EECP) were published in the June 1999 issue of the *Journal of the American College of Cardiology*. Interest in EECP therapy was also spurred by the

announcement of the results of six-month, twelve-month and twenty-four month post-treatment outcomes reported by the International EECF Patient Registry, as well as numerous other studies reported and presented at major scientific meetings, including the American Heart Association (AHA) and the American College of Cardiology (ACC) annual meetings.

#### *Gross Profit*

Gross profit margins for fiscal 2003 and fiscal 2002 were 63% and 70%, respectively. The decrease in overall gross profit for fiscal 2003 compared to 2002 primarily resulted from increases in unit costs, due to lower production levels, as well as overall reductions in the average selling price of EECF systems.

#### *Selling, General and Administrative*

Selling, general and administrative (SG&A) expenses for fiscal 2003 and fiscal 2002 were \$13,715,000 (55% of revenues) and \$13,687,000 (39% of revenues), respectively. The increase in the percentage of SG&A expenses as a percentage of sales was primarily due to the significant decrease in revenues from the prior comparable periods, as discussed above. The increase in SG&A expenses, on an absolute basis, from the comparable prior fiscal periods resulted primarily from a \$600,000 accrual arising from the settlement of litigation in the first quarter, non-recurring charges of \$420,000 for employee severance arrangements and executive recruiting fees in the second quarter, partially offset by overall decreases in sales related expenses due to decreased revenues.

#### *Research and Development*

Research and development (R&D) expenses of \$4,545,000 (18% of revenues) for fiscal 2003 decreased by \$567,000, or 11%, from fiscal 2002 R&D expenses of \$5,112,000 (15% of revenues). R&D expenses are primarily impacted by the PEECH clinical trial in heart failure and other clinical initiatives (including the International EECF Patient Registry), as well as continued product design and development costs.

#### *Provision for Doubtful Accounts*

During fiscal 2003, we charged \$3,728,000 (net of bad debt recoveries of \$494,000) to our provision for doubtful accounts as compared to \$1,304,000 in fiscal 2002. These charges primarily resulted from the write-off of receivables from a major customer during the first quarter of fiscal 2003 of approximately \$3,000,000 due to significant uncertainties related to this customer's ability to satisfy its financial obligations to the Company (see Note E of the accompanying Consolidated Financial Statements), as well as specific reserves against certain domestic and international accounts that defaulted on their payment obligations. During the second quarter of fiscal 2003, we were able to successfully recover all of the units that we had sold under sales-type leases to the aforementioned major customer back into our finished goods inventory and recorded a bad debt recovery of \$479,408, which represented the carrying amount of the equipment at that time.

#### *Interest Expense and Financing Costs*

The increase in interest expense over the prior periods is primarily due to interest on working capital borrowings and related charges under our revolving secured credit facility, as well as loans secured to refinance the November 2000 purchase of our headquarters and warehouse facility.

#### *Interest and Other Income, Net*

The decrease in interest income from the prior fiscal period is the direct result of a decrease in interest income related to certain equipment sold under sales-type leases to a major customer reported in fiscal 2002 and during the first quarter of fiscal 2003, as well as declining interest rates this year over last year, offset by the increase in the average cash balances invested during the current year.

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

In fiscal 2003, we recorded a net benefit for income taxes of \$1,635,000, inclusive of a \$622,000 valuation allowance on deferred tax assets.

### **Liquidity and Capital Resources**

#### *Cash and Cash Flow*

We have financed our operations in fiscal 2004 and 2003 primarily from operations and working capital. At May 31, 2004, we had a cash, cash equivalents, and certificates of deposit balance of \$7,545,589 and working capital of \$9,771,870 as compared to a cash balance of \$5,222,847 and working capital of \$11,478,092 at May 31, 2003. Our

cash, cash equivalents, and certificates of deposit balances increased \$2,332,742 in fiscal year 2004 primarily due to \$1,836,260 in cash provided by operating activities.

The increase in cash provided by our operating activities resulted primarily from lower accounts receivable, which provided cash of \$1,923,284 for the fiscal year ended May 31, 2004. Net accounts receivable were 93% of quarterly revenues for the three-month period ended May 31, 2004, compared to 114% at the end of the three-month period ended May 31, 2003, and net accounts receivable turnover improved to 3.4 times as of May 31, 2004, as compared to 2.5 times as of May 31, 2003. We have tightened our sales credit policy, reduced extended payment terms and provide routine oversight with respect to our accounts receivable credit and collection efforts.

Standard payment terms on our domestic equipment sales are generally net 30 to 90 days from shipment and do not contain "right of return" provisions. We have historically offered a variety of extended payment terms, including sales-type leases, in certain situations and to certain customers in order to expand the market for our EECF products in the US and internationally. Such extended payment terms were offered in lieu of price concessions, in competitive situations, when opening new markets or geographies and for repeat customers. Extended payment terms cover a variety of negotiated terms, including payment in full - net 120, net 180 days or some fixed or variable monthly payment amount for a six to twelve month period followed by a balloon payment, if applicable. During the fiscal years ended May 31, 2004 and 2003, approximately 1% and 5% of revenues, respectively, were generated from sales in which payment terms were greater than 90 days and we offered no sales-type leases during either period. In general, reserves are calculated on a formula basis considering factors such as the aging of the receivables, time past due, and the customer's credit history and their current financial status. In most instances where reserves are required, or accounts are ultimately written-off, customers have been unable to successfully implement their EECF program. As we are creating a new market for the EECF therapy and recognizing the challenges that some customers may encounter, we have opted, at times, on a customer-by-customer basis, to recover our equipment instead of pursuing other legal remedies, which has resulted in our recording of a reserve or a write-off.

Other key factors causing the increase in cash from the prior year provided by our operating activities included the reduction in inventories, which decreased by \$1,065,819 for the fiscal year ended May 31, 2004, reflecting efforts to improve our procurement of raw materials and management of finished goods inventory levels and an increase in accounts payable, accrued expenses and other current liabilities of \$517,056. Additionally, non-cash adjustments for depreciation, amortization, allowance for doubtful accounts and allowance for inventory write-offs to reconcile the net loss of \$3,422,520 to net cash provided by operating activities total \$1,484,870.

Investing activities used net cash of \$1,334,494 during the fiscal year ended May 31, 2004, reflecting investment associated with the purchase of short-term certificates of deposit of \$1,180,540 and the purchase of property and equipment, primarily the implementation of our new enterprise resource planning software (ERP), of \$153,954.

Financing activities provided net cash of \$640,436 during the fiscal year ended May 31, 2004, reflecting \$697,387 received from the exercise of stock options plus new borrowings of \$67,149 related to our new ERP system. Payments of principal on notes and loans were \$124,100 partially offsetting the above.

We cancelled our line of credit in August 2004 and do not currently have an available line of credit.

We believe that our cash flow from operations together with our current cash reserves will be sufficient to fund our business plan and projected capital requirements through at least May 31, 2005; however, despite our improved cash balances, we have incurred significant losses during the last two fiscal years and our long-term ability to maintain current operations is dependent upon achieving profitable operations or through additional debt or equity financing. In the event that additional capital is required, we may seek to raise such capital through public or private equity or debt financings. Future capital funding, if available, may result in dilution to current shareholders.

#### *Off-Balance Sheet Arrangements*

As part of our on-going business, we do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities ("SPEs"), which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of May 31, 2004, we are not involved in any unconsolidated SPE.

### *Contractual Obligations*

The following table presents our expected cash requirements for contractual obligations outstanding as of May 31, 2004:

	Total	Due as of 5/31/05	Due as of 5/31/06 and 5/31/07	Due as of 5/31/08 and 5/31/09	Due Thereafter
Long-Term Debt	\$1,229,315	\$136,478	\$241,890	\$136,293	\$714,654
Operating Leases	138,873	76,446	62,427	--	--
Litigation Settlement	333,500	133,250	200,250	--	--
Severance obligations	35,000	35,000	--	--	--
Employment Agreements	290,685	250,000	40,685	--	--
Total Contractual Cash Obligations	\$2,027,373	\$631,174	\$545,252	\$136,293	\$714,654

### **Effects of Inflation**

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

## **Critical Accounting Policies**

Financial Reporting Release No. 60, which was released by the Securities and Exchange Commission, or SEC, in December 2001, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Note A of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended May 31, 2004 includes a summary of our significant accounting policies and methods used in the preparation of our financial statements. In preparing these financial statements, we have made our best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. Our critical accounting policies are as follows:

### *Revenue Recognition*

We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred or service has been rendered, the price is fixed or determinable and collectibility is reasonably assured. In the United States, we recognize revenue from the sale of our EECP systems in the period in which we deliver the system to the customer. Revenue from the sale of our EECP systems to international markets is recognized upon shipment, during the period in which we deliver the product to a common carrier, as are supplies, accessories and spare parts delivered to both domestic and international customers. Returns are accepted prior to the installation and in-service training subject to a 10% restocking charge or for normal warranty matters, and we are not obligated for post-sale upgrades to these systems.

In most cases, revenue from direct EECP system sales is generated from multiple-element arrangements that require judgment in the areas of customer acceptance, collectibility, the separability of units of accounting, and the fair value of individual elements. Effective September 1, 2003, we adopted the provisions of Emerging Issues Task Force, or EITF, Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables", ("EITF 00-21"), on a prospective basis. The principles and guidance outlined in EITF 00-21 provide a framework to determine (a) how the arrangement consideration should be measured (b) whether the arrangement should be divided into separate units of accounting, and (c) how the arrangement consideration should be allocated among the separate units of accounting. We determined that our multiple-element arrangements are generally comprised of the following elements that would qualify as separate units of accounting: system sales, in-service support consisting of equipment set-up and training provided at the customers facilities and warranty service for system sales generally covered by a warranty period of one year. Each of these elements represent individual units of accounting as the delivered item has value to a customer on a stand-alone basis, objective and reliable evidence of fair value exists for undelivered items, and arrangements normally do not contain a general right of return relative to the delivered item. We determine fair value based on the price of the deliverable when it is sold separately or based on third-party evidence. In accordance with the guidance in EITF 00-21, we use the residual method to allocate the arrangement consideration when it does not have fair value of the EECP system sale. Under the residual method, the amount of consideration allocated to the delivered item equals the total arrangement consideration less the aggregate fair value of the undelivered items. Assuming all other criteria for revenue recognition have been met, we recognize revenue for EECP system sales when delivery and acceptance occurs, for installation and in-service training when the services are rendered, and for warranty service ratably over the service period, which is generally one year.

Upon adoption of the provisions of EITF 00-21 beginning September 1, 2003, we deferred \$92,500 of revenue, net of amortization during the period, related to the fair value of installation and in-service training plus \$658,333 of revenue, net of amortization during the period, related to the warranty service for EECP system sales delivered during the nine-month period ended May 31, 2004. The amount related to warranty service will be recognized as service revenue ratably over the related service period, which is generally one year. Previously, in accordance with Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements," we accrued costs associated with these arrangements as warranty expense in the period the system was delivered and accepted.

We also recognize revenue generated from servicing EECP systems that are no longer covered by a warranty agreement, or by providing sites with additional training, in the period that these services are provided. Revenue related to future commitments under separately priced extended warranty agreements on the EECP system are deferred and recognized ratably over the service period, generally ranging from one year to four years. Deferred revenues related to extended warranty agreements that have been invoiced to customers prior to the performance of these services were \$2,095,618 and \$1,709,551 as of May 31, 2004 and 2003, respectively. Costs associated with the provision of service and maintenance, including salaries, benefits, travel, spare parts and equipment, are recognized in cost of sales as incurred. Amounts billed in excess of revenue recognized are included as deferred revenue in the consolidated balance sheets.



We have also entered into lease agreements for our EECF systems, generally for terms of one year or less, that are classified as operating leases. Revenues from operating leases are generally recognized, in accordance with the terms of the lease agreements, on a straight-line basis over the life of the respective leases. For certain operating leases in which payment terms are determined on a "fee-per-use" basis, revenues are recognized as incurred (i.e., as actual usage occurs). The cost of the EECF system utilized under operating leases is recorded as a component of property and equipment and is amortized to cost of sales over the estimated useful life of the equipment, not to exceed five years. There were no significant minimum rental commitments on these operating leases at May 31, 2004.

We follow SFAS No. 13, "Accounting For Leases," for sales of EECF systems under sales-type leases. In accordance with SFAS No. 13, we record the sale and financing receivable at the amount of the minimum lease payment, less unearned interest income, which is computed at the interest rate implicit in the lease, an allowance for bad debt and executory costs, which are primarily related to product warranties on each unit sold. Unearned interest income is amortized to income in a manner that produces a constant rate of return on the investment in the sales-type lease. The cost of the EECF system acquired by the customer is recorded as cost of sales in the same period that the sale is recorded. At the present time, the Company is no longer offering sales-type leases.

#### *Accounts Receivable/Financing Receivables*

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

In addition, we periodically review and assess the net realizability of our receivables arising from sales-type leases. If this review results in a lower estimate of the net realizable value of the receivable, an allowance for the unrealized amount is established in the period in which the estimate is changed. In the first quarter of fiscal 2003 and the second quarter of fiscal 2004, we decided to write-off financing receivables under sales-type leases of approximately \$2,558,000 and \$680,000, respectively, as a result of significant uncertainties with respect to these customers' ability to meet their financial obligations.

#### *Inventories, net*

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

#### *Deferred Revenues*

We record revenue on extended service contracts ratably over the term of the related warranty contracts. Effective September 1, 2003, we prospectively adopted the provisions of EITF 00-21. Upon adoption of the provisions of EITF 00-21 we began to defer revenue related to EECF system sales for the fair value of installation and in-service training to the period when the services are rendered and for warranty obligations ratably over the service period, which is generally one year.

#### *Warranty Costs*

Equipment sold is generally covered by a warranty period of one year. Effective September 1, 2003, we adopted the provisions of EITF 00-21 on a prospective basis. Under EITF 00-21, for certain arrangements, a portion of the overall system price attributable to the first year warranty service is deferred and recognized as revenue over the service period. As such, we no longer accrue warranty costs upon delivery but rather recognize warranty and related service costs as incurred. Prior to September 1, 2003, we accrued a warranty reserve for estimated costs to provide warranty services when the equipment sale was recognized. The factors affecting our warranty liability included the

number of units sold and historical and anticipated rates of claims and costs per claim. The warranty provision resulting from transactions prior to September 1, 2003 will be reduced in future periods for material and labor costs incurred as related product is returned during the warranty period or when the warranty period elapses.

#### *Income Taxes*

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

Deferred tax liabilities and assets are classified as current or non-current based on the classification of the related asset or liability for financial reporting. A deferred tax liability or asset that is not related to an asset or liability for financial reporting, including deferred tax assets related to carryforwards, are classified according to the expected reversal date of the temporary difference. The deferred tax asset we recorded relates primarily to the realization of net operating loss carryforwards, of which the allocation of the current portion, if any, reflects the expected utilization of such net operating losses in next twelve months. Such allocation is based our internal financial forecast and may be subject to revision based upon actual results.

#### *Stock Compensation*

We have four stock-based employee compensation plans. We account for stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations ("APB No. 25") and have adopted the disclosure provisions of Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure, an amendment of FASB Statement No. 123." Under APB No. 25, when the exercise price of our employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. Accordingly, no compensation expense has been recognized in the consolidated financial statements in connection with employee stock option grants.

Pro forma compensation expense may not be indicative of future disclosures because it does not take into effect pro forma compensation expense related to grants before 1995. For purposes of estimating the fair value of each option on the date of grant, we utilized the Black-Scholes option-pricing model.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in our opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

Equity instruments issued to non-employees in exchange for goods, fees and services are accounted for under the fair value-based method of SFAS No. 123.

#### **Recently Issued Accounting Standards**

In April 2003, the FASB issued Statement of Financial Accounting Standards No. 149 ("SFAS No. 149"), "Amendment of Statement 133 on Derivative Instruments and Hedging Activities," which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS No. 133. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003, except for the provisions that were cleared by the FASB in prior pronouncements. The adoption of SFAS No. 149 has not had a material impact on our financial position and results of operations.

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150 ("SFAS No. 150"), "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This statement establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. In accordance with the standard, financial instruments that embody obligations for the issuer are required to be classified as liabilities. This Statement shall be effective for financial instruments entered into or modified after May 31, 2003, and otherwise shall be effective at the beginning of

the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 has not had a material impact on our financial position and results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 "Consolidation of Variable Interest Entities" ("FIN 46"), as interpreted by FIN 46R. In general, a variable interest entity is a corporation, partnership, trust, or any other legal structure used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. A variable interest entity often holds financial assets, including loans or receivables, real estate or other property. A variable interest entity may be essentially passive or it may engage in activities on behalf of another company. Until now, a company generally has included another entity in its consolidated financial statements only if it controlled the entity through voting interests. FIN 46 changes that by requiring a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. FIN 46's consolidation requirements apply immediately to variable interest entities created or acquired after January 31, 2003. The consolidation requirements apply to older entities in the first interim period beginning after June 15, 2003. Certain of the disclosure requirements apply in all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. We adopted FIN 46 effective January 31, 2003. The adoption of FIN 46 did not have a material impact on our financial position or results of operations.

In November 2002, the Emerging Issues Task Force, ("EITF") reached a consensus opinion on, "Revenue Arrangements with Multiple Deliverables", "(EITF 00-21)". That consensus provides that revenue arrangements with multiple deliverables should be divided into separate units of accounting if certain criteria are met. The consideration of the arrangement should be allocated to the separate units of accounting based on their relative fair values, with different provisions if the fair value is contingent on delivery of specified items or performance conditions. Applicable revenue criteria should be considered separately for each separate unit of accounting. EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. Effective September 1, 2003, we prospectively adopted the provisions of EITF 00-21. Upon adoption of the provisions of EITF 00-21, we deferred net of amortization \$92,500 of revenue related to the fair value of installation and in-service training and \$658,333 of revenue related to the warranty service for EEC system sales recognized for the nine-month period ended May 31, 2004.

In December 2003, the SEC issued Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition" (SAB No. 104), which codifies, revises and rescinds certain sections of SAB No. 101, "Revenue Recognition in Financial Statements", in order to make this interpretive guidance consistent with current authoritative accounting and auditing guidance and SEC rules and regulations. The changes noted in SAB No. 104 did not have a material effect on our financial position or results of operations.

## **ITEM 7A - QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to certain financial market risks, including changes in interest rates. All of the Company's revenue, expenses and capital spending are transacted in US dollars. Our exposure to market risk for changes in interest rates relates primarily to our cash and cash equivalent balances, investments in sales-type leases and the line of credit agreement. The majority of our investments are in short-term instruments and subject to fluctuations in US interest rates. Due to the nature of our short-term investments, we believe that there is no material risk exposure.

## **ITEM 8 - FINANCIAL STATEMENTS**

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

## **ITEM 9 - DISAGREEMENTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## **ITEM 9A - CONTROLS AND PROCEDURES**

The Company carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective. There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

### PART III

#### ITEM 10 - DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this Item will be included in our definitive Proxy Statement, which will be filed with the Securities and Exchange Commission in connection with our 2004 Annual Meeting of Stockholders, and is incorporated herein by reference.

#### ITEM 11 - EXECUTIVE COMPENSATION

The information required by this Item will be included in our definitive Proxy Statement, which will be filed with the Securities and Exchange Commission in connection with our 2004 Annual Meeting of Stockholders, and is incorporated herein by reference.

#### ITEM 12 - SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this Item will be included in our definitive Proxy Statement, which will be filed with the Securities and Exchange Commission in connection with our 2004 Annual Meeting of Stockholders, and is incorporated herein by reference.

#### ITEM 13 - CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item will be included in our definitive Proxy Statement, which will be filed with the Securities and Exchange Commission in connection with our 2004 Annual Meeting of Stockholders, and is incorporated herein by reference.

#### ITEM 14 - PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item will be included in our definitive Proxy Statement, which will be filed with the Securities and Exchange Commission in connection with our 2004 Annual Meeting of Stockholders, and is incorporated herein by reference.

#### ITEM 15 - EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) Financial Statements and Financial Statement Schedules

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

(2) The following Consolidated Financial Statement Schedule is included in Part IV of this report:

Schedule II – Valuation and Qualifying Accounts

All other schedules are omitted because they are not applicable, or not required, or because the required information is included in the Consolidated Financial Statements or notes thereto.

(b) Form 8-K Reports

None

(c) Exhibits

- (3) (a) Restated Certificate of Incorporation (2)
- (b) By-Laws (1)
- (4) (a) Specimen Certificate for Common Stock (1)
- (b) Certificate of Designation of the Preferred Stock, Series A (3)
- (c) Certificate of Designation of the Preferred Stock, Series B (7)
- (d) Form of Rights Agreement dated as of March 9, 1995, between Registrant and American Stock Transfer & Trust Company (5)
- (e) Certificate of Designation of the Preferred Stock, Series C (8)
- (10) (a) 1995 Stock Option Plan (6)
- (b) Outside Director Stock Option Plan (6)
- (c) Employment Agreement dated February 1, 1995, as amended March 12, 1998, and October 10, 2001, between Registrant and John C.K. Hui (4) (9) (13)
- (d) 1997 Stock Option Plan, as amended (10)
- (e) 1999 Stock Option Plan, as amended (11)
- (f) Credit Agreement dated February 21, 2002, between Vasomedical, Inc. and Fleet National Bank (12)
- (g) Agreement dated October 1, 2002, between the Registrant and Peter F. Cohn (14)
- (h) Termination and Settlement Agreement dated October 21, 2002, between the Registrant and D. Michael Deignan (14)

- (i) Employment Agreement dated October 28, 2002, and amended June 30, 2003, between the Registrant and Photios T. Paulson (14) (16)
  - (j) Amendment and Waiver to Credit Agreement dated October 18, 2002, between the Vasomedical, Inc. and Fleet National Bank (14)
  - (k) Amendment No. 2 and Waiver to Credit Agreement dated April 10, 2003, between the Registrant and Fleet National Bank (15)
  - (l) Employment Agreement dated September 8, 2003, between Registrant and Thomas W. Fry (17)
- (22) Subsidiaries of the Registrant

	<u>Name</u>	<u>State of Incorporation</u>	<u>Percentage Owned by Company</u>
	Viromedics, Inc.	Delaware	61%
	180 Linden Avenue Corp.	New York	100%
(23)	Consent of Grant Thornton LLP		
(31)	Certification Reports pursuant to Securities Exchange Act Rule 13a - 14		
(32)	Certification Reports pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		

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- (1) Incorporated by reference to Registration Statement on Form S-18, No. 33-24095.
  - (2) Incorporated by reference to Registration Statement on Form S-1, No. 33-46377 (effective 7/12/94).
  - (3) Incorporated by reference to Report on Form 8-K dated November 14, 1994.
  - (4) Incorporated by reference to Report on Form 8-K dated January 24, 1995.
  - (5) Incorporated by reference to Registration Statement on Form 8-A dated May 12, 1995.
  - (6) Incorporated by reference to Notice of Annual Meeting of Stockholders dated December 5, 1995.
  - (7) Incorporated by reference to Report on Form 8-K dated June 25, 1997.
  - (8) Incorporated by reference to Report on Form 8-K dated April 30, 1998.
  - (9) Incorporated by reference to Report on Form 10-K for the fiscal year ended May 31, 1998.
  - (10) Incorporated by reference to Report on Form 10-K for the fiscal year ended May 31, 1999.
  - (11) Incorporated by reference to Report on Form 10-K for the fiscal year ended May 31, 2000.
  - (12) Incorporated by reference to Report on Form 10-Q for the quarterly period ended February 28, 2002.
  - (13) Incorporated by reference to Report on Form 10-K for the fiscal year ended May 31, 2002.
  - (14) Incorporated by reference to Report on Form 10-Q for the quarterly period ended November 30, 2002.
  - (15) Incorporated by reference to Report on Form 10-Q for the quarterly period ended February 28, 2003.
  - (16) Incorporated by reference to Report on Form 8-K dated June 30, 2003.
  - (17) Incorporated by reference to Report on Form 10-Q for the quarterly period ended February 29, 2004.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, we have duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 16 day of August, 2004.

### VASOMEDICAL, INC.

By: /s/ Photios T. Paulson  
Photios T. Paulson  
President, Chief Executive Officer and Director  
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on August 16, 2004, by the following persons in the capacities indicated:

<u>/s/ Alexander G. Bearn</u> Alexander G. Bearn	Director
<u>/s/ David S. Blumenthal</u> David S. Blumenthal	Director
<u>/s/ Photios T. Paulson</u> Photios T. Paulson	President, Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ Abraham E. Cohen</u> Abraham E. Cohen	Chairman of the Board
<u>/s/ Thomas W. Fry</u> Thomas W. Fry	Chief Financial Officer (Principal Financial and Accounting Officer)
<u>/s/ John C.K. Hui</u> John C.K. Hui	Senior Vice President, Chief Technology Officer and Director
<u>/s/ Kenneth W. Rind</u> Kenneth W. Rind	Director
<u>/s/ E. Donald Shapiro</u> E. Donald Shapiro	Director
<u>/s/ Anthony Viscusi</u> Anthony Viscusi	Director
<u>/s/ Forrest R. Whittaker</u> Forrest R. Whittaker	Director
<u>/s/ Martin Zeiger</u> Martin Zeiger	Director

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated July 23, 2004, accompanying the consolidated financial statements and schedule included in the Annual Report of Vasomedical, Inc. and Subsidiaries on Form 10-K for the fiscal year ended May 31, 2004. We hereby consent to the incorporation by reference of said report in the Registration Statements of Vasomedical, Inc. and Subsidiaries on Forms S-3 (File No. 333-34044, effective April 12, 2000, File No. 333-60341, effective December 28, 1998, File No. 333-33319, effective August 21, 1997, and File No. 33-62329, effective September 18, 1995) and on Forms S-8 (File No. 333-86152, effective April 12, 2002, File No. 333-42692, effective August 1, 2000, File No. 333-85457, effective August 18, 1999, File No. 333-85455, effective August 18, 1999, File No. 333-60471, effective August 3, 1998, File No. 333-11579, effective September 6, 1996, File No. 333-11581, effective September 6, 1996, and File No. 333-11583, effective September 6, 1996).

*Grant Thornton LLP*

GRANT THORNTON LLP

Melville, New York  
July 23, 2004



CERTIFICATION PURSUANT TO SECURITIES EXCHANGE ACT RULE 13A-14

I, Photios T. Paulson, certify that:

1. I have reviewed this report on Form 10-K of Vasomedical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 and 15d-15e) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2004

/s/ Photios T. Paulson  
Photios T. Paulson  
President and Chief Executive Officer

CERTIFICATION PURSUANT TO SECURITIES EXCHANGE ACT RULE 13A-14

I, Thomas W. Fry, certify that:

1. I have reviewed this report on Form 10-K of Vasomedical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 and 15d-15e) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2004

/s/ Thomas W. Fry  
Thomas W. Fry  
Chief Financial Officer

**CERTIFICATION OF PERIODIC REPORT**

I, Photios T. Paulson, President and Chief Executive Officer of Vasomedical, Inc. (the “Company”), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

- (1) the Annual Report on Form 10-K of the Company for the fiscal year ended May 31, 2004 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 16, 2004

/s/ Photios T. Paulson  
Photios T. Paulson  
President and Chief Executive Officer

I, Thomas W. Fry, Chief Financial Officer of Vasomedical, Inc. (the “Company”), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

- (1) the Annual Report on Form 10-K of the Company for the fiscal year ended May 31, 2004 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 16, 2004

/s/ Thomas W. Fry  
Thomas W. Fry  
Chief Financial Officer

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Vasomedical, Inc. and Subsidiaries

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	F-2
Financial Statements	
Consolidated Balance Sheets as of May 31, 2004 and 2003	F-3
Consolidated Statements of Earnings for the years ended May 31, 2004, 2003 and 2002	F-4
Consolidated Statement of Changes in Stockholders' Equity for the years ended May 31, 2004, 2003 and 2002	F-5
Consolidated Statements of Cash Flows for the years ended May 31, 2004, 2003 and 2002	F-6
Notes to Consolidated Financial Statements	F-7 – F-21
Financial Statement Schedule	
Schedule II - Valuation and Qualifying Accounts	S-1

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

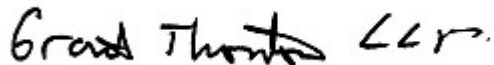
Stockholders and Board of Directors  
**Vasomedical, Inc. and Subsidiaries**

We have audited the accompanying consolidated balance sheets of Vasomedical, Inc. and Subsidiaries (the "Company") as of May 31, 2004 and 2003, and the related consolidated statements of earnings, changes in stockholders' equity and cash flows for each of the three fiscal years in the period ended May 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Vasomedical, Inc. and Subsidiaries as of May 31, 2004 and 2003, and the consolidated results of their operations and their consolidated cash flows for each of the three fiscal years in the period ended May 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

We have also audited Schedule II – Valuation and Qualifying Accounts for each of the three fiscal years in the period ended May 31, 2004. In our opinion, this schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.



GRANT THORNTON LLP

Melville, New York  
July 23, 2004

Vasomedical, Inc. and Subsidiaries  
CONSOLIDATED BALANCE SHEETS

	May 31,	
ASSETS	2004	2003
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$6,365,049	\$5,222,847
Certificates of deposit	1,180,540	--
Accounts receivable, net of an allowance for doubtful accounts of \$699,203 and \$768,629 at May 31, 2004 and 2003, respectively	5,521,853	7,377,118
Inventories, net	2,373,748	3,439,567
Deferred income taxes	--	303,000
Financing receivables, net	--	264,090
Other current assets	272,513	268,231
Total current assets	15,713,703	16,874,853
PROPERTY AND EQUIPMENT, net of accumulated depreciation of \$2,378,576 and \$ 2,338,366 at May 31, 2004 and 2003, respectively	2,430,521	3,233,158
FINANCING RECEIVABLES, net	--	679,296
DEFERRED INCOME TAXES	14,582,000	14,279,000
OTHER ASSETS	297,391	261,243
	\$33,023,615	\$35,327,550
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued expenses	\$3,122,184	\$2,667,861
Current maturities of long-term debt and notes payable	136,478	108,462
Sales tax payable	353,360	461,704
Deferred revenues	1,734,925	789,118
Accrued warranty and customer support expenses	161,917	575,000
Accrued professional fees	91,486	207,793
Accrued commissions	341,483	586,823
Total current liabilities	5,941,833	5,396,761
LONG-TERM DEBT	1,092,837	1,177,804
ACCRUED WARRANTY COSTS	83,000	213,000
DEFERRED REVENUES	1,111,526	920,433
OTHER LIABILITIES	200,250	300,250
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, \$.01 par value; 1,000,000 shares authorized; none issued and outstanding	--	--
Common stock, \$.001 par value; 110,000,000 shares authorized; 58,419,356 and 57,822,023 shares at May 31, 2004 and 2003, respectively, issued and outstanding	58,419	57,822
Additional paid-in capital	51,320,106	50,623,316
Accumulated deficit	(26,784,356)	(23,361,836)
Total stockholders' equity	24,594,169	27,319,302
	\$33,023,615	\$35,327,550

*The accompanying notes are an integral part of these statements.*

Vasomedical, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF EARNINGS

	Fiscal Year Ended May 31,		
	2004	2003	2002
Revenues			
Equipment sales	\$19,302,593	\$22,850,391	\$29,304,349
Equipment rentals and services	2,904,444	1,973,228	1,339,113
Equipment sold under sales-type leases	--	--	4,187,009
	<u>22,207,037</u>	<u>24,823,619</u>	<u>34,830,471</u>
Cost of sales and services	<u>7,590,103</u>	<u>9,251,221</u>	<u>10,538,731</u>
Gross profit	14,616,934	15,572,398	24,291,740
Expenses			
Selling, general and administrative	12,910,997	13,714,913	13,686,958
Research and development	3,748,389	4,544,822	5,112,258
Provision for doubtful accounts	1,296,759	3,728,484	1,304,000
Interest and financing costs	132,062	186,574	98,140
Interest and other income, net	(99,393)	(176,724)	(249,722)
	<u>17,988,814</u>	<u>21,998,069</u>	<u>19,951,634</u>
EARNINGS (LOSS) BEFORE INCOME TAXES	<u>(3,371,880)</u>	<u>(6,425,671)</u>	<u>4,340,106</u>
Income tax (expense) benefit, net	(50,640)	1,634,688	(1,554,000)
NET EARNINGS (LOSS)	<u><u>\$(3,422,520)</u></u>	<u><u>\$(4,790,983)</u></u>	<u><u>\$2,786,106</u></u>
Net earnings (loss) per common share			
- basic	<u><u>\$(0.06)</u></u>	<u><u>\$(0.08)</u></u>	<u><u>\$0.05</u></u>
- diluted	<u><u>\$(0.06)</u></u>	<u><u>\$(0.08)</u></u>	<u><u>\$0.05</u></u>
Weighted average common shares outstanding			
- basic	<u>57,981,963</u>	<u>57,647,032</u>	<u>57,251,035</u>
- diluted	<u>57,981,963</u>	<u>57,647,032</u>	<u>59,468,092</u>

*The accompanying notes are an integral part of these statements.*



**CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

	Common Stock Shares	Common Stock Amount	Additional Paid-in- Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at June 1, 2001	57,195,453	\$57,195	\$49,808,493	\$(21,356,959)	\$28,508,729
Exercise of options and warrants	113,667	114	199,529		199,643
Stock options granted for services			50,126		50,126
Tax benefit of stock options and warrants			58,000		58,000
Net earnings				2,786,106	2,786,106
Balance at May 31, 2002	57,309,120	57,309	50,116,148	(18,570,853)	31,602,604
Exercise of options and warrants	512,903	513	234,487		235,000
Stock options granted for services			50,681		50,681
Tax benefit of stock options and warrants			222,000		222,000
Net loss				(4,790,983)	(4,790,983)
Balance at May 31, 2003	57,822,023	57,822	50,623,316	(23,361,836)	27,319,302
Exercise of options and warrants	597,333	597	696,790		697,387
Net loss				(3,422,520)	(3,422,520)
Balance at May 31, 2004	58,419,356	\$58,419	\$51,320,106	\$(26,784,356)	\$24,594,169

*The accompanying notes are an integral part of these statements.*

Vasomedical, Inc. and Subsidiaries

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year ended May 31,		
	2004	2003	2002
Cash flows from operating activities			
Net earning (loss)	<u>\$(3,422,520)</u>	<u>\$(4,790,983)</u>	<u>\$2,786,106</u>
Adjustments to reconcile net earnings (loss) to net cash provided by (used in) operating activities			
Depreciation and amortization	749,111	1,132,996	962,167
Provision for doubtful accounts, net of write-offs	616,759	2,209,101	904,687
Reserve for inventory obsolescence	119,000	100,000	30,000
Deferred income taxes	--	(1,669,000)	1,573,000
Stock options granted for services	--	50,681	50,126
Changes in operating assets and liabilities			
Accounts receivable	1,923,284	5,643,288	(3,855,663)
Financing receivables, net	258,608	118,126	(3,575,373)
Inventories	1,187,761	1,079,976	(1,694,198)
Other current assets	(4,282)	359,012	(183,356)
Other assets	(69,610)	(79,082)	(142,062)
Accounts payable, accrued expenses and other current liabilities	517,056	(1,286,324)	443,649
Other liabilities	(38,907)	311,813	384,265
	<u>5,258,780</u>	<u>7,970,587</u>	<u>(5,102,758)</u>
Net cash provided by (used in) operating activities	<u>1,836,260</u>	<u>3,179,604</u>	<u>(2,316,652)</u>
Cash flows (used in) investing activities			
Purchase of certificates of deposit, net	(1,180,540)	--	--
Issuance of notes	--	--	(500,000)
Purchase of property and equipment	(153,954)	(326,489)	(319,981)
Net cash (used in) investing activities	<u>(1,334,494)</u>	<u>(326,489)</u>	<u>(819,981)</u>
Cash flows provided by (used in) financing activities			
Proceeds from notes payable	67,149	238,071	2,141,667
Payments on notes payable	(124,100)	(1,070,966)	(1,164,173)
Restricted cash	--	--	1,141,667
Proceeds from exercise of options and warrants	697,387	235,000	199,643
Net cash provided by (used in) financing activities	<u>640,436</u>	<u>(597,895)</u>	<u>2,318,804</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	<u>1,142,202</u>	<u>2,255,220</u>	<u>(817,829)</u>
Cash and cash equivalents - beginning of period	<u>5,222,847</u>	<u>2,967,627</u>	<u>3,785,456</u>
Cash and cash equivalents - end of period	<u>\$6,365,049</u>	<u>\$5,222,847</u>	<u>\$2,967,627</u>
Non-cash investing and financing activities were as follows:			
Inventories transferred to (from) property and equipment, attributable to operating leases - net	\$(240,942)	\$761,986	\$1,130,020
Supplement disclosures:			
Interest paid	\$105,194	\$186,574	\$98,139
Income taxes paid	\$24,213	\$87,963	\$304,263

*The accompanying notes are an integral part of these statements.*

Vasomedical, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

May 31, 2004, 2003 and 2002

NOTE A - BUSINESS ACTIVITIES AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company was incorporated in Delaware in July 1987. During fiscal 1996, the Company commenced the commercialization of its EECP external counterpulsation system ("EECP"), a microprocessor-based medical device for the noninvasive, outpatient treatment of patients with cardiovascular disease. EECP is marketed worldwide to hospitals and physician private practices. To date, net Company's revenues have been generated from customers in the United States.

A summary of the significant accounting policies consistently applied in the preparation of the consolidated financial statements follows:

*Principles of Consolidation*

The consolidated financial statements include the accounts of the Company, its wholly-owned subsidiary and its inactive majority-owned subsidiary. Significant intercompany accounts and transactions have been eliminated.

*Revenue Recognition*

The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred or service has been rendered, the price is fixed or determinable and collectibility is reasonably assured. In the United States, the Company recognizes revenue from the sale of its EECP systems in the period in which the Company delivers the system to the customer. Revenue from the sale of its EECP systems to international markets is recognized upon shipment, during the period in which the Company delivers the product to a common carrier, as are supplies, accessories and spare parts delivered to both domestic and international customers. Returns are accepted prior to the installation and in-service training subject to a 10% restocking charge or for normal warranty matters, and the Company is not obligated for post-sale upgrades to these systems.

In most cases, revenue from direct EECP system sales is generated from multiple-element arrangements that require judgment in the areas of customer acceptance, collectibility, the separability of units of accounting, and the fair value of individual elements. Effective September 1, 2003, the Company adopted the provisions of Emerging Issues Task Force, or EITF, Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables", ("EITF 00-21"), on a prospective basis. The principles and guidance outlined in EITF 00-21 provide a framework to determine (a) how the arrangement consideration should be measured (b) whether the arrangement should be divided into separate units of accounting, and (c) how the arrangement consideration should be allocated among the separate units of accounting. The Company determined that its multiple-element arrangements are generally comprised of the following elements that would qualify as separate units of accounting: system sales, in-service support consisting of equipment set-up and training provided at the customers facilities and warranty service for system sales generally covered by a warranty period of one year. Each of these elements represent individual units of accounting as the delivered item has value to a customer on a stand-alone basis, objective and reliable evidence of fair value exists for undelivered items, and arrangements normally do not contain a general right of return relative to the delivered item. The Company determines fair value based on the price of the deliverable when it is sold separately or based on third-party evidence. In accordance with the guidance in EITF 00-21, the Company uses the residual method to allocate the arrangement consideration when it does not have fair value of the EECP system sale. Under the residual method, the amount of consideration allocated to the delivered item equals the total arrangement consideration less the aggregate fair value of the undelivered items. Assuming all other criteria for revenue recognition have been met, the Company recognizes revenue for EECP system sales when delivery and acceptance occurs, for installation and in-service training when the services are rendered, and for warranty service ratably over the service period, which is generally one year.

Upon adoption of the provisions of EITF 00-21 beginning September 1, 2003, the Company deferred \$92,500 of revenue, net of amortization during the period, related to the fair value of installation and in-service training plus \$658,333 of revenue, net of amortization during the period, related to the warranty service for EECP system sales delivered during the nine-month period ended May 31, 2004. The amount related to warranty service will be recognized as service revenue ratably over the related service period, which is generally one year. Previously, in accordance with Staff Accounting

Bulletin No. 101, "Revenue Recognition in Financial Statements," the Company accrued costs associated with these arrangements as warranty expense in the period the system was delivered and accepted.

The Company also recognizes revenue generated from servicing EECF systems that are no longer covered by a warranty agreement, or by providing sites with additional training, in the period that these services are provided. Revenue related to future commitments under separately priced extended warranty agreements on the EECF system are deferred and recognized ratably over the service period, generally ranging from one year to four years. Deferred revenues related to extended warranty agreements that have been invoiced to customers prior to the performance of extended warranty services were \$2,095,618 and \$1,709,551 as of May 31, 2004 and 2003, respectively. Costs associated with the provision of service and maintenance, including salaries, benefits, travel, spare parts and equipment, are recognized in cost of sales as incurred. Amounts billed in excess of revenue recognized are included as deferred revenue in the consolidated balance sheets.

The Company has also entered into lease agreements for its EECF system, generally for terms of one year or less, that are classified as operating leases. Revenues from operating leases are generally recognized, in accordance with the terms of the lease agreements, on a straight-line basis over the life of the respective leases. For certain operating leases in which payment terms are determined on a "fee-per-use" basis, revenues are recognized as incurred (i.e., as actual usage occurs). The cost of the EECF system utilized under operating leases is recorded as a component of property and equipment and is amortized to cost of sales over the estimated useful life of the equipment, not to exceed five years. There were no significant minimum rental commitments on these operating leases at May 31, 2004.

The Company follows SFAS No. 13, "Accounting For Leases," for its sales of EECF systems under sales-type leases. In accordance with SFAS No. 13, the Company records the sale and financing receivable at the amount of the minimum lease payment, less unearned interest income, which is computed at the interest rate implicit in the lease, an allowance for bad debt and executory costs, which are primarily related to product warranties on each unit sold. Unearned interest income is amortized to income in a manner that produces a constant rate of return on the investment in the sales-type lease. The cost of the EECF system acquired by the customer is recorded as cost of sales in the same period that the sale is recorded. The Company is no longer offering sales-type leases.

#### *Accounts Receivable/Financing Receivables*

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

The changes in the Company's allowance for doubtful accounts are as follows:

	Fiscal Years Ended May 31,		
	2004	2003	2002
Beginning balance	\$768,629	\$1,099,687	\$545,000
Provision for losses on accounts receivable	616,759	1,227,324	954,000
Direct write-offs	(686,185)	(1,543,382)	(399,313)
Recoveries	--	(15,000)	--
Ending balance	<u>\$699,203</u>	<u>\$768,629</u>	<u>\$1,099,687</u>

In addition, the Company periodically reviews and assesses the net realizability of its receivables arising from sales-type leases. If this review results in a lower estimate of the net realizable value of the receivable, an allowance for the unrealized amount is established in the period in which the estimate is changed. In the first quarter of fiscal 2003 and the second quarter of fiscal 2004, management decided to write-off financing receivables under sales-type leases of approximately \$2,558,000 and \$680,000, respectively, as a result of significant uncertainties with respect to these customers' ability to meet their financial obligations. (See Note E).

The changes in the Company's allowance for financing receivables, which primarily relates to balloon payments due at lease end, are as follows:

	Fiscal Year Ended May 31,		
	2004	2003	2002
Beginning balance	\$244,994	\$718,879	\$--
Provision for losses on financing receivables	680,000	--	718,879
Direct write-offs	(924,994)	(473,885)	--
Ending balance	\$--	\$244,994	\$718,879

#### *Concentrations of Credit Risk*

The Company markets the EECF system principally to hospitals and physician private practices. The Company performs credit evaluations of its customers' financial condition and, as a consequence, believes that its receivable credit risk exposure is limited. Receivables are generally due 30 to 90 days from shipment. For the years ended May 31, 2004, 2003 and 2002, no customer accounted for 10% or more of revenues. For the years ended May 31, 2004, 2003 and 2002, no customer accounted for 10% or more of accounts receivable. At May 31, 2003 and 2002, financing receivables were due from one and two customers, respectively. (See Note E).

The Company's revenues were derived from the following geographic areas:

	Fiscal Years Ended May 31,		
	2004	2003	2002
Domestic (United States)	\$21,339,267	\$23,701,619	\$32,105,471
Non-domestic	867,770	1,122,000	2,725,000
	\$22,207,037	\$24,823,619	\$34,830,471

#### *Cash and Cash Equivalents*

Cash and cash equivalents represent cash and short-term, highly liquid investments in certificates of deposit, treasury bills, money market funds, and investment grade commercial paper issued by major corporations and financial institutions that generally have maturities of three months or less. Realized and unrealized gains and losses and declines in value, if any, are charged to earnings. Dividend and interest income are recognized when earned. The cost of securities sold is calculated using the specific identification method. (See Note C)

#### *Certificates of Deposit*

Included in this caption are all certificates of deposit that have original maturities of greater than three months. Realized and unrealized gains and losses and declines in value, if any, are charged to earnings. Dividend and interest income are recognized when earned. The cost of securities sold is calculated using the specific identification method. (See Note C)

#### *Inventories, net*

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

#### *Property and Equipment*

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is provided over the estimated useful lives of the assets, which range from two to thirty-nine years, on a straight-line basis. Accelerated methods of depreciation are used for tax purposes. Leasehold improvements are amortized over the useful life of the related leasehold improvement or the life of the related lease, whichever is less.

### *Deferred Revenues*

The Company records revenue on extended service contracts ratably over the term of the related warranty contracts. Effective September 1, 2003, the Company prospectively adopted the provisions of EITF 00-21. Upon adoption of the provisions of EITF 00-21, the Company began to defer revenue related to EECF system sales for the fair value of installation and in-service training to the period when the services are rendered and for warranty obligations ratably over the service period, which is generally one year.

### *Warranty Costs*

Equipment sold is generally covered by a warranty period of one year. Effective September 1, 2003, the Company adopted the provisions of EITF 00-21 on a prospective basis. Under EITF 00-21, for certain arrangements, a portion of the overall system price attributable to the first year warranty service is deferred and recognized as revenue over the service period. As such, the Company no longer accrues warranty costs upon delivery but rather recognizes warranty and related service costs as incurred. Prior to September 1, 2003, the Company accrued for estimated costs to provide warranty services when the equipment sale is recognized. The factors affecting the Company's warranty liability included the number of units sold and historical and anticipated rates of claims and costs per claim. The warranty provision resulting from transactions prior to September 1, 2003 will be reduced in future periods for material and labor costs incurred as related product is returned during the warranty period or when the warranty period elapses.

### *Research and Development*

Research and development costs are expensed as incurred. Included in research and development costs is amortization expense related to the cost of EECF systems under loan for clinical trials.

### *Income Taxes*

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

Deferred tax liabilities and assets are classified as current or non-current based on the classification of the related asset or liability for financial reporting. A deferred tax liability or asset that is not related to an asset or liability for financial reporting, including deferred tax assets related to carryforwards, shall be classified according to the expected reversal date of the temporary difference. The deferred tax asset recorded by the Company relates primarily to the realization of net operating loss carryforwards, of which the allocation of the current portion, if any, reflects the expected utilization of such net operating losses in the next twelve months. Such allocation is based upon management's internal financial forecast and may be subject to revision based upon actual results.

### *Shipping and Handling Costs*

The Company includes all shipping and handling expenses incurred as a component of cost of sales. Amounts billed to customers related to shipping and handling costs are included as a component of sales.

### *Fair Value of Financial Instruments*

The carrying amounts of cash and cash equivalents, accounts receivable and accounts payable approximate fair value due to the short-term maturities of the instruments. The carrying amount of the financing receivables approximates fair value as the interest rates implicit in the leases approximate current market interest rates for similar financial instruments. The carrying amounts of notes payable approximates their fair value as the interest rates of these instruments approximate the interest rates available on instruments with similar terms and maturities.

### *Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates and assumptions relate to estimates of

collectibility of accounts receivable and financing receivables, the realizability of deferred tax assets, and the adequacy of inventory and warranty reserves. Actual results could differ from those estimates.

*Net Earnings (Loss) Per Common Share*

Basic earnings (loss) per share are based on the weighted average number of common shares outstanding without consideration of potential common stock. Diluted earnings (loss) per share are based on the weighted number of common and potential common shares outstanding. The calculation takes into account the shares that may be issued upon the exercise of stock options and warrants, reduced by the shares that may be repurchased with the funds received from the exercise, based on the average price during the period.

*Stock-Based Employee Compensation*

The Company has four stock-based employee compensation plans, which are described in Note K. The Company accounts for stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations ("APB No. 25") and has adopted the disclosure provisions of Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure, an amendment of FASB Statement No. 123." Under APB No. 25, when the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. Accordingly, no compensation expense has been recognized in the consolidated financial statements in connection with employee stock option grants.

The following table illustrates the effect on net income and earnings per share had the Company applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," to stock-based employee compensation.

	Fiscal Year Ended May 31,		
	2004	2003	2002
Net earnings (loss), as reported	\$(3,422,520)	\$(4,790,983)	\$2,786,106
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards	(1,080,817)	(917,281)	(1,143,120)
Pro forma net earnings (loss)	<u>\$(4,503,337)</u>	<u>\$(5,708,264)</u>	<u>\$1,642,986</u>
Earnings (loss) per share:			
Basic and diluted - as reported	\$(0.06)	\$(0.08)	\$0.05
Basic and diluted - pro forma	\$(0.08)	\$(0.10)	\$0.03

Pro forma compensation expense may not be indicative of future disclosures because it does not take into effect pro forma compensation expense related to grants before 1995. For purposes of estimating the fair value of each option on the date of grant, the Company utilized the Black-Scholes option-pricing model.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options. The fair value of the Company's stock-based awards was estimated assuming no expected dividends and the following weighted-average assumptions are as follows:

	Fiscal Years Ended May 31,		
	2004	2003	2002
Expected life (years)	5	5	5
Expected volatility	89%	89%	86%
Risk-free interest rate	3.4%	3.0%	3.9%
Expected dividend yield	0.0%	0.0%	0.0%

Equity instruments issued to non-employees in exchange for goods, fees and services are accounted for under the fair value-based method of SFAS No. 123.

#### *Impact of New Accounting Pronouncements*

In April 2003, the FASB issued Statement of Financial Accounting Standards No. 149 (“SFAS No. 149”), “Amendment of Statement No. 133 on Derivative Instruments and Hedging Activities,” which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS No. 133. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003, except for the provisions that were cleared by the FASB in prior pronouncements. The adoption of SFAS No. 149 has not had a material impact on the Company’s financial position and results of operations.

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150 (“SFAS No. 150”), “Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity.” This statement establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. In accordance with the standard, financial instruments that embody obligations for the issuer are required to be classified as liabilities. This Statement shall be effective for financial instruments entered into or modified after May 31, 2003, and otherwise shall be effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 has not had a material impact on the Company’s financial position and results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 “Consolidation of Variable Interest Entities” (“FIN 46”), as interpreted by FIN 46R. In general, a variable interest entity is a corporation, partnership, trust, or any other legal structure used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. A variable interest entity often holds financial assets, including loans or receivables, real estate or other property. A variable interest entity may be essentially passive or it may engage in activities on behalf of another company. Until now, a company generally has included another entity in its consolidated financial statements only if it controlled the entity through voting interests. FIN 46 changes that by requiring a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity’s activities or entitled to receive a majority of the entity’s residual returns or both. FIN 46’s consolidation requirements apply immediately to variable interest entities created or acquired after January 31, 2003. The consolidation requirements apply to older entities in the first interim period beginning after June 15, 2003. Certain of the disclosure requirements apply in all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. The Company adopted FIN 46 effective January 31, 2003. The adoption of FIN 46 did not have a material impact on the Company’s financial position or results of operations.

In November 2002, the Emerging Issues Task Force, (“EITF”) reached a consensus opinion on, “Revenue Arrangements with Multiple Deliverables”, (“EITF 00-21”). That consensus provides that revenue arrangements with multiple deliverables should be divided into separate units of accounting if certain criteria are met. The consideration of the arrangement should be allocated to the separate units of accounting based on their relative fair values, with different provisions if the fair value is contingent on delivery of specified items or performance conditions. Applicable revenue criteria should be considered separately for each separate unit of accounting. EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. Effective September 1, 2003, the Company prospectively adopted the provisions of EITF 00-21. Upon adoption of the provisions of EITF 00-21, the Company deferred \$92,500 net of amortization, of revenue related to the fair value of installation and in-service training and \$658,333 net of amortization of revenue related to the warranty service for EECF system sales recognized for the nine-month period ended May 31, 2004.

In December 2003, the SEC issued Staff Accounting Bulletin (SAB) No. 104, “Revenue Recognition” (SAB No. 104), which codifies, revises and rescinds certain sections of SAB No. 101, “Revenue Recognition in Financial Statements”, in order to make this interpretive guidance consistent with current authoritative accounting and auditing guidance and SEC rules and regulations. The changes noted in SAB No. 104 did not have a material effect on the Company’s financial position or results of operations.



NOTE B – EARNINGS (LOSS) PER COMMON SHARE

The following table sets forth the computation of basic and diluted earnings (loss) per share:

	Fiscal Year Ended May 31,		
	2004	2003	2002
Numerator:			
Net earnings (loss)	\$(3,422,520)	\$(4,790,983)	\$2,786,106
Denominator:			
Basic – weighted average shares	57,981,963	57,647,032	57,251,035
Stock options	--	--	1,624,744
Warrants	--	--	592,313
Diluted – weighted average shares	<u>57,981,963</u>	<u>57,647,032</u>	<u>59,468,092</u>
Earnings (loss) per share - basic	<u>\$(0.06)</u>	<u>\$(0.08)</u>	<u>\$0.05</u>
- diluted	<u>\$(0.06)</u>	<u>\$(0.08)</u>	<u>\$0.05</u>

Options and warrants to purchase 5,161,751, 6,190,753 and 2,432,167 shares of common stock were excluded from the computation of diluted earnings per share for the years ended May 31, 2004, 2003 and 2002, respectively, because the effect of their inclusion would be antidilutive.

NOTE C – CASH AND CASH EQUIVALENTS

Cash and cash equivalents consist of the following:

	May 31,	
	2004	2003
Cash accounts	\$2,522,570	961,922
Money market funds	3,842,479	4,260,925
	<u>\$6,365,049</u>	<u>\$5,222,847</u>

NOTE D – INVENTORIES, NET

Inventories, net consist of the following:

	May 31,	
	2004	2003
Raw materials	\$928,269	\$1,374,241
Work in progress	455,731	634,890
Finished goods	989,748	1,430,436
	<u>\$2,373,748</u>	<u>\$3,439,567</u>

At May 31, 2004 and 2003, the Company has recorded reserves for obsolete inventory of \$399,000 and \$280,000, respectively.

NOTE E – FINANCING RECEIVABLES FROM MAJOR CUSTOMERS

In fiscal year 2002, the Company sold its external counterpulsation systems (“EECP” units) to two major customers engaged in establishing independent networks of EECP centers under sales-type leases aggregating revenues of \$4,187,009 in fiscal year 2002. No additional equipment was sold to these customers during fiscal 2003 or 2004.

In late August 2002, the largest customer became delinquent in its scheduled monthly payments under its financing obligations to the Company. In September 2002, the Company was notified by this customer of recent circumstances that precluded their ability to remain current under their financing obligations to the Company. Accordingly, management decided to write-off, in full, all funds due from this customer as of August 31, 2002, which aggregated approximately \$3,000,000, including the present carrying amount of the underlying equipment due to the uncertainty of the Company’s ability to repossess the equipment. During the second quarter of fiscal year 2003, the customer ceased

operations and the Company was able to successfully recover all of the units that it had sold under sales-type leases to the customer back into its finished goods inventory and recorded a bad debt recovery of \$479,000, which represented the carrying amount at that time of the equipment. The second customer became delinquent in its scheduled monthly payments during the fourth quarter of fiscal 2003. During the first and second quarters of fiscal 2004 the customer attempted to remedy the situation and made payments totaling \$70,000. In December 2003, the customer ceased operations. Accordingly, management decided to write-off all funds due from this customer as of November 30, 2003, less the anticipated recovery of equipment and the reduction of related liabilities for sales tax. The write-off of approximately \$680,000 is included as a component of the provision for doubtful accounts in the accompanying Statement of Earnings for the year ended May 31, 2004. In the third quarter of fiscal 2004, the Company recovered all of the EECF systems that had been leased to this customer. The Company is no longer offering sales-type leases.

#### NOTE F - PROPERTY AND EQUIPMENT

Property and equipment is summarized as follows:

	May 31,	
	2004	2003
Land	\$200,000	\$200,000
Building and improvements	1,382,270	1,376,106
Office, laboratory and other equipment	1,246,089	1,111,827
EECF systems under operating leases or under loan for clinical trials	1,700,867	2,617,624
Furniture and fixtures	162,068	148,164
Leasehold improvements	117,803	117,803
	<u>4,809,097</u>	<u>5,571,524</u>
Less: accumulated depreciation and amortization	<u>(2,378,576)</u>	<u>(2,338,366)</u>
	<u>\$2,430,521</u>	<u>\$3,233,158</u>

#### NOTE G - DEFERRED REVENUE

The changes in the Company's deferred revenues are as follows:

	Fiscal Year Ended May 31,		
	2004	2003	2002
Deferred Revenue at the beginning of the year	\$1,709,551	\$991,204	\$243,151
<b>ADDITIONS</b>			
Deferred extended service contracts	1,871,439	1,478,933	1,156,244
Deferred in-service training	340,000	--	--
Deferred warranty obligations	1,040,000	--	--
<b>RECOGNIZED AS REVENUE</b>			
Deferred extended service contracts	(1,485,372)	(760,586)	(408,191)
Deferred in-service training	(247,500)	--	--
Deferred warranty obligations	(381,667)	--	--
Deferred revenue at end of the year	<u>2,846,451</u>	<u>1,709,551</u>	<u>991,204</u>
Less: current portion	<u>(1,734,925)</u>	<u>(789,118)</u>	<u>(272,000)</u>
Long-term deferred revenue at end of the year	<u>\$1,111,526</u>	<u>\$920,433</u>	<u>\$719,204</u>

NOTE H – WARRANTY LIABILITY

The changes in the Company’s product warranty liability are as follows:

	Fiscal Year Ended May 31,		
	2004	2003	2002
Beginning balance	\$788,000	\$991,000	\$1,055,000
Expense for new warranties issued	164,000	724,000	780,000
Warranty claims	(707,083)	(927,000)	(844,000)
Ending balance	<u>\$244,917</u>	<u>\$788,000</u>	<u>\$991,000</u>

NOTE I – LONG-TERM DEBT AND LINE OF CREDIT AGREEMENT

The following table sets forth the computation of long-term debt:

	May 31,	
	2004	2003
Facility loans (a)	\$1,022,933	\$1,072,717
Term loans (b)	206,382	213,549
	1,229,315	1,286,266
Less: current portion	(136,478)	(108,462)
	<u>\$1,092,837</u>	<u>\$1,177,804</u>

(a) The Company purchased its headquarters and warehouse facility and secured notes of \$641,667 and \$500,000, respectively, under two programs sponsored by New York State. These notes, which bear interest at 7.8% and 6%, respectively, are payable in monthly installments consisting of principal and interest payments over fifteen-year terms, expiring in September 2016 and January 2017, respectively, and are secured by the building.

(b) In fiscal years 2003 and 2004, the Company financed the cost and implementation of a management information system and secured several notes, aggregating approximately \$305,219. The notes, which bear interest at rates ranging from 7.5% through 12.5%, are payable in monthly installments consisting of principal and interest payments over four-year terms, expiring at various times between August and October 2006.

Maturities of long-term debt are as follows at May 31, 2004:

<u>Fiscal Year</u>	<u>Amount</u>
2005	\$136,478
2006	148,212
2007	93,678
2008	65,769
2009	70,524
Thereafter	714,654
	<u>\$1,229,315</u>

At May 31, 2004 and 2003, the Company maintained a secured revolving credit line with a bank. The credit line provided for borrowings up to \$5,000,000, (\$2,000,000, at any time that consolidated net income for the immediately preceding three-month period is less than \$1), primarily based upon eligible accounts receivable, as defined therein, at the Libor Rate plus 200 basis points or the published Prime Rate plus 50 basis points. The agreement allowed for borrowings absent compliance with the financial covenants as long as such eligible borrowings are collateralized by cash. In April 2003, the Company repaid all outstanding borrowings under the agreement instead of maintaining restricted cash balances. At May 31, 2004 and 2003, the Company did not meet the minimum net income, interest coverage, leverage ratio and tangible net worth covenants and future compliance with each of these covenants in the near term is not certain. The agreement, which was due to expire in February 2005, was cancelled by the Company in August 2004.

## NOTE J - STOCKHOLDERS' EQUITY AND WARRANTS

In fiscal 2002, warrants to purchase 15,000 shares of common stock were exercised, aggregating \$31,200 in proceeds to the Company. In fiscal 2003, warrants to purchase 500,000 shares of common stock were exercised, aggregating \$225,000 in proceeds to the Company. No warrants were exercised or cancelled in fiscal 2004.

All outstanding warrants expire in October 2006. Warrant activity for the years ended May 31, 2002, 2003 and 2004 is summarized as follows:

	Employees	Consultants	Total	Price Range
Balance at June 1, 2001	500,000	342,500	842,500	\$0.45 - \$2.08
Exercised	--	(15,000)	(15,000)	\$2.08
Balance at May 31, 2002	500,000	327,500	827,500	\$0.45 - \$2.08
Exercised	(500,000)	--	(500,000)	\$0.45
Cancelled	--	(127,500)	(127,500)	\$2.08
Balance at May 31, 2003	--	200,000	200,000	\$0.91
Balance at May 31, 2004	--	200,000	200,000	\$0.91
Number of shares exercisable	--	200,000	200,000	\$0.91

## NOTE K - OPTION PLANS

### *1995 Stock Option Plan*

In May 1995, the Company's stockholders approved the 1995 Stock Option Plan for officers and employees of the Company, for which the Company reserved an aggregate of 1,500,000 shares of common stock. In December 1997, the Company's Board of Directors terminated the 1995 Stock Option Plan with respect to new option grants.

### *Outside Director Stock Option Plan*

In May 1995, the Company's stockholders approved an Outside Director Stock Option Plan for non-employee directors of the Company, for which the Company reserved an aggregate of 300,000 shares of common stock. In December 1997, the Company's Board of Directors terminated the Outside Director Stock Option Plan with respect to new option grants.

### *1997 Stock Option Plan*

In December 1997, the Company's stockholders approved the 1997 Stock Option Plan (the "1997 Plan") for officers, directors, employees and consultants of the Company, for which the Company has reserved an aggregate of 1,800,000 shares of common stock. The 1997 Plan provides that a committee of the Board of Directors of the Company will administer it and that the committee will have full authority to determine the identity of the recipients of the options and the number of shares subject to each option. Options granted under the 1997 Plan may be either incentive stock options or non-qualified stock options. The option price shall be 100% of the fair market value of the common stock on the date of the grant (or in the case of incentive stock options granted to any individual principal stockholder who owns stock possessing more than 10% of the total combined voting power of all voting stock of the Company, 110% of such fair market value). The term of any option may be fixed by the committee but in no event shall exceed ten years from the date of grant. Options are exercisable upon payment in full of the exercise price, either in cash or in common stock valued at fair market value on the date of exercise of the option. The term for which options may be granted under the 1997 Plan expires August 6, 2007.

In January 1999, the Company's Board of Directors increased the number of shares authorized for issuance under the 1997 Plan by 1,000,000 shares to 2,800,000 shares. At May 31, 2004, there were 153,168 shares available for future grants under the 1997 Plan.

### *1999 Stock Option Plan*

In July 1999, the Company's Board of Directors approved the 1999 Stock Option Plan (the "1999 Plan"), for which the Company reserved an aggregate of 2,000,000 shares of common stock. The 1999 Plan provides that a committee of the Board of Directors of the Company will administer it and that the committee will have full authority to determine the identity of the recipients of the options and the number of shares subject to each option. Options granted under the 1999 Plan may be either incentive stock options or non-qualified stock options. The option price shall be 100% of the fair market value of the common stock on the date of the grant (or in the case of incentive stock options

granted to any individual principal stockholder who owns stock possessing more than 10% of the total combined voting power of all voting stock of the Company, 110% of such fair market value). The term of any option may be fixed by the committee but in no event shall exceed ten years from the date of grant. Options are exercisable upon payment in full of the exercise price, either in cash or in common stock valued at fair market value on the date of exercise of the option. The term for which options may be granted under the 1999 Plan expires July 12, 2009. In July 2000, the Company's Board of Directors increased the number of shares authorized for issuance under the 1999 Plan by 1,000,000 shares to 3,000,000 shares. In December 2001, the Board of Directors of the Company increased the number of shares authorized for issuance under the 1999 Plan by 2,000,000 shares to 5,000,000 shares.

In January 2001, the Board of Directors granted stock options under the 1999 Plan to a consultant to purchase 25,000 shares of common stock at an exercise price of \$3.81 per share (which represented the fair market value of the underlying common stock at the time of the respective grant). The Company charged \$60,000 to operations over the one-year period in which services were rendered. In December 2001, the Board of Directors granted stock options under the 1999 Plan to a consultant to purchase 25,000 shares of common stock at an exercise price of \$2.95 per share (which represented the fair market value of the underlying common stock at the time of the respective grant). These stock options were fair-valued at \$50,250, which the Company charged to operations over the one-year period in which services were rendered. During fiscal 2003 and 2002, the Company charged \$25,000 and \$50,000, respectively, to operations for these grants.

In fiscal 2003, the Board of Directors granted stock options under the 1999 Plan to directors and employees to purchase an aggregate of 1,175,000 shares of common stock, at exercise prices ranging from \$0.71 to \$1.67 per share (which represented the fair market value of the underlying common stock at the time of the respective grants). In fiscal 2004, the Board of Directors granted stock options under the 1999 Plan to directors and employees to purchase an aggregate of 725,000 shares of common stock, at exercise process ranging from \$0.91 to \$1.31 per shares (which represented the fair market value of the underlying common stock at the time of the respective grants). At May 31, 2004, there were 1,517,169 shares available for future grants under the 1999 Plan.

Activity under all the plans for the years ended May 31, 2002, 2003 and 2004, is summarized as follows:

	Shares Available for Grant	Outstanding Options		
		Number of Shares	Exercise Price per Share	Weighted Average Exercise Price
Balance at May 31, 2001	1,218,168	4,332,823	\$0.78 - \$5.15	\$2.26
Shares authorized	2,000,000			
Options granted	(1,084,100)	1,084,100	\$1.78 - \$4.02	\$3.61
Options exercised	--	(98,667)	\$0.88 - \$2.44	\$1.71
Options canceled	125,333	(125,333)	\$0.88 - \$5.00	\$3.90
Balance at May 31, 2002	2,259,401	5,192,923	\$0.78 - \$5.15	\$2.51
Options granted	(1,175,000)	1,175,000	\$0.71 - \$1.67	\$0.95
Options exercised	--	(12,903)	\$0.78	\$0.78
Options canceled	354,267	(364,267)	\$0.88 - \$5.15	\$3.77
Balance at May 31, 2003	1,438,668	5,990,753	\$0.71 - \$5.15	\$2.13
Options granted	(725,000)	725,000	\$0.92 - \$1.31	\$1.06
Options exercised	--	(597,333)	\$0.71 - \$1.22	\$1.17
Options canceled	956,669	(956,669)	\$0.91 - \$2.97	\$1.88
Balance at May 31, 2004	1,670,337	5,161,751	\$0.71 - \$5.15	\$2.10

The following table summarizes information about stock options outstanding and exercisable at May 31, 2004

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at May 31, 2004	Weighted Average Remaining Contractual Life (yrs.)	Weighted Average Exercise Price	Number Exercisable at May 31, 2004	Weighted Average Exercise Price
\$0.71 - \$1.04	2,227,874	6.4	\$0.95	1,327,874	\$0.88
\$1.22 - \$1.78	263,250	5.0	\$1.68	263,250	\$1.68
\$1.91 - \$2.78	805,127	4.0	\$1.97	800,127	\$1.97
\$2.89 - \$4.28	1,697,500	5.3	\$3.60	1,471,997	\$3.61
\$4.59 - \$5.15	168,000	6.1	\$4.69	168,000	\$4.69
	5,161,751	5.6	\$2.14	4,031,248	\$2.30

The weighted-average fair value of options granted during fiscal years 2004, 2003 and 2002 was \$1.06, \$0.95 and \$2.50, respectively. At May 31, 2004, there were approximately 11,823,000 remaining authorized shares of common stock after reserves for all stock option plans, stock warrants and shareholders' rights.

#### NOTE L- INCOME TAXES

During the fiscal year ended May 31, 2004, the Company recorded a provision for state income taxes of \$50,640. In fiscal 2003, the Company recorded a benefit for income taxes of \$1,634,688, inclusive of \$256,312 in current tax expense and a deferred benefit of \$1,891,000. In fiscal 2002, the Company recorded an expense for income taxes of \$1,554,000, inclusive of \$39,000 in current tax expense and a deferred tax expense of \$1,515,000.

As of May 31, 2004, the Company had recorded deferred tax assets of \$14,582,000 (net of a \$1,908,000 valuation allowance) related to the anticipated recovery of tax loss carryforwards. The amount of the deferred tax assets considered realizable could be reduced in the future if estimates of future taxable income during the carryforward period are reduced. Ultimate realization of the deferred tax assets is dependent upon the Company generating sufficient taxable income prior to the expiration of the tax loss carryforwards. Management believes that the Company is positioned for long-term growth despite the financial results achieved during fiscal years 2004 and 2003, and that based upon the weight of available evidence, that it is "more likely than not" that the net deferred tax assets will be realized. The "more likely than not" standard is subjective, and is based upon management's estimate of a greater than 50% probability that its long range business plan can be realized.

Ultimate realization of any or all of the deferred tax assets is not assured, due to significant uncertainties associated with estimates of future taxable income during the carryforward period. The Company's estimates are largely dependent upon achieving considerable growth resulting from the successful commercialization of the EECF therapy into the congestive heart failure indication. Such future estimates of future taxable income are based on the beliefs of the Company's management, as well as assumptions made by and information currently available to the Company's management. Certain critical assumptions associated with the Company's estimates include:

- that the results from the PEECH clinical trial will be sufficiently positive to enable the EECF therapy to obtain approval for a national Medicare reimbursement coverage policy plus other third-party payer reimbursement policies specific to the congestive heart failure indication;
- that the reimbursement coverage will be both broad enough in terms of coverage language and at an amount adequate to enable successful commercialization of the EECF therapy into the congestive heart failure indication.

Additional 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;
- other 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 the Company's SEC reports.

The amount of the deferred tax assets considered realizable could be reduced in the future if estimates of future taxable income during the carryforward period are reduced or if the accounting standards are changed to reflect a more stringent standard for evaluation of deferred tax assets.

The recorded deferred tax asset includes an increase to the valuation allowance of \$1,286,000 during fiscal year ended May 31, 2004.

The Company's deferred tax assets are summarized as follows:

	2004	2003	2002
Net operating loss and other carryforwards	\$14,468,000	\$13,368,000	\$11,344,000
Accrued compensation	118,000	153,000	--
Bad debts	238,000	244,000	493,000
Other	1,666,000	1,439,000	854,000
Total gross deferred tax assets	16,490,000	15,204,000	12,691,000
Valuation allowance	(1,908,000)	(622,000)	--
Net deferred tax assets	<u>\$14,582,000</u>	<u>\$14,582,000</u>	<u>\$12,691,000</u>

The deferred tax benefit for fiscal years May 31, 2004, 2003 and 2002 does not include the tax benefit associated with the current exercises of stock options and warrants, aggregating \$0, \$222,000, and \$58,000, respectively, which was credited directly to additional paid-in capital.

At May 31, 2004, the Company had net operating loss carryforwards for Federal and state income tax purposes of approximately \$42,612,000, expiring at various dates from 2006 through 2022. Expiration of net operating loss carryforwards are as follows:

Fiscal Year	Amount
2005	\$96,516
2006	336,198
2007	517,934
2008	558,968
2009	470,994
Thereafter	40,630,952
	<u>\$42,611,562</u>

Under current tax law, the utilization of tax attributes will be restricted if an ownership change, as defined, were to occur. Section 382 of the Internal Revenue Code provides, in general, that if an "ownership change" occurs with respect to a corporation with net operating and other loss carryforwards, such carryforwards will be available to offset taxable income in each taxable year after the ownership change only up to the "Section 382 Limitation" for each year (generally, the product of the fair market value of the corporation's stock at the time of the ownership change, with certain adjustments, and a specified long-term tax-exempt bond rate at such time). The Company's ability to use its loss carryforwards would be limited in the event of an ownership change.

The following is a reconciliation of the effective income tax rate to the federal statutory rate:

	2004		2003		2002	
	Amount	%	Amount	%	Amount	%
Federal statutory rate	\$(1,146,439)	(34.0)	\$(2,185,000)	(34.0)	\$1,475,000	34.0
State taxes, net	50,640	1.5	34,000	.5	56,000	1.3
Permanent differences	23,839	0.8	33,320	.5	23,000	.5
Utilization of net operating loss	--	--	--	--	--	--
Change in valuation allowance relating to operations	1,286,000	(38.1)	622,000	9.7	--	--
Other	(163,400)	(4.9)	(139,008)	(2.1)	--	--
	<u>\$50,640</u>	<u>1.5</u>	<u>\$(1,634,688)</u>	<u>(25.4)</u>	<u>\$1,554,000</u>	<u>35.8</u>

## NOTE M - COMMITMENTS AND CONTINGENCIES

### *Employment Agreements*

In October 2002, the Company entered into an employment agreement with its new President and Chief Operating Officer, Gregory D. Cash. The agreement, which expired in October 2004, provided for certain settlement benefits, including a lump-sum payment of twelve months of base salary in the event of a change of control, as defined, or a termination payment in an amount equal to six months of base salary in the event of termination without cause, as defined. Such agreement was modified on June 30, 2003 reflecting this employee's promotion to President and Chief Executive Officer. In March 2004 this employee resigned to pursue other business interests and all monetary compensation under the employment agreement was terminated.

In October 2003, the Company entered into an employment agreement with its new Chief Financial Officer. The agreement, which expires in September 2005, provides for certain settlement benefits, including a lump-sum payment of twelve months of base salary in the event of a change of control, as defined, or a termination payment in an amount equal to six months of base salary in the event of termination without cause, as defined.

The approximate aggregate minimum compensation obligation under active employment agreements at May 31, 2004 are summarized as follows:

<u>Fiscal Year</u>	<u>Amount</u>
2005	\$250,000
2006	40,685
	<u>\$290,685</u>

### *Leases*

The Company leases additional warehouse space under two noncancelable operating leases, of which one expires on October 31, 2004 and the other on September 30, 2006. Rent expense was \$72,000, \$99,000 and \$85,000 in fiscal 2004, 2003 and 2002, respectively.

Approximate aggregate minimum annual obligations under these lease agreements and other equipment leasing agreements at May 31, 2004 are summarized as follows:

<u>Fiscal Year</u>	<u>Amount</u>
2005	\$76,446
2006	48,189
2007	14,238
	<u>\$138,873</u>

### *Consulting Agreements*

In September 2003, the Company and its then Chief Financial Officer entered into a termination and consulting agreement. As a result of this termination, the Company will pay to the former employee a severance payment of \$140,000 in equal monthly installments through September 2004. The Company recorded a charge to operations during the three-month period ended November 30, 2003 to reflect this obligation. Further, the consulting agreement provides for the continued vesting of stock options that had been previously granted to the employee, which would have otherwise vested during the term of the agreement. The terms of the original option grants provided for vesting throughout the period that the former employee was employed by or provided services to the Company. There were no other modifications to any of his previously granted stock options.

### *Litigation*

In June 2001, an action was commenced in the New York Supreme Court, Nassau County, against the Company by the former holder of a warrant to purchase 100,000 shares of the Company's stock seeking undefined damages based upon a claim that the Company breached an agreement to register the common shares underlying the warrant at the "earliest practicable date" after due demand by the warrant holder had been made. In October 2002, the Company settled this matter for \$600,000 through the execution of an agreement that enables the Company to satisfy this obligation over a four-year period (\$200,000 in fiscal 2003, \$66,500 in fiscal 2004, \$133,000 each in fiscal years 2005 and 2006 and \$66,500 in fiscal 2007). Accordingly, the Company recorded a \$600,000 charge to operations in fiscal 2003. In December 2002, the Company paid \$200,000 to the warrant holder pursuant to the terms of the settlement agreement.



In or about late June 2002, the Company was notified by a letter from the domestic counsel for Foshan Life Sciences Co. Ltd. (“FLSC”), a joint venture comprised of a Florida company and Vamed Medical Instrument Company Limited (“Vamed”), a Chinese company with whom the Company had an agreement to manufacture the Company’s EECF Model MC2 system, that FLSC was initiating an arbitration proceeding before the Hong Kong International Arbitration Council (“HKIAC”) to recover compensatory and punitive damages in excess of \$1,000,000 and injunctive relief based upon claims of breach of the manufacturing agreement, tortious interference and misappropriation of confidential information and trade secrets. Although possessing several substantive defenses to these claims, the Company initially has challenged the HKIAC’s right to hear and determine the dispute on the ground that FLSC is neither a legitimate nor recognized party to the manufacturing agreement which provides for such arbitration and, therefore, is not entitled to enforce the same. The Company demanded on July 3, 2002 that FLSC deposit with the HKIAC security to cover the Company’s costs of arbitration. To date, FLSC has neither responded to the Company’s demand for security nor apparently filed a formal statement of claim with the HKIAC.

#### 401(k) Plan

In April 1997, the Company adopted the Vasomedical, Inc. 401(k) Plan to provide retirement benefits for its employees. As allowed under Section 401(k) of the Internal Revenue Code, the plan provides tax-deferred salary deductions for eligible employees. Employees are eligible to participate in the next quarter enrollment period after employment. Participants may make voluntary contributions to the plan up to 15% of their compensation. In fiscal year 2004, 2003 and 2002, the Company made discretionary contributions of approximately \$ 35,535, \$35,000 and \$20,000, respectively, to match a percentage of employee contributions.

#### NOTE N – 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, 2004 and 2003.

<i>(in 000s except Earnings (loss) per share data)</i>	Three months ended							
	May 31, 2004	Feb. 29, 2004	Nov. 30, 2003	Aug. 31, 2003	May 31, 2003	Feb. 28, 2003	Nov. 30, 2002	Aug. 31, 2002
	(a)				(c)			
					(b)			
Revenues	\$5,927	\$5,950	\$4,903	\$5,427	\$6,488	\$7,153	\$6,644	\$4,539
Gross Profit	\$3,903	\$4,017	\$3,210	\$3,488	\$3,970	\$4,383	\$4,640	\$2,580
Net Earnings (Loss)	\$(759)	\$(310)	\$(2,087)	\$(267)	\$14	\$26	\$(597)	\$(4,234)
Earnings (loss) per share – basic	\$(0.01)	\$(0.01)	\$(0.04)	\$(0.00)	\$0.00	\$0.00	\$(0.01)	\$(0.07)
- diluted	\$(0.01)	\$(0.01)	\$(0.04)	\$(0.00)	\$0.00	\$0.00	\$(0.01)	\$(0.07)
Weighted average common shares outstanding –								
- basic	58,384	57,887	57,828	57,827	57,817	57,809	57,658	57,478
- diluted	58,384	57,887	57,828	57,827	58,453	58,078	57,658	57,478

- (a) Net Loss for the second quarter of fiscal 2004 was adversely affected by the write-off of approximately \$680 related to significant uncertainties related to the ability of a major customer to satisfy its financial obligations to the Company, (see Note E).
- (b) Net Loss for the first quarter of fiscal 2003 was adversely affected by the write-off of approximately \$3,000 related to significant uncertainties related to the ability of a major customer to satisfy its financial obligations to the Company, (see Note E).
- (c) Net Loss for the second quarter of fiscal 2003 was adversely affected by the settlement of litigation of \$600 and approximately \$300 in severance obligations, principally to the Company’s former Chief Executive Officer, (see Note M).

Vasomedical, Inc. and Subsidiaries

Schedule II – Valuation and Qualifying Accounts

Column A	Column B	Column C		Column D	Column E
		Additions			
	Balance at beginning of period	(1) Charged to costs and expenses	(2) Charged to other accounts	Deductions	Balance at end of period
<b>Allowance for doubtful accounts</b>					
Year ended May 31, 2004	\$768,629	\$616,759	\$--	\$686,185	\$699,203
Year ended May 31, 2003	\$1,099,687	\$1,227,324	\$--	(a) \$1,558,382	\$768,629
Year ended May 31, 2002	\$545,000	\$954,000	\$--	\$399,313	\$1,099,687
<b>Valuation Allowance- Financing Receivables</b>					
Year ended May 31, 2004	\$244,994	\$680,000	\$--	\$924,994	\$--
Year ended May 31, 2003	\$718,879		\$--	\$473,885	\$244,994
Year ended May 31, 2002	\$--	\$718,879	\$--	\$--	\$718,879
<b>Reserve for obsolete inventory</b>					
Year ended May 31, 2004	\$280,000	\$119,000	\$--	\$--	\$399,000
Year ended May 31, 2003	\$180,000	\$100,000	\$--	\$--	\$280,000
Year ended May 31, 2002	\$150,000	\$30,000	\$--	\$--	\$180,000
<b>Valuation Allowance – Deferred Tax Asset</b>					
Year ended May 31, 2004	\$622,000	\$1,286,000	\$--	\$--	\$1,908,000
Year ended May 31, 2003	\$--	\$622,000	\$--	\$--	\$622,000
Year ended May 31, 2002	\$--	\$--	\$--	\$--	\$--
<b>Provision for warranty obligations</b>					
Year ended May 31, 2004	\$788,000	\$164,000	\$--	\$707,083	\$244,917
Year ended May 31, 2003	\$991,000	\$724,000	\$--	\$927,000	\$788,000
Year ended May 31, 2002	\$1,055,000	\$780,000	\$--	\$844,000	\$991,000

(a) accounts receivable written off, net of \$15,000 in recoveries in fiscal 2003

# C O R P O R A T E   D I R E C T O R Y

## SENIOR MANAGEMENT

### **Photios T. Paulson**

Interim CEO, Vasomedical Inc.  
Former Vice President,  
bioMérieux N.A. Inc.  
Former Chairman, bioMérieux Vitek, Inc.

### **John C. K. Hui, PhD**

Senior Vice President and  
Chief Technology Officer

### **Thomas W. Fry**

Chief Financial Officer

### **Harold Kaefer**

Vice President,  
Engineering and Manufacturing

### **Wayne F. Stewart**

Vice President, Domestic Sales

### **Thomas R. Varricchio**

Vice President, Clinical and Regulatory Affairs

### **Brian M. Weber**

Vice President, Marketing

### **Kenneth W. Rind, PhD**

Founding General Partner of Israel Infinity Venture  
Capital Fund and Oxford Venture Funds

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Dean Emeritus  
Former Dean, New York Law School

### **Anthony Viscusi**

President and CEO, Vasomedical Inc.  
(Retired)

### **Forrest R. Whittaker**

President and Chief Operating Officer,  
Teleflex  
Medical Division, Teleflex, Inc.  
Former President, Respiratory Group  
of Tyco Healthcare

### **Martin Zeiger**

Independent Consultant  
Former Senior Vice President,  
Strategic Business Development,  
Barr Laboratories, Inc.  
Former General Counsel,  
Barr Laboratories

### **David R. Homes Jr., MD, FACC**

Consultant,  
Cardiovascular Disease Division  
Director,  
Cardiac Catheterization Laboratory  
Professor of Medicine  
Mayo Clinic and Foundation  
St. Mary's Hospital

## GENERAL COUNSEL

### **Beckman, Lieberman & Barandes LLP**

Attorneys at Law  
100 Jerico Quadrangle  
Jericho, New York 11753

## AUDITORS

### **Grant Thornton LLP**

Certified Public Accountants  
445 Broadhollow Road  
Melville, New York 11747

## BOARD OF DIRECTORS

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Senior Vice President of Merck and Co., Inc.

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Practicing cardiologist affiliated with  
Weill-Cornell Medical College

### **John C. K. Hui, PhD**

Senior Vice President and Chief Technology Officer,  
Vasomedical Inc.

### **Photios T. Paulson**

Interim CEO, Vasomedical Inc.  
Former Vice President,  
bioMérieux N.A. Inc.  
Former Chairman, bioMérieux Vitek, Inc.

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Professor of Medicine  
Chief, Cardiovascular Medicine  
University of California, San Diego

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Professor of Medicine  
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Director, Cardiovascular Clinic  
University of Florida  
Eminent Scholar (Cardiology)

#### **Arthur Feldman, MD, PhD, FACC**

Magee Professor and Chairman  
Department of Medicine  
Thomas Jefferson Medical College

## REGISTRAR AND TRANSFER AGENT

### **American Stock Transfer and Trust Company**

59 Maiden Lane  
New York, New York 10038  
800.937.5449

## OTHER AVAILABLE INFORMATION

A copy of the Company's Annual Report on Form 10-K  
for the year ended May 31, 2004, as filed with the  
Securities and Exchange Commission, is available  
without charge to interested stockholders upon a  
written request to:

Vasomedical Inc.  
Attn.: Investor Relations  
180 Linden Avenue  
Westbury, New York 11590

Or visit our website at  
[www.vasomedical.com](http://www.vasomedical.com)

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