VASOMEDICAL, INC
Form 10-K
April 01, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

[X] ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2012
[ ]TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File No. 0-18105

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

Delaware	11-2871434
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
180 Linden Avenue, Westbury, New York	11590
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (516) 997-4600
Securities registered under Section 12(b) of the Act: None
Securities registered under Section 12(g) of the Act:

Common Stock, $.001 par value	OTCBB
(Title of Class)	Name of each exchange on which registered

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. [ ]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. [ ]

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files)
Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. Large accelerated filer [ ] Accelerated filer [ ] Non-accelerated filer [ ] Smaller reporting company [X]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [ ] No [X]

The aggregate market value of common stock held by non-affiliates was approximately $29,336,000 based on the closing sales price of the common stock as quoted on the OTCBB on March 25, 2013.

At March 25, 2013, the number of shares outstanding of the issuer's common stock was 162,977,996.

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PART I

ITEM 1 – BUSINESS

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

General Overview

Vasomedical, Inc. was incorporated in Delaware in July 1987. Unless the context requires otherwise, all references to “we”, “our”, “us”, “Company”, “registrant”, “Vasomedical” or “management” refer to Vasomedical, Inc. and its subsidiaries 1995, we have been engaged in designing, manufacturing, marketing and supporting EECP® Enhanced External Counterpulsation systems, based on our proprietary technology, to physicians and hospitals throughout the United States and in select international markets.

In 2010, the Company, through its wholly-owned subsidiary Vaso Diagnostics d/b/a VasoHealthcare, organized a group of medical device sales professionals and entered into the sales representation business as the exclusive representative for the sale of select General Electric Company (GE) diagnostic imaging equipment to specific market segments in the 48 contiguous states of the United States and the District of Columbia.

In September 2011, the Company acquired Fast Growth Enterprises Limited (FGE), a British Virgin Islands company, which owns and controls two Chinese operating companies - Life Enhancement Technology Ltd. and Biox Instruments Co. Ltd., respectively - to expand its technical and manufacturing capabilities and to enhance its distribution network, technology, and product portfolio. Also in September 2011, the Company restructured to further align its business management structure and long-term growth strategy, and now operates through three wholly-owned subsidiaries. Vaso Diagnostics d/b/a VasoHealthcare continues as the operating subsidiary for the sales representation of GE diagnostic imaging products; Vasomedical Global Corp. operates the Company’s Chinese companies; and Vasomedical Solutions, Inc. was formed to manage and coordinate our EECP® equipment business as well as other medical equipment operations.

The Company will seek to achieve greater profitability by expanding our U.S. and international market product portfolio. In addition, the Company plans to actively pursue other accretive acquisitions and to expand its sales representation business..

Business Segments

We manage and evaluate our operations based on the products and services we offer. Under this approach, we operate through two segments - Sales Representation and Equipment. Our principal manufacturing facilities are located domestically in New York, and internationally in China.

Sales Representation

The Sales Representation segment currently operates under a sales representative agreement with GE Healthcare (the "GEHC Agreement"), the healthcare business unit of GE, which commenced July 1, 2010. The GEHC Agreement had an initial term of three years and in 2012 was extended for an additional two years to June 30, 2015, subject to earlier termination under certain circumstances. All revenues and expenses in this segment arise through its operations under the GEHC Agreement.

Under the GEHC Agreement, the Company earns commissions based upon achieving certain calendar year targets. Our annual commission rate increases retroactively to January 1 when targets are met as the year progresses. The progressive nature of our agreement can thus result in significantly higher commissions due us in the fourth and first quarters as compared to the second and third quarters of the calendar year.

Equipment

The Equipment segment operates through two subsidiaries: Vasomedical Solutions and Vasomedical Global. The segment primarily designs, manufactures and distributes medical devices, including EECP systems, ambulatory monitoring devices, and patient management devices. Vasomedical Solutions maintains a manufacturing facility in New York and markets EECP® therapy systems and other medical equipment both in the United States and in select international markets. Vasomedical Global currently operates engineering development and production facilities in China. In addition to being the primary supplier of medical equipment to Vasomedical Solutions, it also sells its ambulatory monitoring products directly to end users in China and other countries.

Sales and Marketing

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

The sales and marketing efforts of our equipment segment are led by a vice president of sales and marketing as well as a director of national sales, who supervises a team of sales managers covering various regions in the United States. We market our EECP® systems internationally through distributors in various countries throughout Europe, the Middle East, Asia and Latin America.

Competition

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

In the United States our competitors in our EECP® business are Applied Cardiac Systems Inc., Cardiomedics Inc. and Scottcare Cardiovascular Solutions.

Market Overview - EECP®

Cardiovascular disease (CVD) is the leading cause of death in the world and is among the top three diseases in terms of healthcare spending in nearly every country. CVD claimed approximately 788,000 lives in the United States in 2009 and was responsible for 1 of every 3 deaths, according to The American Heart Association (AHA) Heart and Stroke Statistical 2013 Update (2013 Update). An estimated 83.6 million American adults suffer from some form of cardiovascular disease. Among these, 15.4 million have coronary heart disease (CHD).

We have FDA clearance to market our EECP® therapy for use in the treatment of stable and unstable angina, congestive heart failure, acute myocardial infarction, and cardiogenic shock; however, our current marketing efforts are focused in the area of making EECP® therapy the first treatment of choice after medication for chronic stable angina and congestive heart failure. Medicare and other third-party payers currently reimburse for the treatment of angina pectoris patients with moderate to severe symptoms who are refractory to medications and who, in the opinion of a cardiologist or cardiothoracic surgeon, are not candidates for invasive procedures. Patients with co-morbidities of

heart failure, diabetes, peripheral vascular disease, etc. are also reimbursed under the same criteria, provided the primary diagnosis and indication for treatment with EECP® therapy is refractory angina symptoms.

Angina

Angina pectoris is the medical term for a recurring pain or discomfort in the chest, neck or arm due to coronary artery disease (CAD). The number of angina patients in the United States in 2010 is approximately 7.8 million, according to the 2013 Update. There are approximately 100,000 to 150,000 new refractory angina patients each year who do not adequately respond to medication, and are not amenable to invasive revascularization procedures such as percutaneous coronary interventions (PCI), with angioplasty and coronary stent placement or coronary artery bypass grafting (CABG). Currently our EECP® therapy is mostly prescribed for these patients because of the potential to meet the guidelines for reimbursement of EECP® therapy.

In February 1999, the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers the Medicare program for approximately 49.4 million beneficiaries in 2012, issued a national coverage policy for the use of external counterpulsation therapy in the treatment of refractory angina. Medicare reimbursement guidelines have a significant impact in determining the available market for EECP® therapy. We believe that the majority of the patients who receive EECP® therapy are Medicare patients, and many of the younger patients are covered by third-party payers. An important element of our strategy is to grow the market for EECP® therapy by expanding reimbursement coverage to include a broader range of angina patients than the current coverage policy provides and enable EECP® therapy to compete more with other therapies for ischemic heart disease. Please see the "Reimbursement" section of this Form 10-K for a more detailed discussion of reimbursement issues.

Congestive Heart Failure (CHF)

CHF is a condition in which the heart loses its pumping capacity to supply the metabolic needs of all other organs. The condition affects both sexes and is most common in people over age 50. Symptoms include angina, shortness of breath, weakness, fatigue, swelling of the abdomen, legs and ankles, rapid or irregular heartbeat and low blood pressure. CHF is treated with medication, mechanical devices such as implantable cardioverter-defibrillator (ICD) therapy, percutaneous mechanical assist devices or left ventricular assist devices (LVAD), and, in certain severe cases, surgery, including heart transplants. 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 2013 Update, in 2010 approximately 5.1 million adults in the United States were suffering heart failure and about 670,000 new cases of the disease occur each year. The prevalence of the disease is growing as a result of the aging of the population and the improved survival rate of people after heart attacks. Because the condition frequently entails visits to the emergency room and in-patient treatment centers, two-thirds of all hospitalizations for people over age 65 are due to heart failure. In the U.S. under the provisions of the current Patient Protection and Affordable Care Act (PPACA), starting in October 2011, every hospital's 30-day hospital readmission rate for CHF, AMI and pneumonia is evaluated by CMS and if found to be in the lowest quartile, CMS is authorized by the Hospital Readmission Reduction Program to penalize the hospital by reducing by 1% the hospital's entire Medicare payment for the year. This 1% penalty will be applied for the calendar year 2013 and will be increased to 2% in 2014 and 3% in 2015.

We will continue to educate the marketplace that EECP® therapy is a therapy for ischemic cardiovascular disease and that patients with a primary diagnosis of heart failure, diabetes, peripheral vascular disease, etc. are also eligible for reimbursement under the current coverage policy, provided the primary indication for treatment with EECP® therapy is angina or angina equivalent symptoms and the patient satisfies other listed criteria. Please see the "Reimbursement" section of this Form 10-K for a more detailed discussion of reimbursement issues.

Other Potential Applications of EECP® Therapy

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

- Cerebral vascular disease, specifically ischemic stroke.
- Cardiac syndrome X
- Erectile dysfunction
- Chronic kidney disease
- Diabetes mellitus

It is believed that there is sufficient clinical and scientific evidence in these and other potential applications to demonstrate EECP® therapy's safety and efficacy. However, large randomized control studies appear to be needed to confirm the preliminary findings and drive market clearance and reimbursement.

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

The EECP® Therapy Systems

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

Clinical Studies on EECP® Therapy

There are at least 160 papers published in peer-reviewed medical journals related to EECP® therapy since 1992, and many more published in scientific and medical conferences all over the world. (In 2012 there were 18 new articles on EECP® therapy published in peer reviewed journals.) Most of these journal publications are clinical reports on the results in patients with chronic stable angina and/or heart failure. With only a few exceptions, these reports are generated using Vasomedical EECP® therapy systems. In summary, this body of literature contains evidence from a variety of institutions and investigators demonstrating the pathophysiological mechanisms underlying the benefits of EECP® therapy and the beneficial clinical outcomes of EECP® therapy.

Beneficial Clinical Outcomes

It has been well documented that the following benefits are sustained for up to three to five years:

- Increased myocardial perfusion to ischemic regions of the heart in patients with coronary artery disease (CAD);
- Improved cardiac functions and exercise capacity in patients with CAD and heart failure;
- Elimination or reduction in angina and heart failure symptoms;
- Improved CCS angina function class and heart failure NYHA function class;
- Reduced frequency of angina episodes and nitroglycerin usage in patients with refractory angina;
- Improved quality of life in patients with angina and heart failure.

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Mechanisms of Action

During the past several years, the mechanisms of action of EECP® therapy have been the subject of many investigations, and independent research aiming to fully explain the precise scientific means by which EECP® therapy achieves its long-term beneficial effects and further studies continue to be conducted and published every year. There is evidence to suggest that the EECP® therapy triggers a neurohormonal response that induces the production of growth and vasodilatation factors that promotes recruitment of new arteries and dilates existing blood vessels. This recruitment of new arteries, known as collateral blood vessels, bypass blocked or narrowed vessels and increase blood flow to ischemic areas of the heart muscle that were receiving an inadequate supply of blood. There is also evidence to support a mechanism related to improved function of the endothelium, which regulates the luminal size of the arteries and controls the dilation of the arteries to ensure adequate blood flow to all organs, thus reducing constriction of blood vessels that supply oxygenated blood to the body's organs and tissues. In addition, it is now clear that during EECP® therapy the hemodynamic effect reduces circulating proinflammatory cytokines, arterial stiffness and smooth muscle cells proliferation and migration, slowing down the progression of atherosclerotic processes. These evidences supporting the mechanisms of action will lead to exploration of additional clinical applications of EECP® therapy.

Significant Economic Benefits

Beginning in 1998, we sponsored the International EECP® Patient Registry (IEPR™) with the Department of Epidemiology Data Center at the University of Pittsburgh, Graduate School of Public Health as the coordinating center responsible for data collection, processing, as well as performing error and consistency checks and analysis. The IEPR™ is a voluntary registry recording consecutive patients enrolled in clinical sites undergoing for at least 1 hour of EECP® therapy. There are at least 26 papers published in medical peer-reviewed journals and more than 85 presentations in major scientific/clinical conferences using data collected in the IEPR™. The IEPR™ also examined the economic impact of EECP® treatment by collecting data on emergency department (ED) visits and hospitalizations in patients with refractory angina and LVD. Patients with refractory angina and LVD exert an enormous burden on health care resources primarily because of the number of recurrent emergency department (ED) visits and hospitalizations. Results from 450 patients with LVD (ejection fraction no more than 40%) treated with EECP® therapy for their refractory angina with data on all-cause ED visits and hospitalization rates within six months before EECP® therapy were compared with those at six months after EECP® therapy, and were analyzed and published in Congestive Heart Failure in February 2007. Despite the unfavorable risk profile, refractory angina patients with LVD achieved a substantial reduction in all-cause ED visits and hospitalization rates at 6-month follow-up.

The mean number of 6-month ED visits per patient decreased from 0.9±2.0 pre-EECP to 0.2±0.7 post-EECP (a 78% reduction), and 6-month hospitalizations were reduced from 1.1±1.7 to 0.3±0.9 (a 73% reduction). The significant reduction in ED visits and hospitalizations post-EECP® therapy is consistent with findings presented elsewhere. EECP® therapy has the potential to save billions of dollars in healthcare costs each year, and, as this is becoming an increasingly important issue of the nations healthcare system, the Company is communicating to payers of these benefits as part of its campaign to expand reimbursement for EECP® therapy.

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

Sales and Marketing – EECP®

Domestic Operations

We sell EECP® therapy systems, ambulatory monitoring devices and patient management devices to treatment providers such as hospitals, clinics and physician private practices in the United States through our sales managers throughout the nation supervised by a director of national sales, who reports to a vice president of sales and marketing. The efforts of our sales organization are supported by in-house administration and clinical educators who are responsible for training and certification of physicians and therapists, as well as updating customers on new clinical developments, especially relating to EECP® therapy. The Company also markets certain products, accessories and supplies through an online store.

Our domestic marketing activities support physician education and physician outreach programs, exhibition at national and regional medical conferences, as well as sponsoring seminars at professional association meetings. These programs are designed to support our field sales organization and increase awareness of EECP® therapy in the medical community. Our marketing activities also include promotion of awareness among third-party payers and potential patients of the benefits of EECP® treatment for patients suffering from CHF as well as angina.

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

International Operations

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

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

International sales may be subject to certain risks, including export/import licenses, tariffs, and other trade regulations. In addition, there can be no assurance that we will be successful in maintaining our existing distribution agreements or entering into any additional distribution agreements, or that our international distributors will be successful in marketing EECP® therapy.

Competition in the EECP® Market

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

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

Government Regulations on EECP® Systems

We are subject to extensive regulation by numerous government regulatory agencies, including the FDA and similar foreign agencies. We are required to comply with applicable laws, regulations and standards governing the development, preclinical and clinical testing, manufacturing, quality testing, labeling, promotion, import, export, and distribution of our medical devices.

Clearance by U.S. FDA

Our EECP® therapy systems are currently classified by the US FDA as Class III devices, which include devices for which there is insufficient information demonstrating that general and special controls will provide reasonable assurance of safety and effectiveness, and which are life-sustaining, life-supporting or implantable devices, are of substantial importance in preventing impairment of human health, or pose a potential unreasonable risk of illness or injury. The FDA generally must clear a Class III device for marketing in the United States by a premarket approval (PMA), unless it is considered as a preamendments device – device that was commercially distributed before May 28, 1976 – and thus can be cleared by premarket notification, or 510(k). The Company's initial system received FDA 510 (k) clearance in 1995, with later models receiving clearance at various times between 2000 and 2004.

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

On December 5, 2012, the FDA convened the Circulatory System Devices Panel of the Medical Devices Advisory Committee to discuss the classification of External Counter-Pulsating (ECP) devices for various intended uses. As one of the remaining pre-amendments Class III devices, ECP's safety and effectiveness are being reviewed by the FDA to determine whether the classification for the device should remain as class III and require a PMA application or be down-classified into class I (General Controls) or Class II (Special Controls). In the December 5, 2012 panel meeting, the FDA recommended a split classification to include Class II for refractory angina and Class III for all other intended uses. If FDA issues a final rule to classify some indications of ECP into Class III, companies wishing to continue to market ECP for these indications must file a PMA application within the specified timeframe that is designated in the final classification order. To support approval, the information in the PMA (including clinical data) would have to demonstrate a reasonable assurance of safety and effectiveness. New devices or changes to existing devices would require approval of a PMA or PMA supplement. If a company does not file a PMA within the specified timeframe or otherwise does not receive an approval order for their product, the products are considered to be misbranded and should be removed from the market.

At this time, we have no information on when the FDA will publish a draft rule for public comments and, if after the public commenting period the final rule does classify indications other than refractory angina into Class III, what timeframe will be designated for filing PMA. We will continue to monitor the development on this matter and take appropriate actions accordingly.

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

Clinical Trials

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

obtain all necessary approvals, exemptions and consents before future clinical trials, and furthermore, the results of clinical testing that a sponsor undertakes may be insufficient to obtain clearance or approval of the tested product.

Pervasive and Continuing FDA Regulation

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

The FDA also enforces post-marketing controls that include the requirement to submit medical device reports to the agency when a manufacturer becomes aware of information suggesting that any adverse events are related to its marketed products. The FDA relies on medical device reports to identify product problems and utilizes these reports to determine, among other things, whether it should exercise its enforcement powers. The FDA also may require post-market surveillance studies for specified devices.

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

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

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

Foreign Regulation

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

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

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

Patient Privacy

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

Practice Guidelines for EECP® Therapy

Medical professional societies periodically issue Practice Guidelines to their members and make them available publicly. The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) have jointly produced guidelines in the area of cardiovascular since 1980. The ACCF/AHA practice guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches to the diagnosis, management, and prevention of specific diseases or conditions.

On November 19, 2012 the ACCF/AHA Task Force on Practice Guidelines issued its new Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease. EECP® therapy retained the same IIb Class of Recommendation (COR) rating it received in the ACC/AHA 2002 Guideline Update for the Management of Patients with Chronic Stable Angina. The new Guideline also gave EECP® therapy the same B rating for Level of Evidence (LOE) as the 2002 Guideline.

According to the Guideline, a class IIb rating maintains that procedures and treatments may be considered for patients. Additional studies with broad objectives are needed and further registry data would be helpful. This classification finds that the benefits of treatments are greater than or equal to the risk of treatment.

While the 2012 Guideline's rating for EECP therapy recognizes its importance as the first alternative therapy for ischemic heart diseases, it appears that only clinical data up to 2010 were considered by the Writing Committee. The Company continues to communicate with the ACCF/AHA Task Force, particularly the Writing Committee for the Guideline, to explore options to raise the Class of Recommendation for EECP® therapy based on more current data than referenced in the 2012 Guideline..

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

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

Reimbursement for EECP® Therapy

Reimbursement coverage and payment rates are important factors in the sales of our products, and we depend in large part on the availability of reimbursement programs. Medicare, Medicaid, as well as private health care insurance and managed-care plans determine eligibility for coverage of a product or therapy based on a number of factors, including the payer's determination that the product is reasonable and necessary for the diagnosis or treatment of the illness or injury for which it is administered according to the scope of clinical evidence available, accepted standards of medical care in practice, the product's cost effectiveness, whether the product is experimental or investigational, impact on health outcomes and whether the product is not otherwise excluded from coverage by law or regulation.

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

Current Medicare Coverage in Angina

In February 1999, CMS, the federal agency that administers the Medicare program for approximately 47.7 million beneficiaries now, issued a national coverage policy under HCPCS code G0166 for the use of the EECP® therapy system. Key excerpts from the coverage read as follows:

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

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

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

The physician office setting and the hospital outpatient facility are the only entities currently authorized to receive reimbursement for the EECP® therapy under the Medicare program and reimbursement is not permitted to other individuals or entity types, which include, but are not limited to, nurse practitioners, physical therapists, ambulatory surgery centers, nursing homes, comprehensive outpatient rehabilitation facilities, outpatient dialysis facilities, and independent diagnostic testing facilities. The 2012 national average payment rate per hourly EECP® therapy session in the physician office setting and the hospital outpatient facility is $144 and $99, respectively. Actual reimbursement rates vary throughout the country and range from $120 to $194 per hourly EECP® therapy session in the physician office setting. The national average payment rate varied considerably (from $130 in 2000 to $208 in 2003 for physician offices), but has become stable since 2004, as in the summary below:

Year	Physician Office	Hospital
2004	$137	$113
2005	$138	$102
2006	$138	$104
2007	$147	$107
2008	$156	$109
2009	$150	$102
2010	$148	$104
2011	$153	$102
2012	$151	$94
2013	$144	$99

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

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

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

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

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

Coverage with Other Third-Party Payers

Since the establishment of reimbursement for EECP® therapy by the federal government, an increasing number of private third-party payers have routinely provided coverage for the use of EECP® therapy for the treatment of angina and have issued positive coverage policies, which are generally similar to Medicare's coverage policy in scope. In addition, some third-party payers began limited coverage of EECP® therapy for the treatment of CHF. On the other hand, there are private insurance carriers that continue to adjudicate EECP® treatment claims on a case-by-case basis. We continue to pursue a constructive dialogue with many private insurers for the establishment of positive and expanded coverage policies for EECP® treatment that include CHF patients.

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

Reimbursement in International Markets

The reimbursement environment for EECP® therapy in international markets is fragmented and coverage varies. Our reimbursement strategy has changed to be more proactive and create opportunities through our distribution partners. Our current efforts on behalf of EECP® therapy in both the private and public healthcare sectors of selected international markets are being initiated jointly by the company and its distributors in their designated territories. We do not anticipate a significant impact on financial performance in the next fiscal year, given the long lead time from

submission to approval of international dossiers for each reimbursement authority.

Other Medical Equipment

In our effort to diversify our medical equipment offering, in May 2008 we first obtained exclusive distribution rights for the BIOXTM series ECG Holter and ambulatory blood pressure monitoring products in the North American market. Between April 2009 and June 2011 the Company received multiple 510(k) clearances from the US FDA for various BIOX series ECG Holter, ambulatory blood pressure and combination monitors, as well as the associated analysis and reporting software. The Company now offers a complete line of BIOXTM series diagnostic products for ambulatory monitoring needs.

In September 2011, the Company acquired the company that controls BIOX and now includes its operations in the consolidated financial results. In combination with BIOX, the Company is also promoting its joint engineering design and manufacturing capabilities for potential OEM opportunities as well as pursuing international sales opportunities for the product line through its global distribution channel.

The growing market for ECG Holter and ambulatory blood pressure monitoring products worldwide is expected to exceed $150 million by 2015. While there are multiple competitors in the marketplace, we believe that due to certain special features of our products, and through our sales and marketing efforts in niche markets, we will increase sales revenue and create opportunities for other products the Company manufactures or distributes.

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

Strategic Objectives

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

a) Maintain and grow our equipment business, by

i) Continuing to align the cost structure with revenue growth, including increased funding of marketing initiatives;

ii) Expanding our direct sales force to significantly increase revenue, particularly from EECP® equipment and service sales;

iii) Increasing our international efforts to grow international sales of all our device offerings; and

iv) Pursuing accretive acquisitions of medical device companies in the international marketplace.

b) Continue to diversify our product offerings, by

i) Identifying and introducing other medical device products and opportunities that fit into our target market; and

ii) Working with select partners to develop our medical device OEM business.

c) Work with all stakeholders to expand reimbursement coverage for EECP® therapy, by

i) Submitting up-to-date treatment effectiveness data and cost saving evidence to CMS and third party payers for consideration of EECP® as a first line treatment option for angina and for expansion of coverage to include heart failure; and

ii) Possibly conducting clinical trials to expand coverage, including the potential use of EECP® as a treatment for other ailments including diabetes, chronic kidney disease, and erectile dysfunction.

d) Maintain and improve business performance in our sales representation segment by expanding the GE Healthcare product modalities we represent, and possibly building new teams to represent other vendors.

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

Intellectual Properties

We own eleven US patents including eight utility patents and three design patents that expire at various times between now and 2023. We will from time to time file other patent applications regarding specific enhancements to the current EECP® models, future generation products, and methods of treatment in the future. Moreover, trademarks have been registered for the names “EECP”, “AngioNew”, “Natural Bypass”, “Vasomedical”, “Vasomedical EECP” , “VasoGlo “VasoSolutions” and “VasoHealthcare”.

Through our China-based subsidiaries, we own three utility patents and various trademarks. We also own five software copyright certificates in China, related to Holter ECG and ambulatory blood pressure data analysis and reporting. We pursue a policy of seeking patent protection, both in the US and abroad, for our proprietary technology. We believe that we have a solid patent foundation in the field of external counterpulsation devices and that the number of patents and applications demonstrates our technical leadership, dating back to the mid-1980s. Our patent portfolio focuses on the areas of external counterpulsation control and the overall design and arrangement of the external counterpulsation apparatus, including the console, treatment bed, fluid distribution, and inflatable cuffs. None of our current competitors have a significant patent portfolio in the area of external counterpulsation devices.

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

Employees

As of December 31, 2012, we employed 194 full-time persons, of which 32 are employed through our facility in Westbury, New York, 90 through our VasoHealthcare subsidiary and 72 are in China. None of our employees are represented by a labor union. We believe that our employee relations are good.

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

Manufacturing

Vasomedical Solutions maintains its manufacturing facility in the Westbury, NY location to satisfy domestic and international needs for the TS4 and Lumenair EECP® systems, and Vasomedical Global operates production facilities at the Life Enhancement Technology Co. Ltd. (LET) and BIOX facilities in China. LET manufactures AngioNew® and Lumenair EECP® systems and Biox manufactures ambulatory monitoring devices. Our VasoHealthcare subsidiary maintains an office in Greensboro, North Carolina.

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

We believe our manufacturing capacity and warehouse facility are adequate to meet the current and immediately foreseeable future demand for the production of our medical devices. We believe our suppliers of the other medical

devices we distribute or represent are capable of meeting our demand for the foreseeable future.

ITEM 1A - RISK FACTORS

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

Financial Risks

Achieving profitable operations is dependent on several factors.

Our ability to achieve and sustain profitability is dependent on many factors, primarily being the sufficient and timely generation and recognition of revenue in our Sales Representation segment, the success of our marketing and sales efforts in the Equipment segment, as well as the success of our other strategic initiatives, including our China acquisitions.

Risks Related to Our Business

We currently derive the significant amount of our revenue from our agreement with GEHC.

On May 19, 2010, we signed a sales representation agreement with GEHC, the healthcare business unit of the General Electric Company, for the sale of select GEHC diagnostic imaging products. Under the GEHC Agreement, we have been appointed the exclusive representative for these products to specific market segments in the 48 contiguous states of the United States and the District of Columbia. The GEHC Agreement had an initial term of three years commencing July 1, 2010 and in 2012 was extended for two years to June 30, 2015, subject to extension and also subject to earlier termination under certain circumstances

A significant amount of our revenue and prior periods net income arise from activities under this contract. Moreover, our growth depends partially on the territories, customer segments and product modalities assigned to us by GEHC, and thus relies on our ability to demonstrate our added value as a channel partner, and maintain a positive relationship with GEHC. There is no assurance that the agreement will be renewed before it expires or terminated prior to its expiration pursuant to its termination provisions. Should GEHC terminate or not renew the agreement, it would have a material adverse effect on our financial condition and results of operations. See also Recent Development above.

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

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

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

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

Health care providers, such as hospitals and physician private practices in the U.S., that purchase or lease medical devices such as the EECP® therapy system for use on their patients generally rely on third-party payers, principally Medicare, Medicaid and private health insurance plans, to reimburse all or part of the costs and fees associated with

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

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

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

We face competition from other companies and technologies.

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

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

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

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

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

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

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

Our operations in China are also subject to the laws of the People's Republic of China with which we must be in compliance in order to conduct these operations.

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws.

We cannot predict the nature of any future laws, regulations, interpretations, or applications, nor can we predict what effect additional governmental regulations or administrative orders, either domestically or internationally, 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 have foreign operations and are subject to the associated risks of doing business in foreign countries

During the years ended December 31, 2012 and 2011, the Company had and continues to have operations in China. Operating internationally involves additional risks relating to such things as currency exchange rates, different legal and regulatory environments, political, economic risks relating to the stability or predictability of foreign governments, differences in the manner in which different cultures do business, difficulties in staffing and managing foreign operations, differences in financial reporting, operating difficulties, and other factors. The occurrence of any of these risks, if severe enough, could have a material adverse effect on the consolidated financial position, results of operations and cash flows of the Company.

Commercial law is still developing in China and there are limited legal precedents to follow in commercial transactions. There are many tax jurisdictions each of which may have changing tax laws. Applicable taxes include value added taxes ("VAT"), corporate income tax, and social (payroll) taxes. Regulations are often unclear. Tax declarations (reports) are subject to review and taxing authorities may impose fines, penalties and interest. These facts create risks in China.

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 or clearance by other jurisdictions. If we, or any of our international distributors, fail to obtain or maintain required pre-market approvals or fail to comply with foreign regulations, foreign regulatory authorities may require us to file revised governmental notifications, cease commercial sales of our products in the applicable countries or otherwise cure the problem. Such enforcement action by regulatory authorities may be costly.

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

We depend on suppliers for the supply of certain products.

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

We depend on management and other key personnel.

We are dependent on a limited number of key management and technical personnel. The loss of one or more of our key employees may harm our business if we are unable to identify other individuals to provide us with similar services. We do not maintain "key person" insurance on any of our employees. In addition, our success depends upon our ability to attract and retain additional highly qualified management, sales, manufacturing and research and development personnel in our various operations. We face competition in our recruiting activities and may not be able to attract or retain qualified personnel.

We may not have adequate intellectual property protection.

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

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

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

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

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

Risks Related to Our Industry

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

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

Technological change is difficult to predict and to manage.

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

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

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

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

We do not know the effects of healthcare reform proposals.

The healthcare industry is undergoing fundamental changes resulting from political, economic and regulatory influences. In the United States, the Affordable Care Act was passed providing increased access to healthcare for the uninsured, control the escalation of healthcare expenditures within the economy and use healthcare reimbursement policies to balance the federal budget.

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

Risks Related to our Securities

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

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

Our common stock is subject to price volatility.

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

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

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

Additional Information

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

ITEM 2 – PROPERTIES

We lease an 18,000 square foot headquarters and manufacturing facility at 180 Linden Avenue, Westbury, New York 11590 under a lease with a term that expires on August 31, 2015.The annual rental expense for the lease is approximately $132,000. We believe that our current facility is adequate for foreseeable current and future needs and that there will be no difficulty in acquiring comparable facilities if we do not extend our current lease.

We also lease approximately 1,500 square feet of office space in New York City under a lease that expires on May 31, 2017. The annual rent for this lease is approximately $38,000.

We lease our engineering and production facilities in China. We lease approximately 9,000 square feet at an annual cost of approximately $46,000 in Wuxi, China and approximately 11,000 square feet at an annual cost of approximately $23,000 in Foshan, China.

Our Sales Representation segment primarily operates from a facility in Greensboro, North Carolina, where we lease 2,600 square feet of office space at an annual rental expense of approximately $48,000. The current lease for the Greensboro, North Carolina office will expire by the end of May, 2013, and we do not believe there will be difficulty in relocating the office should we decide not to renew the lease.

PART II

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

Our common stock currently trades on OTCBB under the symbol VASO. The number of record holders of common stock as of March 25, 2013, was approximately 1,100, which does not include approximately 8,600 beneficial owners of shares held in the name of brokers or other nominees. The table below sets forth the range of high and low trade prices of the common stock for the fiscal periods specified.

	Year ended December 31, 2012		June 1, 2011 - December 31, 2011		Year ended May 31, 2011	
	High	Low	High	Low	High	Low
First quarter	$0.35	$0.19	$0.51	$0.28	$0.24	$0.18
Second quarter*	$0.29	$0.18	$0.43	$0.21	$0.21	$0.18
Third quarter	$0.26	$0.19	N/A	N/A	$0.31	$0.18
Fourth quarter	$0.24	$0.15	N/A	N/A	$0.74	$0.34

* Second quarter is from September 1, 2011 through December 31, 2011 in the transitional period.

The last bid price of the Company's common stock on March 25, 2013, was $0.18 per share.

Dividend Policy

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

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

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

Except for historical information contained in this report, the matters discussed are forward-looking statements that involve risks and uncertainties. When used in this report, words such as "anticipates", "believes", "could", "estimates" "expects", "may", "plans", "potential", "intends", and similar expressions, as they relate to the Company or its manageme identify forward-looking statements. Such forward-looking statements are based on the beliefs of the Company's management, as well as assumptions made by and information currently available to the Company's management. Among the factors that could cause actual results to differ materially are the following: the effect of business and economic conditions; the effect of the dramatic changes taking place in the healthcare environment; the impact of competitive procedures and products and their pricing; medical insurance reimbursement policies; unexpected manufacturing or supplier problems; unforeseen difficulties and delays in the conduct of clinical trials and other product development programs; the actions of regulatory authorities and third-party payers in the United States and overseas; uncertainties about the acceptance of a novel therapeutic modality by the medical community; continuation of the GEHC agreement; and the risk factors reported from time to time in the Company's SEC reports. The Company

undertakes no obligation to update forward-looking statements as a result of future events or developments.

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

Overview

Vasomedical, Inc. was incorporated in Delaware in July 1987. Unless the context requires otherwise, all references to "we", "our", "us", "Company", "registrant", "Vasomedical" or "management" refer to Vasomedical, Inc. and its subsidiaries. 1995, we have been primarily engaged in designing, manufacturing, marketing and supporting EECP® Enhanced External Counterpulsation systems, based on our unique proprietary technology, to physicians and hospitals throughout the United States and in select international markets.

In 2010, the Company, through its wholly-owned subsidiary Vaso Diagnostics d/b/a VasoHealthcare, organized a group of medical device sales professionals and entered into the sales representation business as the exclusive representative for the sale of select General Electric Company (GE) diagnostic imaging equipment to specific market segments in the 48 contiguous states of the United States and the District of Columbia.

In September 2011, the Company acquired two Chinese operating companies, Life Enhancement Technologies Ltd. and Biox Instruments Co. Ltd. to expand its technical and manufacturing capabilities and to enhance its distribution network, technology, and product portfolio. Also in September 2011, the Company restructured to further align its business management structure and long-term growth strategy and now operates through three wholly-owned subsidiaries. Vaso Diagnostics d/b/a VasoHealthcare will continue as an operating subsidiary for the sales representation of GE diagnostic imaging products; Vasomedical Global Corp. will operate the Company's Chinese companies; and Vasomedical Solutions, Inc. was formed to manage and coordinate our EECP® therapy business as well as other medical equipment operations.

In 2011, we changed our fiscal year end to December 31 from May 31. We made this change to better align our financial reporting period, as well as our annual planning and budgeting process, with our business cycle, and the fiscal year of our China operations and of General Electric. This Annual Report on Form 10-K reports our financial results for the year ended December 31, 2012 (our first full fiscal year since the change), the seven-month transition period from June 1, 2011 through December 31, 2011 and the year ended May 31, 2011. For purposes of comparison, we have included the unaudited financial results for the year ended December 31, 2011 and the seven months ended December 31, 2010. See Note S to our Consolidated Financial Statements for additional information.

Results of Operations – For the Years Ended December 31, 2012 and 2011

Net revenues decreased by $1,872,000, or 6%, to $29,240,000 in the year ended December 31, 2012, from $31,112,000 in the year ended December 31, 2011. We reported a net loss applicable to common stockholders of $3,381,000 for the year ended December 31, 2012 as compared to net income of $2,175,000 for the year ended December 31, 2011. Our total net income (loss) was $(0.02) and $0.02 per basic and diluted common share for the years ended December 31, 2012 and 2011, respectively.

Revenues

Revenue in our Equipment segment increased 34% to $6,023,000, including $1,472,000 in revenue from FGE, for the year ended December 31, 2012 from $4,498,000, including $413,000 in FGE revenue, for the year ended December 31, 2011. Equipment segment revenue from equipment sales increased by $1,713,000, or 69%, to $4,191,000 for the year ended December 31, 2012 as compared to $2,478,000 for the year ended December 31, 2011. The increase in equipment sales is due primarily to a $1,059,000 increase in sales by FGE, as well as a 92% increase in international EECP® sales, driven by increased volume and higher average selling price, partially offset by a 4% decrease in domestic sales, mainly a net result of lower deliveries and higher average selling price.

We anticipate that demand for EECP® systems will remain soft domestically unless there is greater clinical acceptance for the use of EECP® therapy in treating patients with angina or angina equivalent symptoms who meet

the current reimbursement guidelines, or a favorable change in current reimbursement policies by CMS or third party payors to consider EECP therapy as a first-line treatment option for angina or cover some or all Class II & III heart failure patients. Patients with angina or angina equivalent symptoms eligible for reimbursement under current policies include many with serious comorbidities, such as heart failure, diabetes, peripheral vascular disease and/or others. We also anticipate a growth in the FGE revenue due to the growing medical device market in China and as a result of our expanded international marketing effort.

Equipment segment revenue from equipment rental and services decreased 9% to $1,832,000 in the year ended December 31, 2012 from $2,021,000 in the year ended December 31, 2011. Revenue from equipment rental and services represented 30% of total Equipment segment revenue in the year ended December 31, 2012 and 45% in the year ended December 31, 2011. The decrease in revenue generated from equipment rentals and services is due primarily to decreased accessory part sales and rental revenues.

Commission revenues in the Sales Representation segment decreased by 13% to $23,217,000 in the year ended December 31, 2012, as compared to $26,614,000 in the year ended December 31, 2011. The decrease was due primarily to lower commission rates earned in 2012. As discussed in Note B, the Company defers recognition of commission revenue until underlying equipment acceptance is complete. As of December 31, 2012, $13,686,000 in deferred commission revenue was recorded in the Company's consolidated condensed balance sheet, of which $4,370,000 is long-term.

Gross Profit

The Company recorded gross profit of $20,594,000, or 70% of revenue, for the year ended December 31, 2012 compared to $21,917,000, or 70% of revenue, for the year ended December 31, 2011. The decrease of $1,323,000 was due primarily to lower revenue in the Sales Representation segment, partially offset by higher gross profit in the Equipment segment.

Equipment segment gross profit increased to $3,324,000, or 55% of Equipment segment revenues, for the year ended December 31, 2012 compared to $2,124,000, or 47% of Equipment segment revenues, for the year ended December 31, 2011 due to higher sales volume and improved margins resulting from the FGE acquisition. Equipment segment gross profits are dependent on a number of factors, particularly the mix of new and refurbished EECP® systems and the mix of models sold, their respective average selling prices, the ongoing costs of servicing EECP® systems, as well as certain fixed period costs, including facilities, payroll and insurance.

Sales Representation segment gross profit was $17,269,000, or 74% of Sales Representation segment revenues, for the year ended December 31, 2012, a decrease of $2,523,000, or 13%, from segment gross profit of $19,792,000, or 74% of segment revenue, for the year ended December 31, 2011. The decrease was due primarily to lower commission rates earned in 2012. Cost of commissions decreased by $874,000, or 13%, to $5,947,000 for the year ended December 31, 2012, as compared to cost of commissions of $6,821,000 in 2011. Cost of commissions reflects commission expense associated with recognized commission revenues. Commission expense associated with deferred revenue is recorded as deferred commission expense until the related commission revenue is earned.

Operating (Loss) Income

Operating loss was $3,508,000 for the year ended December 31, 2012 compared to operating income of $3,701,000 for the year ended December 31, 2011. The change from operating income to operating loss was primarily attributable to an operating loss of $153,000 in our Sales Representation segment for the year ended December 31, 2012, compared to operating income of $6,689,000 for the year ended December 31, 2011 in that segment. The 2012 segment loss reflects the impact of both the lower commission rates and higher SG&A costs incurred in conjunction with the extension of the GEHC agreement. Equipment segment operating loss in the year ended December 31, 2012 was $1,805,000, as compared to an operating loss of $2,021,000 in the year ended December 31, 2011. The decrease in operating loss was primarily due to higher gross profit, partially offset by higher SG&A costs, reflecting the inclusion of a full year of FGE operations in 2012 as compared to four months of FGE operations included in the 2011 consolidated financial statements.

Selling, general and administrative ("SG&A") expenses for the years ended December 31, 2012 and 2011 were $23,526,000, or 80% of revenues, and $17,690,000, or 57% of revenues, respectively, reflecting an increase of

$5,836,000 or approximately 33%. The increase in SG&A expenditures in the year ended December 31, 2012 resulted primarily from increased compensation and benefits expenses in the Sales Representation segment incurred in conjunction with the extension of the GEHC agreement. SG&A also increased in the Equipment segment due to higher administrative compensation costs, higher sales and marketing expenses, mainly related to reimbursement consulting, and the inclusion of FGE costs, as well as higher corporate expenses, mainly accounting, legal and director's fees.

Research and development ("R&D") expenses of $576,000, or 2% of revenues (or 9,6% of Equipment segment revenues), for the year ended December 31, 2012 increased by $51,000, or 10%, from $525,000, or 2% of revenues, for the year ended December 31, 2011. The increase is primarily attributable to an increase in development costs for our EECP® systems.

Interest and Financing Costs

Interest and financing costs for the year ended December 31, 2012 was $2,000 compared to $33,000 in the year ended December 31, 2011. Interest and financing costs in 2011 consisted mainly of interest on a short-term note to finance the Company's insurance premiums and interest charged on a trade payable to a related party.

Interest and Other Income, Net

Interest and other income for the year ended December 31, 2012 and 2011, was $181,000 and $241,000, respectively, a decrease of $60,000. The decrease was due to reductions in government grants obtained by one of the Company's Chinese companies, partially offset by higher interest income earned on the Company's cash balances and financing receivables.

Amortization of Deferred Gain on Sale-leaseback of Building

The amortization of deferred gain on the sale-leaseback of building for the year ended December 31, 2012 and 2011 was $31,000 and $53,000, respectively. The gain resulted from the Company's sale-leaseback of its Westbury facility.

Income Tax Benefit (Expense), Net

During the year ended December 31, 2012, we recorded income tax expense of $52,000 compared to the year ended December 31, 2011, when the Company recorded an income tax expense of $275,000. The Company utilized $0.8 million and $6.1 million in net reporting loss carryforwards for the years ended December 31, 2012 and 2011, respectively. Income tax expense decreased mainly due to lower taxable income in 2012, resulting in lower Federal Alternative Minimum Tax liability and lower state tax liabilities.

Ultimate realization of any or all of the deferred tax assets is not assured due to significant uncertainties and material assumptions associated with estimates of future taxable income during the carry-forward period. The Company believes it is premature to recognize additional deferred tax assets based on such uncertainties. However, such assessments may change as the representation business of VasoHealthcare matures.

Results of Operations – For the Seven Months Ended December 31, 2011 and 2010

Net revenues increased by $14,748,000, or 169%, to $23,489,000 for the seven months ended December 31, 2011, from $8,741,000 for the seven months ended December 31, 2010. We reported net income applicable to common stockholders of $3,891,000 for the seven months ended December 31, 2011 as compared to a loss of $2,604,000 for the seven months ended December 31, 2010. Our total net income (loss) was $0.03 and $(0.02) per basic and diluted common share for the seven months ended December 31, 2011 and 2010, respectively.

Revenues

Revenue in our Equipment segment decreased 23% to $2,576,000, including $413,000 in FGE revenue, for the seven months ended December 31, 2011 from $3,328,000 for the seven months ended December 31, 2010. Equipment segment revenue from equipment sales decreased approximately 27% to $1,473,000 for the seven months ended December 31, 2011 as compared to $2,025,000 for the seven months ended December 31, 2010. The decrease in

equipment sales is due primarily to a 59% decrease in the number of EECP® units sold internationally, coupled with a minor reduction in average selling price, as well as a 10% reduction in domestic sales driven mainly by lower average selling prices on certain used systems shipped. In addition, excluding FGE sales, revenue from other medical equipment increased 18% for the seven months ended December 31, 2011 as compared to the seven months ended December 31, 2010.

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

Equipment segment revenue from equipment rental and services decreased 15% to $1,103,000 for the seven months ended December 31, 2011 from $1,304,000 for the seven months ended December 31, 2010. Revenue from equipment rental and services represented 43% of total Equipment segment revenue for the seven months ended December 31, 2011 and 39% for the seven months ended December 31, 2010. The decrease in revenue generated from equipment rentals and services is due primarily to decreased field service and recognized service contract revenues.

Commission revenues in the Sales Representation segment were $20,913,000 for the seven months ended December 31, 2011, compared to $5,413,000 for the seven months ended December 31, 2010. As discussed in Note B, the Company defers recognition of commission revenue until underlying equipment acceptance is complete. As of December 31, 2011, $14,085,000 in deferred commission revenue was recorded in the Company's consolidated condensed balance sheet, of which $5,378,000 is long-term.

Gross Profit

The Company recorded gross profit of $16,756,000, or 71% of revenue, for the seven months ended December 31, 2011 compared to $5,820,000, or 67% of revenue, for the seven months ended December 31, 2010. The increase of $10,936,000 was due primarily to higher revenue in the Sales Representation segment, partially offset by lower gross profit rates resulting from higher commission expense..

Equipment segment gross profit decreased to $1,243,000, or 48% of Equipment segment revenues, for the seven months ended December 31, 2011 compared to $1,532,000, or 46% of Equipment segment revenues, for the seven months ended December 31, 2010 due mainly to lower sales volume. The decrease in absolute dollars was partially offset by an increase in gross profit percentage, which arose primarily from the inclusion of higher margins on FGE sales. Equipment segment gross profits are dependent on a number of factors, particularly the mix of new and refurbished EECP® systems and the mix of models sold, their respective average selling prices, the ongoing costs of servicing EECP® systems, and certain fixed period costs, including facilities, payroll and insurance.

Sales Representation segment gross profit was $15,513,000 for the seven months ended December 31, 2011 compared to $4,220,000 for the seven months ended December 31, 2010. Cost of commissions of $5,400,000 and $1,193,000, for the seven month periods ended December 31, 2011 and 2010, respectively, reflects commission expense associated with recognized commission revenues. Commission expense associated with deferred revenue is recorded as deferred commission expense until the related commission revenue is earned.

Operating Income

Operating income was $5,189,000 for the seven months ended December 31, 2011 as compared to an operating loss of $2,445,000 for the seven months ended December 31, 2010. The change from an operating loss to operating income was primarily attributable to operating income of $7,417,000 in our Sales Representation segment for the seven months ended December 31, 2011, as compared to an operating loss of $2,234,000 for the seven months ended December 31, 2010 in that segment. The 2010 segment loss reflects additional start-up costs and the deferral of commission revenue and expense in the seven months ended December 31, 2010. Equipment segment operating loss for the seven months ended December 31, 2011 was $1,603,000, including $578,000 in shared-based expenses, as compared to an operating loss of $59,000, including $226,000 in shared-based expenses, for the seven months ended

December 31, 2010. The increase in operating loss was primarily due to lower gross profit and higher SG&A costs.

Selling, general and administrative ("SG&A") expenses for the seven months ended December 31, 2011 and 2010 were $11,243,000, or 48% of revenues, and $8,004,000, or 92% of revenues, respectively, reflecting an increase of $3,239,000 or approximately 40%. The increase in SG&A expenditures for the seven months ended December 31, 2011 resulted primarily from increased wages, benefits, travel, and insurance expenses related to the Sales Representation segment, which was in its start-up phase during the seven months ended December 31, 2010. SG&A also increased in the Equipment segment due to higher sales and marketing expenses mainly related to reimbursement consulting, and the inclusion of FGE costs, as well as higher corporate expenses, mainly accounting, legal and director's fees.

During the seven months ended December 31, 2011, the Company recorded a provision for doubtful accounts and commission adjustments of $866,000 as compared to the seven months ended December 31, 2010 when the Company recorded a provision for doubtful accounts and commission adjustments of $1,150,000. Of the seven months ended December 31, 2011 provision, $55,000 was to accrue for bad debt expense and $811,000 was to reduce gross deferred revenues for estimated adjustments.

Research and development ("R&D") expenses of $324,000, or 1% of revenues, for the seven months ended December 31, 2011 increased by $63,000, or 24%, from $261,000, or 3% of revenues, for the seven months ended December 31, 2010. The increase is primarily attributable to an increase in clinical research expenses.

Interest and Financing Costs

Interest and financing costs for the seven months ended December 31, 2011 was $9,000 compared to $8,000 in the seven months ended December 31, 2010. Interest and financing costs consisted of interest on a short-term note to finance the Company's insurance premiums and interest charged on a trade payable to a related party.

Interest and Other Income, Net

Interest and other income for the seven months ended December 31, 2011 and 2010, were $177,000 and $17,000, respectively. In the seven months ended December 31, 2011 other income primarily consisted of a government grant obtained by one of the Company's Chinese companies. Interest income reflects interest earned on the Company's cash balances and financing receivables.

Amortization of Deferred Gain on Sale-leaseback of Building

The amortization of deferred gain on sale-leaseback of building for the seven months ended December 31, 2011 and 2010 was $31,000. The gain resulted from the Company's sale-leaseback of its Westbury facility.

Income Tax Benefit (Expense), Net

During the seven months ended December 31, 2011, we recorded income tax expense of $276,000 compared to the seven months ended December 31, 2010, when the Company recorded an income tax expense of $8,000. The Company utilized $6.1 million in net reporting loss carryforwards for the seven month period ended December 31, 2011. Income tax expense increased mainly due to Federal Alternative Minimum Tax liability and certain state tax liabilities in excess of net operating loss carryforwards.

Ultimate realization of any or all of the deferred tax assets is not assured due to significant uncertainties and material assumptions associated with estimates of future taxable income during the carry-forward period. The Company believes it is premature to recognize additional deferred tax assets based on such uncertainties. However, such assessments may change as the representation business of VasoHealthcare matures.

Liquidity and Capital Resources

Cash and Cash Flow – For the year ended December 31, 2012

We have financed our operations primarily from working capital. At December 31, 2012, we had cash and cash equivalents of $11,469,000, short-term investments of $110,000 and working capital of $7,538,000.

Cash provided by operating activities was $9,431,000 during the year ended December 31, 2012, which consisted of the net loss after adjustments of $1,681,000, offset by cash provided by changes in operating assets and liabilities of $11,112,000. The changes in the account balances primarily reflect decreases in accounts and other receivables of $10,854,000, partially offset by an increase in accrued expenses of $2,090,000. These changes in account balances are due mainly to the operations of our Sales Representation segment. At February 28, 2013 the Company's cash balances were approximately $12.9 million.

Investing activities during the year ended December 31, 2012 used cash of $402,000, mainly related to the acquisition of equipment and software.

Financing activities during the year ended December 31, 2012 provided cash of $153,000, primarily arising from the exercise of stock warrants, partially offset by the repayment of notes payable to a related party.

Liquidity

While the Company achieved substantial profitability for the year ended December 31, 2011, it has historically incurred operating losses and incurred a loss for the year ended December 31, 2012. The Company will seek to achieve profitability through growth in our China operations and by expanding our product portfolio. In addition, the Company plans to pursue other accretive acquisitions in the international and domestic markets and to expand our sales representation business. We anticipate a return to profitability in 2013.

While we expect to continue to generate positive operating cash flows in fiscal 2013, the progressive nature of the GEHC Agreement can cause related cash inflows to vary widely during the year.

Based on our operations through December 31, 2012 and current business outlook for 2013, we believe internally generated funds from our Equipment and Sales Representation segments will be sufficient for the Company to continue operations through at least January 1, 2014.

Off-Balance Sheet Arrangements

We do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities (SPES), which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of December 31, 2012, we are not involved in any unconsolidated SPES.

Related Party Transactions

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

The consulting agreement (the "Agreement") between Vasomedical, Inc. and Edgary Consultants, LLC ("Consultant") commenced on March 1, 2011 and ended on February 28, 2013. The Agreement provided for the engagement of Consultant to assist the Company in seeking broader reimbursement coverage of EECP® therapy.

In consideration for the services provided by Consultant under the Agreement, the Company had agreed to issue to Consultant or its designees, up to 18,500,000 shares of restricted common stock of the Company, 3,000,000 shares of

which were issued in March 2011 and the balance was to be earned based on performance . Mr. Lieberman received 600,000 of these restricted shares from the initial issuance. The Company has recorded the fair value of the shares issued to Consultant as a prepaid expense and amortized the cost ratably over the two year agreement. The unamortized value is reported as Deferred Related Party Consulting Expense in our accompanying consolidated balance sheet as of December 31, 2012. The agreement ended on February 28, 2013 and has not been renewed. No performance-based shares were issued and no additional compensation is expected to be paid under the agreement. Consultant, at its own expense, is continuing to investigate avenues through CMS and commercial payers to extend coverage and increased reimbursement for our EECP® therapy.

Through the Company's acquisition of FGE in September 2011, it assumed the liability for $288,000 in unsecured notes payable to the President of LET and his spouse, of which $95,000 was repaid in December 2011, and $190,000, bearing interest at 6% per annum, was paid in full in March 2012. In addition, $30,000 and $10,000 in pre-acquisition earnings were distributed to current BIOX management during the year ended December 31, 2012 and the seven months ended December 31, 2011, respectively. The Company also recorded $196,000 in loans and advances made to officers of FGE during the seven months ended December 31, 2011, of which $25,000 remained outstanding at December 31, 2012. These loans and advances are short term and do not bear interest.

Effects of Inflation

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

Critical Accounting Policies and Estimates

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

Revenue Recognition

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

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

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

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

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

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

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

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

Revenue and Expense Recognition for VasoHealthcare

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

Accounts Receivable, net

The Company’s accounts receivable are due from customers engaged in the provision of medical services and from GEHC. Credit is extended based on evaluation of a customer’s financial condition and, generally, collateral is not required. Accounts receivable are generally due 30 to 90 days from shipment and are stated at amounts due from customers net of allowances for doubtful accounts, returns, term discounts and commission adjustments. Accounts that remain outstanding longer than the contractual payment terms are considered past due. Estimates are used in determining the allowance for doubtful accounts based on the Company’s historical collections experience, current trends, credit policy and a percentage of its accounts receivable by aging category. In determining these percentages,

we look at historical write-offs of our receivables. The Company also looks at the credit quality of their customer base as well as changes in their credit policies. The Company continuously monitors collections and payments from our customers, and writes off receivables when all efforts at collection have been exhausted. While credit losses have historically been within expectations and the provisions established, the Company cannot guarantee that it will continue to experience the same credit loss rates that they have in the past.

Inventories, net

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

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

Deferred Revenues

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

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

Warranty Costs

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

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

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

Net Income (Loss) per Common Share

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

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Income Taxes

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

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

The Company also complies with the provisions of the ASC Topic 740, "Income Taxes", which prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. Based on its analysis, except for certain liabilities assumed in the FGE acquisition, the Company has determined that it has not incurred any liability for unrecognized tax benefits as of December 31, 2012 and December 31, 2011. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. No amounts were accrued for the payment of interest and penalties at December 31, 2012 and December 31, 2011. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

Share-based Employee Compensation

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

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

Recently Issued Accounting Pronouncements

Adoption of New Standards

Other Comprehensive Income: Presentation of Comprehensive Income

In June 2011, new guidance was issued that amends the current comprehensive income guidance. The new guidance allows the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single or continuous statement of comprehensive income or in two separate but consecutive statements. The amendments in this update do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The new guidance is to be applied retrospectively and is effective for fiscal years, and interim periods, beginning after

December 15, 2011, with early adoption permitted. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Intangibles—Goodwill and Other: Testing Goodwill for Impairment

In September 2011, an accounting standard update regarding testing of goodwill for impairment was issued. This standard update gives companies the option to perform a qualitative assessment to first assess whether the fair value of a reporting unit is less than its carrying amount. If an entity determines it is not more likely than not that the fair value of the reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. The new guidance is to be applied prospectively effective for annual and interim goodwill impairment tests beginning after December 15, 2011, with early adoption permitted. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Standards Issued But Not Yet Effective

In February 2013, new guidance was issued that amends the current comprehensive income guidance. The new guidance requires entities to disclose the effect of each item that was reclassified in its entirety out of accumulated other comprehensive income and into net income on each affected net income line item. For reclassification items that are not reclassified in their entirety into net income a cross reference to other required disclosures is required. The adoption of this new guidance is to be applied prospectively, and for annual reporting periods beginning after December 15, 2012 and interim periods within those years. The adoption of this new guidance will not have an impact on the Company's consolidated financial position, results of operations or cash flows.

ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

ITEM 9A - CONTROLS AND PROCEDURES

Report on Disclosure Controls and Procedures

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

Our CEO and our CFO have evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2012 and have concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2012 due to the deficiencies described in Management's Report on Internal Control over Financial Reporting below. The Company intends to engage additional accounting personnel, including an accounting controller, and strengthen its internal controls with regard to its closing process, related disclosures, and the approval of certain transactions.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company as defined in Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial statements for external purposes in

accordance with accounting principles generally accepted in the United States of America. Internal control involves maintaining records that accurately represent our business transactions, providing reasonable assurance that receipts and expenditures of company assets are made in accordance with management authorization, and providing reasonable assurance that unauthorized acquisition, use or disposition of company assets that could have a material effect on our financial statements would be detected or prevented on a timely basis.

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

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Based on this evaluation and those criteria, the Company's CEO and CFO concluded that the Company's internal control over financial reporting was not effective as of December 31, 2012, due to the following deficiencies at the Company's Fast Growth Enterprises (FGE) subsidiary and at the two Chinese operating companies FGE owns or controls:

- Insufficient controls and management review over the recording of certain transactions.
- Lack of accounting personnel with appropriate level of knowledge and experience in accounting principles generally accepted in the United States of America and related accounting systems and closing process.

This report does not include an attestation report of the Company's Independent Registered Public Accounting Firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's Independent Registered Public Accounting Firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only Management's report in this Annual Report.

PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors of the Registrant

As of March 25, 2013, the members of our Board of Directors are:

Name of Director	Age	Principal Occupation	Director Since
Simon Srybnik	96	Chairman of the Board and Director	June, 2007
Peter C. Castle (1) (2) (3)	44	Director	August, 2010
David Lieberman (1)	68	Vice Chairman of the Board and Director	February, 2011
Jun Ma	49	President, Chief Executive Officer and Director	June, 2007
Behnam Movaseghi (1) (2) (3)	59	Director	July, 2007
Edgar Rios	61	Director	February, 2011

(1) Member of the Executive Committee, which was formed in January, 2012.
(2) Member of the Audit Committee
(3) Member of Compensation Committee

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

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

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

David Lieberman has been a director of the Company and the Vice Chairman of the Board, since February 2011. Mr. Lieberman has been a practicing attorney in the State of New York for more than 35 years, specializing in corporation and securities law. He is currently a senior partner at the law firm of Beckman, Lieberman & Barandes, LLP, which firm performs certain legal services for the Company. Mr. Lieberman is a former Chairman of the Board of Herley Industries, Inc., which company was sold in March, 2011.

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

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

Edgar G. Rios has been a director of the Company since February 2011. Mr. Rios currently is President of Edgary Consultants, LLC. and was appointed a director in conjunction with the Company's consulting agreement with Edgary Consultants, LLC. Mr. Rios is co-founder and managing director of Wenzi Capital Partners, a venture capital and private equity firm. Mr. Rios was Executive Vice President, General Counsel, Secretary, and Director of AmeriChoice Corporation from its inception in 1989 through its acquisition by UnitedHealthcare in 2002. He is a co-founder of AmeriChoice and was part of the management team that grew revenues to $675 million in 2001. Prior to co-founding AmeriChoice, Mr. Rios was a co-founder of a number of businesses that provided technology services and non-technology products to government purchasers. Over the years, Mr. Rios also has been an investor, providing seed capital to various technology and nontechnology start-ups. Mr. Rios also serves as a member of the Board of Trustees of Meharry Medical School and as a director and secretary of the An-Bryce Foundation. Mr. Rios holds a J.D. from Columbia University Law School and an A.B. from Princeton University.

Committees of the Board of Directors

Executive Committee

The primary purpose of the Executive Committee is to function when the Board of Directors is not in session. During the intervals between meetings of the Board, the Committee shall have and may exercise the powers of the Board, except as limited by Delaware statute. It will also take such other action and do such other things as may be referred to it from time to time by the Board.

Audit Committee and Audit Committee Financial Expert

The Board has a standing Audit Committee. The Board has affirmatively determined that each director who serves on the Audit Committee is independent, as the term is defined by applicable Securities and Exchange Commission ("SEC") rules. During the year ended December 31, 2012, the Audit Committee consisted of Peter Castle, who has served as the committee chair since August 2010, and Behnam Movaseghi, who joined the committee in November 2011. The members of the Audit Committee have substantial experience in assessing the performance of companies, gained as members of the Company's Board of Directors and Audit Committee, as well as by serving in various capacities in other companies or governmental agencies. As a result, they each have an understanding of financial statements. The Board believes that Peter Castle fulfills the role of the financial expert on this committee.

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

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

Compensation Committee

Our Compensation Committee annually establishes, subject to the approval of the Board of Directors and any applicable employment agreements, the compensation that will be paid to our executive officers during the coming year, as well as administers our stock-based benefit plans. During the year ended December 31, 2012, the Compensation Committee consisted of Behnam Movaseghi, who served as the committee chair, and Peter Castle. None of these persons have been officers or employees of the Company or, except as otherwise disclosed, had any relationship requiring disclosure herein.

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

MEETINGS OF THE BOARD OF DIRECTORS AND COMMITTEES

During the year ended December 31, 2012 there were:

- 5 meetings of the Board of Directors
- 6 meetings of the Audit Committee
- 4 meetings of the Executive Committee