HeartSTAT Technology, Inc.
Form 10SB12G
October 20, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-SB

GENERAL FORM FOR REGISTRATION OF SECURITIES
OF SMALL BUSINESS ISSUERS
UNDER SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

HEARTSTAT TECHNOLOGY, INC.
(Name of small business issuer in its charter)

DELAWARE	20-1680252
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

530 WILSHIRE BLVD, #304 SANTA MONICA, CA 90401
(Address of principal executive offices) (Zip Code)

Issuer's telephone number: 310-451-7400

Securities to be registered under Section 12(b) of the Act: NONE

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

COMMON STOCK, $0.001 PAR VALUE
(Title of class)

PART I

ITEM 1. DESCRIPTION OF BUSINESS.

INTRODUCTION

HEARTSTAT TECHNOLOGY, Inc., ("HEARTSTAT" or the "Company") is a Delaware corporation originally incorporated on October 12, 1995, under the name of "Hospital Software of America, Inc." The Company has undergone name changes that are described in the history of the company below. Most recently HEARTSTAT was renamed from Tec Factory, Inc. pursuant to a March, 18, 2004 agreement by which the technology assets of HEARTSTAT, INC. WERE ACQUIRED BY TEC FACTORY, INC. Unless otherwise specified, the "Company", "HEARTSTAT", "we", "our" and "us" refer to HEARTSTAT TECHNOLOGY INC. Our principal executive offices are located at 530 Wilshire Blvd, Suite 304, Santa Monica, CA 90401 and our telephone number is 310-451-7400.

HISTORY OF THE COMPANY

HEARTSTAT Technology, Inc. was originally incorporated on October 12, 1995, as Hospital Software of America, Inc. On November 29, 1995, the Company changed its name to "New Health Technologies, Inc., and at the same time effected at 10,000 to 1 reverse stock split, reducing the outstanding shares from 300,000,000 to 30,000.

On August 28, 1996, the Company changed its name to "Pubbs Worldwide, Inc. and at the same time, effected a 35 to 1 reverse stock split, reducing the number of issued and outstanding shares from 14,000,000 to 400,000. The Company changed its name to Pubbs Worldwide, Inc. in order to better reflect its acquisition of Hubbs Development, Inc., which was in the business of operating restaurants and retail sales of food, beer, wine and beverages.

On April 5, 1999, the Company changed its name to "Chasen's International Corporation". The name change was affected in anticipation of a share exchange agreement between the Company and a group of shareholders, which owned a controlling interest in Chasen's Restaurant and Jockey Club in Beverly Hills, California. Management of the Company believed that changing the name of the Company to Chasen's International Corporation would provide the Company instant name recognition. The Company affected a stock split of 100 to 1 at this time.

On July 6, 1999, the Company changed it corporate name to "Tril-MediaNet.com" after the anticipated share exchange agreement and acquisition of Chasen's did not materialize. It was believed that the new name would allow the Company to better continue its software business development and technology operations and avoid any conflict with the trademarks and ownership of the name Chasen's.

On November 21, 2000, the Company changed its name to Tec Factory, Inc. and was planning to purchase Tec Factory Fort Lauderdale, LLC and Tec Factory Los Angeles, LLC from Web Capital Ventures, Inc. This transaction was not concluded. The Company had negligible operations between November 2000 and February 6, 2004.

On February 6, 2006 the Company concluded an agreement to purchase the technology assets of HEARTSTAT, INC. AND on February 17, 2004 the Company amended its corporate name to HEARTSTAT Technology, Inc. in anticipation of closing and Agreement for the Purchase of Assets based on the February 6, 2004 agreement.

On March 18, 2004, the Company concluded a preliminary February 6, 2004 agreement to purchase the technology referred to herein as the "HEARTSTAT Technology". The HEARTSTAT Technology consists of patents and technology for a non-invasive monitoring of blood flow, perfusion and other cardiovascular and heart measures. (See description of HEARTSTAT Technology below.)

There were no stock splits or other changes to the Company securities effected at the time of this name change and subsequent Agreement for the Purchase of Assets.

The Company's common stock is currently quoted on the National Association of Securities Dealers' Over the Counter Pink Sheets and has been trading under the current symbol "HSTA" effective March 1, 2004. From November 28, 2000 the stock previously traded under the symbols "TECF". From August 10, 1999 till November 27, 2000 the stock traded under the symbol "TMDN". From June 4, 1999 till August 9, 1999 the stock traded under the symbol "CIIT" and previously from June 9, 1998 the stock traded under the symbol "HUBS".

The Agreement for the Purchase of Assets, dated February 6, 2004 provided for the issuance of 38,000,000 shares of common stock and the assumption of $370,000 of debt plus two royalty agreements as consideration for the purchase for a 100% ownership of the HEARTSTAT Technology. At February 6,

2004, the Company's board of directors and shareholders approved the terms of the HeartSTAT Agreement for the Purchase of Assets. This agreement was accounted for as an arms length transaction.

The Company has also agreed with Interest Holders that they would not have the ability to sell any of their stock under rule 144 or 144K until the company delivers its first revenue to market.

As per the terms of Asset Acquisition Agreement there were two royalties payable by the Company to SolutionMED Ventures of 1.2% and CNPB, Inc. (owned by the inventor, Ted Russell and his spouse) of 2.2% on all product revenues related to HEARTSTAT Technology. Complete royalty agreements are attached hereto as an exhibit to the Agreement for the Purchase of Assets.

Pursuant to the Asset Acquisition Agreement the Company agreed with the interest holders that Ted W. Russell could exclusively license in perpetuity the HEARTSTAT Technology for the purpose of financing and concluding product commercialization activities if the Company (HEARTSTAT Technology, Inc.) were to fail to raise at least $2,500,000 of net proceeds for product development by September 6, 2005 with an allowance that the Company has a 90-day period to cure the financing inadequacy to prevent the license from being effected. The terms of the license would include a provision that Mr. Russell, or an independent entity will repay the Company for any actual investment capital received at the rate of 20% of any net income of Mr. Russell's independent commercial operations of producing derivative products using the HEARTSTAT Technology. In addition, the Company would receive a royalty on net revenues of such derivative products as follows:

1. A royalty equal to 3% of net revenues if at lest $1.3 million of investment capital was received
2. A royalty equal to 2% of net revenues if at least $650,000 but less than $1.3 million of investment capital was received, or
3. A royalty equal to 1% of net revenues if less than $650,000 of investment capital was received.

* Exhibit B disclosing all terms and conditions to of this exclusive license is attached to the Agreement for the Purchase of Assets.

THE COMPANY

Commencing March 18, 2004 HEARTSTAT Technology, Inc. intends to complete development of and initiate manufacture and marketing of a product line of hospital devices for monitoring patient blood flow, perfusion, and other cardiovascular and heart values. Our system is completely noninvasive and operates continuously on a heart beat-by-beat basis. It works with a simple disposable single-patient-use sensor that has several advantages for patient safety. The system also monitors the patient's blood pressure (BP).

Along with its cardiovascular measurement advancements, our system is uniquely "patient practical". Instead of patient complications that are caused by present invasive and noninvasive pump-up monitoring devices, we believe ours is the only known comfortable monitor system. These advantages and the system's simplicity were created for providing unrestricted preventive monitoring for all categories of patients. Moreover, the disposable patient sensor was created to also reduce hospital sepsis, a significant problem of reused blood pressure cuffs in hospital care.

Our mission involves well over a decade of product development that was funded with substantial investment. It started with a predecessor continuous noninvasive blood pressure (CNBP) monitor product system that was invented by our CEO; cleared for marketing by the FDA in 1986: and test marketed (several hundred units, by hospital users) in the early 1990s; which we believe this confirmed the system's practicality and acceptability for critical care monitoring. Rather than proceed with marketing of that blood pressure product, our CEO determined that much greater need and market opportunity existed for blood flow and perfusion monitoring, whereupon he initiated a research and product development program, based in part on using as the sensing "platform" of that CNBP system, that led to his inventing our present technology, pursuant to which he has performed and arranged independent assessment and has applied for several patents that are pending.

Please read the information under the heading "FORWARD- LOOKING STATEMENTS AND ASSOCIATED RISKS" below, which describes and refers to some of the important risks and uncertainties.

FORWARD-LOOKING STATEMENTS AND ASSOCIATED RISKS

Some of the statements in this report or incorporated by reference are forward-looking, including, without limitation, the statements under the caption "Management's Discussion and Analysis or Plan of Operation". Forward-looking statements include those that contain words like "may," "will," "could," "should," "project," "believe," "anticipate," "expect," "plan," "estimate," "forecast," "potential," "intend," "maintain," "continue" and variations of these words or comparable words. In addition, all of the non-historical information herein is forward-looking, including any statement or implication about a future time, result or other circumstance. Forward-looking statements are not a guarantee of future performance and involve risks and uncertainties. Actual results may differ substantially from the results that the forward-looking statements suggest for various reasons. These forward-looking statements are made only as of the date of this report. We do not undertake to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise.

The forward-looking statements included herein are based on, among other items, assumptions that we will be able to meet our operating cash and any debt service requirements, that we will be able to successfully resolve disputes and other business matters as anticipated, that competitive and technological conditions within the medical device and electronic component industries will not affect us materially or adversely, that we will retain key personnel, that our forecasts will reasonably anticipate market demand for our products, and that there will be no significant unanticipated cost increases or other material adverse change in our operations or business. Among the factors that could cause actual results to differ materially are the following:

- the effect of the dramatic changes taking place in the healthcare environment;
- the impact of competitive procedures and products and their pricing;
- unforeseen difficulties and delays in the conduct of clinical trials, regulatory approvals for marketing and product development programs;
- medical insurance reimbursement policies and 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;

- potential effects of inflation;

- lack of earnings visibility;
- dependence upon certain customers or markets;
- dependence upon suppliers;
- unforeseen manufacturing problems;
- difficulties in integrating any acquired businesses and realizing cost savings or productivity gains;
- dependence on key personnel;
- difficulties regarding hiring and retaining qualified personnel in a competitive labor market; and
- Risks of doing business in international markets.

Other factors that could cause results to vary materially from current expectations are referred to elsewhere in this report.

Assumptions regarding the foregoing involve judgments that are difficult to make and future circumstances that are difficult to predict correctly. Forecasting and other management decisions are subjective in many respects and thus susceptible to interpretations and periodic revisions based on actual experience and business developments, the impact of which may cause us to alter our internal forecasts, and which may in turn affect expectations or future results. We do not undertake to announce publicly the changes that may occur in our expectations. Readers are cautioned against giving undue weight to any of the forward-looking statements. The inclusion of forward-looking information should not be regarded as a representation by us or any other person that our objectives or plans will be achieved. We are setting out some of the more specific risk factors below in full for the convenience of the readers:

WE REQUIRE SUBSTANTIAL FUNDING.

Our funding requirements are significant and may exceed the proceeds of any new financing. Unless we obtain sufficient funds, either as a result of an offering of our securities or pursuant to a strategic alliance or license or sale of our proposed products or technology, we may fail in our business mission and cease to operate. The principal cash requirements are for compensating our engineering and other technical employees and consultants, equipment, working capital, and other expenses:

- Compensation to executive officers;
- Expenses relating to the product development of our system;
- Expenses relating to clinical testing and our submission to the FDA;
- Patent expenses for protecting our technology in multiple countries;
- Expenses relating to the start of production and marketing; and
- General and administrative expenses relating to the general operation of our business.

WE HAVE NOT COMPLETELY DEVELOPED OUR MONITORING SYSTEM AND MAY NEVER COMPLETE

OUR DEVELOPMENT EFFORT OR INTRODUCE A PRODUCT.

We are engaged in the development of products using our hemodynamic monitoring system that is based on what we believe is a new technology that we invented. We have two product monitoring models that use the same physical system under development. Our failure to commercialize either or both product models, or any future models, or the lack of acceptance thereof by clinical users could have a material adverse effect upon our business, financial condition and prospects.

We cannot predict with any certainty the amount of money that will be required for this development effort due to possible unforeseen technologic complexities. We may not have anticipated the capital requirements for developing our system and products. If we do not find raise adequate funds, we may have to discontinue our development efforts. Even with adequate funds, we cannot assure you that we will be able to develop a functional product.

HOSPITALS AND THE MEDICAL PROFESSION MAY NOT ACCEPT OUR MONITORING SYSTEM.

Hospitals and the medical profession in general, which constitutes the potential market for our product system, may never accept our products for a number of reasons, including:

- Reluctance or failure to accept the principles of our technology as valid;
- Reluctance to purchase equipment with new technology that is not widely used in other hospitals because of concerns about potential adverse consequences;
- Reluctance to purchase equipment from a new, undercapitalized company, regardless of the validity of theoretical basis for the monitoring system; and
- Insufficient confidence in our ability to provide ongoing service.

WE HAVE NOT GENERATED ANY REVENUE SINCE OUR ORGANIZATION, AND OUR INDEPENDENT ACCOUNTANTS HAVE INCLUDED AN EXPLANATORY PARAGRAPH IN THEIR REPORT ON OUR FINANCIAL STATEMENTS.

The HEARTSTAT system has not produced any revenue to date and our research and development efforts have been limited in 2004 while we have been raising final funding and completing this merger transaction. The report of our independent accountants includes an explanatory paragraph stating that our continuing losses and accumulated deficit raise substantial doubt as to our ability to continue as a going concern. We do not expect to generate revenue prior to obtaining our final FDA clearance. We cannot assure you that we will ever receive FDA approval or generate revenue.

WE MAY BE DEPENDENT UPON DEVELOPING RELATIONSHIPS WITH STRATEGIC PARTNERS, AND CANNOT ASSURE YOU WE WILL DERIVE ANY ANTICIPATED BENEFITS FROM SUCH A RELATIONSHIP.

For market acceptance of our new system, we may establish a relationship with a company that manufactures or markets medical devices. However, we cannot give any assurance we will be able to enter into agreements with one or more of such strategic partners. If we do not enter into such agreements, our cash resources may be inadequate and result in either an acceleration of our need for additional funding or a need to reduce our operations. Also, we would be dependent upon the ability and willingness of the strategic partner to perform its obligations under the agreement in a timely manner. We cannot predict the amount and timing of resources that any strategic partner may devote to our products; this may be affected by factors not within our control. These factors include:

- A change in management or direction by the strategic partner;
- The introduction or development by the strategic partner or one of its affiliates of products that may compete with our products; and
- The strategic partner's ongoing perception of the market acceptability of our products, the fit of our products within the partner's product line and our patent protection.

If any future strategic partner were to breach or terminate its agreement with us or not perform its obligations in the manner contemplated by us or otherwise fails to conduct its collaborative activities with us in a timely manner, the commercialization of our products could be delayed or terminated. Any such delay or termination could have a material adverse effect upon our business.

If we enter into agreements with one or more strategic partners, conflicts of interest could arise between us and one or more strategic partners which, depending upon the nature of the conflict, could have a material adverse effect upon our business, prospects and financial condition. We must anticipate that any of our strategic partners may have other interests in related fields. Our strategic partners or their affiliates may develop, either alone or with others, products in this field or in related fields that are competitive or have applications which are competitive with those of our hemodynamic monitoring system. The competing products could affect the support provided to our products and may result in a withdrawal of support for our products which could have a material adverse effect upon our business, prospects and financial condition.

WE PRESENTLY HAVE NO MARKETING CAPABILITY, AND MAY HAVE TO RELY ON OTHERS FOR THIS.

If we develop and obtain FDA marketing approval for our monitoring system, we must develop a marketing capability. We presently have no marketing employees, and the proceeds from a future

financing may not be sufficient to develop a satisfactory marketing program. An intensive marketing program must be implemented in order to educate the medical profession as to both our technology and our product system. In this connection, we must demonstrate to the medical profession that our system will monitor blood pressure and flow parameters at least as accurately as other methods and will provide other clinical advantages not currently available. We cannot assure you that we will be able to make such demonstration.

WE HAVE NO MANUFACTURING CAPABILITY AND WILL RELY ON OTHERS TO PRODUCE PRODUCT COMPONENTS.

We as yet have no manufacturing facilities and we anticipate that, when we develop our product monitoring system, our production will consist of assembly, testing and quality operations, and will rely on vendors and subcontractors to provide components that we will use in assembling our products. We cannot assure you that we will be able to produce nor have our products manufactured.

WE MUST COMMIT RESOURCES TO PRODUCTION PRIOR TO RECEIPT OF PURCHASE COMMITMENTS AND COULD LOSE SOME OR ALL OF THE ASSOCIATED INVESTMENT.

Our product sales may primarily be pursuant to purchase orders for current delivery, rather than pursuant to long-term supply contracts. As a result, we must commit resources to the production of products without advance purchase commitments from customers. Our inability to sell products could

have a material adverse effect on our financial condition, results of operations and cash flows.

WE ARE SUBJECT TO GOVERNMENT REGULATIONS AND HAVE NO ASSURANCE OF REGULATORY APPROVAL.

Medical devices are subject to extensive regulation by the Federal government, principally the FDA, as well as regulatory bodies in other countries, including the European Community's International Standards Association. We cannot market any product in the United States unless marketing is cleared by the FDA. The marketing of products which receive FDA clearance to market may be suspended, and recall of products may be ordered if the FDA determines that we are not complying with applicable regulatory or performance standards. We cannot assure you that we will receive any required FDA or other regulatory approval. The failure to obtain FDA approval could result in a termination of our business. Furthermore, if additional clinical testing is required, we may not have adequate funds to have such tests performed.

We also must comply with the manufacturing quality requirements of FDA, whereby quality assurance procedures are confirmed with FDA inspections. Although FDA is known to provide reasonable opportunity for other firms to correct deficiencies relating to non-life-support products like ours, there can be no assurance that the manufacturing of our products in the United States would be prohibited until any deficiencies were corrected.

We are also governed by other Federal, state and local laws of general applicability. These laws include, but are not limited to, those regulating conditions enforced by the Occupational Safety and Health Administration and other environmental laws enforced by the United States Environmental Protection Agency. Various states and countries have comparable laws.

WITHOUT INSURER APPROVAL FOR REIMBURSEMENT FOR NON-HOSPITAL USES OF OUR PRODUCTS, PHYSICIANS MAY BE RELUCTANT TO PURCHASE OUR SYSTEM.

Although specific reimbursement approval is not known to be necessary for our principal hospital market, our ability to market our products in non-hospital markets may depend on our obtaining reimbursement approval from insurance companies, Medicare and Medicaid for use of our products. We cannot assure you that such reimbursement will be available.

BECAUSE WE ARE A SMALL COMPANY IN A FIELD DOMINATED BY LARGE INTERNATIONAL MEDICAL PRODUCT COMPANIES, WE MAY NOT BE ABLE TO COMPETE WITH THESE COMPANIES EVEN IF WE ARE SUCCESSFUL IN DEVELOPING OUR PRODUCTS.

The market for hospital patient monitoring devices is dominated by major international companies like Philips Medical, General Electric Medical, Baxter (Edwards Life Sciences), Siemens, Tyco (Mallincrodt/Nellcor), Abbott Laboratories, Datascope, and Nihon Kohden. These companies supply

conventional blood pressure and pulse oximeter devices and sensors, multi-parameter monitor systems and cardiac output computers and heart catheterization components. In addition, small companies existing (MedWave and Tensys Medical) market continuous noninvasive blood pressure monitors. The large companies have the financial resources, product recognition, advertising budgets, distribution arrangements and relationships with hospitals that could prevent us from developing any meaningful market share regardless of the capabilities of our products. They also have the financial ability to develop new competitive products to respond aggressively to any market success we may realize. As a result, we cannot assure that we will be able to compete successfully with these dominant companies or develop any

significant market share.

WE MAY NOT BE ABLE TO PROTECT OUR INTELLECTUAL PROPERTY RIGHTS.

We have applied for patents but have not perfected patent protection for our technology. We cannot assure you that any patents will be granted or that any patents that are granted will adequately protect our intellectual property rights. If we are granted patents, they may not be upheld if challenged. Any challenge to the validity of our patent rights, regardless of whether we ultimately prevail, could be expensive and could require us to expend significant resources in any such litigation, without assurance of success. Litigation may be necessary to determine the scope and validity of our proprietary rights. In instances in which we hold any patents or patent licenses, any patents held by us may be challenged, invalidated or circumvented, or the rights granted under any patents may not provide us with competitive advantages. Furthermore, others may design around our patents and other proprietary technologies. We presently rely upon non-disclosure agreements with our employees and consultants who are engaged in our development effort. Any breach of these agreements by any of these employees or consultants could have a material and adverse effect upon our business.

WE ARE SUBJECT TO COMPETITIVE CHANGES IN TECHNOLOGY.

The health care field is subject to changes in technology. Advances in health care sciences create markets for new products while reducing the market for other products. Accordingly, unless we have access to the most current technology, we may not be able start or continue to market our products. We cannot assure you that we will have access to the latest technological developments, which may impair our ability to market our products.

WE HAVE POTENTIAL EXPOSURE FOR PRODUCT LIABILITY AND PRODUCT RECALL, AND THE AVAILABILITY OF INSURANCE HAS NOT BEEN CONFIRMED.

Clinical trials, manufacturing, marketing and sales of our potential products by us or any strategic partner may expose us to liability claims resulting from the use of the products. We currently do not carry any product liability insurance. Despite experience of a five-year record without claims or complaints for a predecessor prototype system that is similar to that of our product system, it is possible that we will be unable to obtain such insurance or, if it can be obtained, that it will not provide sufficient coverage at a reasonable cost. The inability to obtain sufficient coverage at an acceptable cost or otherwise to obtain protection against potential liability could prevent or inhibit the commercialization of our proposed products. A successful product liability claim or a product recall may have a material adverse effect upon our business, prospects and financial condition.

WE ARE DEPENDENT ON OUR PRESIDENT AND CHIEF TECHNOLOGY OFFICER, (TECHNOLOGY INVENTOR), AND WE NEED ADDITIONAL PERSONNEL.

We are dependent upon the services of Ted W. Russell, our president and chief technology officer and a principal stockholder. Mr. Russell is the inventor and principally responsible for the development of our technology. Prior to our organization, he was chief executive officer of other companies, including companies engaged in developing and marketing blood pressure monitoring products. In 1995 in relation to an accident injury and rehabilitation requirements, Mr. Russell took advantage of protection afforded by the federal bankruptcy act.

The Company's Chief Executive Officer, James Hudson, is serving on an interim basis during the Company's research and development phase until a full time CEO is hired assume the full time

position.. We will require the services of other qualified executive, technical and marketing personnel. In seeking such personnel, we will compete with many other companies, largely in the health care field, which are major companies that are better known and capitalized than we are. To the extent that we are not successful in our efforts to hire qualified individuals, these work requirements may be performed by Mr. Russell, Mr. Hudson, or other employees and consultants. Our failure to hire qualified executive personnel could have a material adverse effect upon our business and financial condition.

THE VOLATILITY OF OUR STOCK PRICE COULD AFFECT THE VALUE OF AN INVESTMENT IN OUR STOCK AND OUR FUTURE FINANCIAL POSITION.

The market price of our stock has fluctuated pursuant to the acquisition and our preparations for developing and marketing our products, and can be affected by economic and political uncertainties. Declines in the market price of our stock could adversely affect our ability to retain personnel with higher-priced stock incentives, to acquire businesses or assets in exchange for stock and/or to conduct future financing activities with the sale of stock.

HOSPITAL NEED

Our technology was created to address what we believe are vital shortcomings of cardiovascular measurement in hospital care, described below:

Invasive monitoring is costly and inherently risky, and noninvasive flow monitoring has been impractical. Instead, noninvasive blood pressure ("BP"), pulse oximeter and ECG monitoring are used, parameters that inadequately specify patient condition. ECG ignores hemodynamics and lacks practicality for preventive monitoring. Pulse oximeter devices measure relative hemoglobin oxygen content in the blood, but this is often misleading without knowing perfusion, which is the amount of oxygen being delivered to cell tissue for sustainment. Noninvasive pump-up BP devices operate every 5 to 15 minutes; an estimated 12 billion BP measurements are taken yearly despite their lacking consistent accuracy, continuous surveillance, and practicality while causing patient problems due to pressure cuff inflations.

Patient critical care is hampered by not monitoring blood flow perfusion and heart load (flow resistance) which are both largely controlled with arterial elasticity (stiffness and stress). These are earlier and more relevant markers of patient condition than BP, because blood flow depends on artery condition and control mechanisms that alter flow in order to keep blood pressure constant for as long as possible, e.g., until shock occurs. Thus, BP does not warn of a deteriorating condition, such as blood infection or internal bleeding until late in the progression when intervention is costly or too late to save a patient.

Pulse oximeters are often relied on as an indicator of perfusion; this is misleading because these devices give no indication of reduced blood flow transport, they continue to display normal measurements even when flow becomes effectively shut down. Moreover, during periods of reduced blood flow, pulse oximeter values can be many minutes latent without being recognized as being potentially erroneous by the anesthesiologist, thus also giving false indications of respiratory condition.

Although blood flow is generally well accepted as being more clinically relevant for patient safety, BP and pulse oximeter monitoring are used as a proxy for measuring flow and cardiovascular disease because flow has been

impractical to measure. Along with delaying intervention, BP is significantly inaccurate when blood flow is reduced, which is common with disease, as well as when flow is elevated for real life activity and anxiety. Our hemodynamic technology enables identifying and correcting BP measurement error that is related to flow variations. Moreover even when measured accurately, BP yields little information about its companion blood flow because the relationship between flow and pressure is unpredictable with cardiovascular disease and other conditions.

In hospital care, the focus often is moment-to-moment sustainment. The brain requires uninterrupted "perfusion", or blood flow transport of oxygen and other nutrients. The body's total blood flow, the "cardiac output", is measured, but this is ineffective to assess brain flow safety and is performed

only on a NON-PREVENTIVE basis for a small percentage of patients because of heart catheterization and other risks and complexities. With blood flow measurement being impractical, perfusion has been referred to as a "HOLY GRAIL"; being of highest concern by doctors and nurses, but impractical to measure.

The aforementioned problems in part explain why an estimated quarter of the population are said to be untreated or treated inappropriately. Exemplifying effects of monitoring inadequacy in hospital care, authorities "have produced very convincing evidence that the so-called vital signs of every day medical care have little to do with the survival of the critically ill patient." (C. BRYAN-BROWN, BLOOD FLOW TO ORGANS: PARAMETERS FOR SURVIVAL IN CRITICAL ILLNESS, CRITICAL CARE MEDICINE 16:170, 1988). This recognition is a hint of the high priority and substantial expenditures that are at stake in achieving early intervention in preventive monitoring. These are the greatest controllable costs and patient risks in hospital care, and the need for improvement is well recognized. A survey by General Electric Medical indicated that most critical care providers believe "non-invasive hemodynamic monitoring is their number one unmet need."

THE PRODUCT SYSTEM

Our system was created to improve patient safety and longevity; it is needed because physicians and other care providers are regularly misled about abnormal blood flow conditions and cardiovascular diseases. With a simple noninvasive disposable sensor and science-based technology, we believe our preventive monitoring will enable earlier intervention in surgery and critical care. Because of how the body works, blood pressure and pulse oximeter devices cannot provide critical early warning of patient complications that are the greatest controllable costs and risks of hospital healthcare. We believe that our system can be the basis of multiple product models of expanded measurement capacity because the system measures and computes several parameters, generally categorized as follows:

BLOOD FLOW ...the basic cardiovascular function; provides early & more specific warning of problems;

PERFUSION ... for indicating when the brain is at risk of inadequate oxygen in surgery;

POX LATENCY ... for avoiding false pulse oximeter indications of respiratory function in surgery;

CONTINUOUS BLOOD PRESSURE (CNBP) ... uniquely price-competitive, simple, & unlimited practical use;

CARDIAC OUTPUT ... for hemodynamic determinations of heart disease & reducing heart catheterizations;

HEART LOAD ...for more effective safety in management of anesthesia and coronary care;

BIOPHYSICAL STRESS ... for quantifying cardiovascular disease and warning of impending heart attacks.

Our system's blood flow perfusion monitoring is intended for avoiding brain impairment that occurs for up to 50% of surgery patients with cardiovascular disease, and for reducing mortality and costly drugs and extended care related to septic shock, drug interactions and pulmonary catheter complications. These conditions cause approximately 300,000 patient deaths annually in U.S. hospitals and great legal malpractice risks. Our system technology can also be significant for managing the most costly hospital treatment modality, congestive heart failure ("CHF"). The specific application needs are:

- BRAIN FUNCTION IMPAIRMENT IN SURGERY. A basic function of anesthesiology is to "prop-up" the patient's BP, which occurs with drugs that constrict blood flow in body regions and organs that include a patient's limbs. This is the variable, high resistance part of the body's total cardiac output blood flow; in healthy patients before surgery it is approximately two-thirds of the cardiac output. The high resistance flow is the Blood Flow Safety Reserve (BFSR) that is critical for maintaining brain flow. Separate from the reduced flow of anesthesiology, cardiovascular disease reduces resting BFSR by as much as 60% (SAFAR, CIRC 63:2 1981). Mostly because of this, up to half of surgery patients with cardiovascular disease incur "BND" or "Brain Neuropsychiatric Dysfunction" (J. E. COTTRELL, CHF ANESTH SUNY-BRKLYN, ANESTH NEWS FEB. 1997; S. NEWMAN, PERFUSION 4:93, 1989; M. NEWMAN, CHIEF THOR ANESTH OF DUKE UNIV PER R.

WINSLOW, WSJ 12/8/01; T. MONK, ANESTHESIOLOGY NEWS 4/01; PLC SMITH, LANCET, 4/86). Pulse oximeter monitoring provides no warning of flow shut down to less than 5% of normal flow (LAWSON, ANESTH, 10/87). Also, neither cardiac output (when measured) nor BP is a marker for monitoring the BFSR that our system measures in a patient's limb. Thus, we believe anesthesiologists will be able to identify high risk patients and reduce surgery morbidity and potential malpractice risk by using our system in pre-surgery assessments and during surgery and recovery.

- SEPTIC SHOCK. Septic shock (systemic inflammatory response syndrome) afflicts 751,000 and kills 215,000 hospitalized patients annually. (STUDY OF 1995 HOSPITAL DISCHARGE RECORDS, CRITICAL CARE MEDICINE, REPORTED BY TM BURTON, WSJ, 9/11/01) Although BP hides this condition until the dangerous late-stage, we believe that elevated blood flow of this toxic blood condition can be monitored for early intervention. An authoritative physician consultant of Siemens Medical estimated our system could facilitate the prevention of 40% of septic shock cases (M. IMHOFF, PHD., STADISCHE KLINIKEN DORTMUND, GERMANY, 7/98).

- DRUG THERAPY COMPLICATIONS. Because blood flow varies more greatly and earlier than BP, WE anticipate practical flow monitoring can help reduce the reported U.S. hospital annual death rates of 90,000 due to adverse drug reactions and drug administration errors that result from 2.1 million incidents. (B. H. POMERANTZ, PROF. NEUROSCIENCE, UNIV TORONTO, A. P. 4/98).

- CATHETERIZATION GUIDANCE. By continuously monitoring blood flow, BP, and heart loads, we believe our system can provide screening and safety by supplementing and/or reducing costly and risky echocardiography and heart catheterization studies. (A. F. CONNORS, UVA JAMA 275:889, 1997 AND J. E. DALEN, JAMA 276:11, 1996)

- EMERGENCY USE. We believe continuous blood flow and BP monitoring should be vital for early intervention to prevent cardiogenic shock due to internal bleeding in ER and emergency transport.

- SEPSIS MANAGEMENT. A surgically clean or sterile packaged BICS sensor is intended to improve an important hospital sepsis issue. According to studies, reusable BP cuffs are a major medium for in-hospital cross-contaminating infections e.g., (staphylococci) that extend hospitalization and costs. (MA BEARD, SPHYGMOMANOMETERS - RESERVOIR OF PATHOGENIC BACTERIA, MED J OF AUSTR, 10/69; ALSO A.J. BERRY, PREVENTION OF BLOOD-BORNE INFECTIONS (HEPATITIS B & AIDS), ASA NEWSLETTER 7/88.

- THERAPEUTIC MANAGEMENT. In coronary intensive care, we believe the monitoring of blood flow, heart load and arterial biophysical stresses can improve the management of heart attack recuperation and congestive heart failure patients ("CHF"). Because of reduced heart attack mortality, CHF has become the most costly hospital therapy in at least one leading hospital, involving numerous and lengthy hospitalizations for many CHF patients. More effective treatment is needed, especially because the NIH has estimated the CHF patient population of 4.8 million will grow to 20 million in five years. After assessment with cardiac output studies, we believe our system can allow early discharge of CHF patients for remote continuous home monitoring over the internet.

- DISEASE MANAGEMENT. Blood pressure is not a specific measure of cardiovascular disease. It does not measure the forces that alter and damage the structure of vessel walls. Instead, scientists indicate that dynamic (higher frequency) biophysical elastic forces are relevant. (D.A. MCDONALD, BLOOD FLOW IN ARTERIES, ARNOLD, 1974, P268-82.) Physiologic simulations with our system technology indicate that the progression of cardiovascular disease depends upon ongoing worsening stresses that are produced by heart rate, flow resistance and artery elasticity (stiffness). For very brief instants during heart beats, artery forces can exceed by many times the known limits of artery structure. We believe this can be the underlying impetus of the coronary artery inflammation and end-stage rupture that triggers 75% of heart attacks. (AS PROMULGATED BY LEADING RESEARCHERS SUCH AS DR. ERIC TOPOL AND DR. STEVEN NISSEN OF CLEVELAND CLINIC; SEE NEW STUDIES QUESTION VALUE OF OPENING ARTERIES, G. KOLATA, NY TIMES, 3/21/04). These biophysical phenomena also reduce blood flow, and increase flow resistance and heart work. Thus, we believe our system's practical monitoring of this science based measure can be the means of valid motivational compliance for insurers and meaningful management by physicians.

TECHNOLOGY

We believe our system technology overcomes obstacles for hospital preventive monitoring. We believe it is the only system, noninvasive or invasive, capable of measuring artery blood flow and resistance, heart loads, perfusion, BP and biophysics. Also, we believe it is the only system known to avoid invasive and intolerable noninvasive BP measurement methods by lightly applying a sensor to a patient's limb. Along with noninvasive comfort; the

system design includes reducing inaccuracy caused by patient movement and sensor misplacement; and its simplicity averts new operator training.

The system uses a disposable noninvasive single-patient sensor cuff, the "BICS" (biophysic interval cuff sensor). This enables measuring more than one physiologic variable simultaneously ("multivariate" sensing). The system also performs a breakthrough solutioning of flow, pressure and elasticity on a continuous heart beat-by-beat basis. It computes these parameters using FFT (fast Fourier transform) frequency mathematics that adjust for complex flow-pressure waveform phasic timing at each physiologic waveform frequency.

These innovations enable the first practical application of a scientifically famous `WM' technology that determines the pressure forces that propel the blood flow and derive the flow waveform. Although previously impractical because the original `WM' application involved two difficult and risk-prone heart catheterization sensors, it produced unprecedented clinical accuracy, including for extreme pharmacologically induced vasoactive conditions in which all other methods are very unreliable. Our system concurrently employs two independent `WM' applications; one of which enables our system's improved BP monitoring accuracy and monitoring of cardiac output, heart loads and biophysics.

COMPETITION

The market leaders are GE, Philips, Datascope, Tyco-Nellcor, Baxter (Edwards Life Sciences), Siemens and Nihon-Kohden. We believe patient monitoring systems of these and other smaller companies lack means of early intervention because they lack blood flow and perfusion monitoring. The only flow monitoring is by specialized cardiac output systems that mostly involve heart catheterization and are restricted to use in only approximately five percent (5%) of the patient population due to risks, costs and complexities. Cardiac output systems are impractical for preventive monitoring. Cardiac output blood flow measurement is usually limited to heart procedures and for making fluid volume adjustments on the sickest patients, whereas we believe our blood flow monitoring system is specific to vital complications that occur widely and unpredictably in the critical care patient population, as well as practical for preventive monitoring of all hospital patients.

FLOW PERFUSION AND BIOPHYSICS: Present cardiac output monitoring involves heart catheterization and A-line componentry, esophageal ultrasound and multi-electrode impedance devices. Cardiac output is not cost effective or otherwise practical for preventive monitoring of approximately 95% of surgery and critical care patients. We believe that no practical system for monitoring blood flow, perfusion or biophysic hemodynamics is known of or to be under development. We expect to prevent competition with strong patents and with our proprietary sensing system that would involve a complicated long-lead time to duplicate.

CNBP: For BP monitoring, approximately 12% of patients are measured continuously with risk-prone direct INVASIVE intra-arterial catheterization that involves artery cut-down, tubing insertion, infusions, and transducer kits. Otherwise, monitoring is with NONINVASIVE PUMP-UP CUFF monitors that can measure intermittently only every 5-15 minutes so as to avoid arm pump-up trauma. The avoidance of treatment delay and arm nerve palsy are rationale for replacing these devices with CNBP monitors; however, experience shows these issues are not so significant as to justify high prices relative to intermittent models. Two small companies market a CNBP device. We believe these and earlier devices have suffered from:

- High purchase prices that are twice that of intermittent devices and sensor replacement costs that are unacceptable. We believe a large market exists only for a price-competitive CNBP.

- Systems suffer from constrictive sensors that impair blood flow and are not tolerated long by conscious patients, as well as motion insensitivity and ineffective waveform signal processing compensation. Sensor fragility and positioning complexity are also impracticalities.

We believe our proprietary sensing (which provides a low cost design with patient comfort and user simplicity) and our flow-compensated CNBP monitoring, as our "platform" model; can be a basis for volume sales. Moreover, we believe that any competitors would not be able to offer an upgrade to blood flow monitoring, which we believe will be the principal part of our market success.

INTELLECTUAL PROPERTY / PATENTS

U.S. and worldwide PCT patents were filed in 2001 and 2003 by Mr. Ted Russell with patent counsel, Dr. David Garrod, J.D., PhD, Esq. at Patterson, Belknap, Webb & Tyler LLP. These cover the first known practical applications of the `WM' technology and our invented flow-based elasticity relationship and solutioning process, as well as our sensor, calibration processes, and measurement algorithms for blood flow, perfusion, cardiac output, heart loads and biophysic stress. They also cover multivariate blood pressure monitoring, waveform display algorithms and expert system artificial intelligence applications. Based on a comprehensive search, the filed 225 claims (50 independent) are believed novel, patentable and likely to result in many patents. In June of 2004 the Company has also engaged the services of the firm Jones Day in connection with its European Patent Office prosecution of most of its patent applications in various countries.

PRODUCT DEVELOPMENT AND STATUS

The Company is the beneficiary of over $6 million of expenditures for research and development, clinical studies, FDA clearance and a marketing introduction that confirmed user acceptability with prior generation CNBP revenues. During 1980-1993 as Chief Executive Officer and President of Cortronic Corporation and Cortronic Medical Corporation, Mr. Russell invented and managed development; testing, FDA clearance and marketing of a CNBP monitor for which no other claims of ownership exist or is believed could exist. During the period 1994-96 he initially developed various blood flow related technologies that employ some of the features of the CNBP system. Our cost re-engineered preproduction unit is in clinical engineering. R&D expenditures continued through March 18, 2004 by various Interest holders. We plan to finalize product development within a year when we will complete software, clinical testing and final product design work. Thereafter, we plan to start manufacturing and commence marketing of two product models after an additional six months, depending on timing for FDA clearance (SEE "GOVERNMENT REGULATION").

MARKET FOR OUR PRODUCTS

We estimate from various market information sources that the available hospital market for our products initially is $1 billion compared to our estimate of the present market of $2.1 billion of patient monitoring devices and sensors. We expect that our principal products will be flow perfusion monitors for surgery and flow models for surgery and critical care; and that a projected 15%-20% of our shipments will be CNBP monitors and 15%-20% of our longer term shipments will be models with cardiac output and biophysic stress monitoring.

It is estimated that preventive monitoring systems exist at more than 276,000 critical care beds, which is approximately 30% of all US hospital beds.

The first applications for our systems are expected to be surgery and recovery, followed by relatively near-simultaneous adoption for uses in ICU, coronary care, catheterization labs, and ER, as well as somewhat later use in dialysis, electrophysiology (pacemakers), MRI, radiology and congestive heart failure (CHF) management.

STRATEGIES

Our marketing is to emphasize patient safety benefits of

- PERFUSION MONITORING for brain safety and for more reliable pulse oximeter monitoring in surgery;
- FLOW AND HEART LOAD MONITORING to avoid septic and cardiogenic shock and manage heart failure; and
- BIOPHYSIC AND HEART LOAD MONITORING to avoid and manage recuperation from heart attacks.

We believe our system addresses the greatest controllable costs and risks of hospital healthcare. Adverse complications of septic shock, drug problems and cardiac output heart catheterization (excluding surgery complications and CHF management) are estimated by us from studies to cause over 60 unexpected patient deaths and $6 million of costs annually in average 200-bed hospitals and up to three-times this for large hospitals, excluding malpractice costs (D.W. BATES, JAMA 277:307, 1997).

Our principal business strategies are:

- GROWTH FACTOR #1: Hospital contract-based sensor purchases (for flow perfusion systems) that can avoid the delay of hospital capital budgeting. We plan to also sell a competitively priced CNBP "platform" model and modules (no sensor required) that can capture existing capital budgets and also allow users to upgrade to flow monitoring with sensor purchases from operating funds.

- GROWTH FACTOR #2: We believe a major impetus for market acceptance will be malpractice risk avoidance when a practical flow perfusion monitor exists, as was true for the pulse oximeter market. We plan to employ tactics similar to those that were reportedly employed to accelerate acceptance and standardization of the Nellcor pulse oximeter system (CONVEYED TO TW RUSSELL BY LJ LLOYD, PRESIDENT, NELLCOR INC., 1987).

- CAPITAL EFFICIENT MARKETING: We believe the foolproof operational simplicity of our system is ideal for cost-effective dealer marketing start up, and for a subsequent transition to direct selling.

- ATTRACTIVE OPERATING MARGINS: We plan to achieve market leadership and large profit margins. Our third generation design engineering estimates portend a low-cost, price competitive system unit. Most models are to use a single system for commonality efficiencies.

- SPECIAL OPPORTUNITIES: We plan to pursue a private-label marketing partnership with a major supplier, and/or other special opportunities, to expand our market and benefit our shareholders.

GOVERNMENT REGULATION

The testing, manufacture and sale of our products are subject to regulation by various governmental authorities, principally the FDA and corresponding state and foreign agencies. Pursuant to the Federal Food, Drug, and Cosmetic Act and related regulations, the FDA regulates preclinical and

clinical testing, manufacture, labeling, distribution and promotion of medical devices. If we do not comply with applicable requirements, we can be subject to, among other things: fines; injunctions; civil penalties; recall or seizure of products; total or partial suspension of production; failure of the government to grant pre-market clearance or approval for devices; withdrawal of marketing clearances or approvals; and criminal prosecution.

A medical device may be marketed in the United States only if the FDA gives prior authorization, unless it is subject to a specific exemption. Devices classified by the FDA as posing less risk than class III devices are categorized as class I or II and are eligible to seek "510(k) clearance." 510(k) clearance generally is granted when submitted information establishes that a proposed device is "substantially equivalent" in intended use and other factors, such as technological characteristics, to a class I or II device already legally on the market or to a "pre-amendment" class III device, which is one that has been in commercial distribution since before May 28, 1976, for which the FDA has not called for PMA applications which are defined below. For any devices that are cleared through the 510(k) process, modifications or enhancements that could significantly affect safety or effectiveness, or constitute a major change in the intended use of the device, will require new 510(k) submissions. We believe that presently

a minimum of three months are required from the date of submission to obtain 510(k) clearance, but the clearance can take up to six months or substantially longer. We cannot assure you that any of our devices or device modifications will receive 510(k) clearance in a timely fashion, or at all.

Our FDA-cleared predecessor CNBP system was classified as a class II device pursuant to our submission of clinical study data. Outwardly and with respect to patient safety, our present system operates identically, so that we believe our clearance will be straightforward. Blood flow and perfusion are not complex or foreign concepts; substantially different new proposed devices of other companies, such as a Cerebral Oximeter of Somanetics Corporation, relative to compared to preexisting "substantially equivalent" devices, receive class II clearance. We have every reason to believe that our future products will be categorized as a class II device; although no assurances exist this will be the case.

A device requiring prior marketing authorization that does not qualify for 510(k) clearance is categorized as class III, which is reserved for devices classified by the FDA as posing the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices that are not substantially equivalent to a legally marketed class I or class II device. Class III devices generally must receive approval pursuant to a pre-market approval, or PMA, application, which requires proving the safety and effectiveness of the device to the FDA. The process of obtaining PMA approval can be expensive and uncertain. This can require from one to three or more years after filing, and some are never approved.

If human clinical trials of a device are required, whether for a 510(k) or a PMA application, and the device presents a "significant risk," the sponsor of the trial, which is usually the manufacturer or the distributor of the device, will have to file an investigational device exemption, or IDE, application before beginning human clinical trials. The IDE application must be supported by data, typically including the results of animal and laboratory testing. If the IDE application is approved by the FDA and one or more appropriate Institutional Review Boards, or IRBs, human clinical trials may

begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a "nonsignificant risk" to the patient, a sponsor may begin the clinical trial after obtaining approval for the study by the IRB at each clinical site without the need for FDA approval.

In 1986, our predecessor "platform" CNBP model received 510(k) clearance from the FDA for use on adults and pediatrics. Approximately 1,000 monitors were supplied to dealers and users in Japan, Europe and the US during 1989-92. We may rely on this FDA clearance to market a CNBP monitor if we judge that the functionality of our CNBP "platform" product is substantially unchanged. Alternately, we may submit for a new clearance for our CNBP model, whereby we will submit results of a new clinical study if our system monitoring algorithms of this initial CNBP "platform" are changed significantly. We believe that this would involve a comparative hospital clinical accuracy study for 20-30 patients similar to what was submitted for the predecessor system. Such studies, especially for a comfortable noninvasive device like our system, do not involve a PMA or IDE and are generally relatively easy to arrange a hospital IRB approval for (see below) and conduct. We will complete clinical accuracy studies and submit for a 510(k) clearance for our products that measure blood flow, perfusion, cardiac output, heart loads and biophysics.

We believe "Grandfathering" advantages are likely to apply. Pursuant to its evaluation and lacking a CNBP class, the FDA requested a clinical study that specifically assessed the patient safety of our low pressure cuff sensing; class II clearance was granted by FDA after such study results were submitted. Grandfathering provisions enable invoking prior clinical results and experience. The sensing operation of our system technology is identical to the predecessor CNBP, so that patient safety aspects are proven because of our predecessor CNBP. Because the history of use of the cuff sensor system was devoid of any patient concerns or FDA "incident" reports, we believe expedited "Grandfathering" criteria will apply for all our monitor system product clearances regarding safety of our sensing system. Also, after each FDA clearance of each product model parameter (BP, flow, stress), grandfathering provisions regarding accuracy for such parameter is expected to should apply to subsequent models that include same parameters. However, there can be no assurances that grandfathering advantages will be allowed for us.

The Company maintains a relationship with and plans to retain an FDA consultant, a past FDA director, who is a proven expediter of the FDA clearance process.

Any devices we manufacture or distribute pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by FDA and some state agencies. Manufacturers of medical devices marketed in the United States must comply with detailed Quality System Regulation, or QSR, requirements, which include testing, control, documentation and other quality assurance procedures. Manufacturers must also comply with Medical Device Reporting requirements. These requirements require a manufacturer to report to FDA any incident in which its product may have caused or contributed to a death or serious injury, or in which its product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to a death or serious injury. Labeling and promotional activities are subject to scrutiny by FDA and, in some circumstances, by the Federal Trade Commission. FDA enforcement policy prohibits promoting approved medical devices for unapproved uses.

We are subject to routine inspection by the FDA and some state agencies for compliance with QSR requirements and other applicable regulations. From

experience, we believe our initial FDA QSR inspection will occur within approximately one year of our initial product shipment. We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances.

If any of our current or future FDA clearances or approvals are rescinded or denied, sale of our applicable products in the United States would be prohibited during the period we do not have such clearances or approvals. In such cases we would consider shipping the product internationally and/or assembling it overseas if permissible and if we determine such product to be ready for commercial shipment. The FDA's current policy is that a medical device that is not in commercial distribution in the United States, but which needs 510(k) clearance to be commercially distributed in the United States, can be exported without submitting an export request and prior FDA clearance provided that

- the company believes the device can be found to be substantially equivalent through a 510(k) submission,
- the device is labeled and intended for export only,
- the device meets the specifications of the foreign purchaser, and
- other conditions of the export provisions of the Federal Food, Drug, and Cosmetic Act and the Export Reform Act are satisfied.

Congress has enacted the Medical Device User Fee Modernization Act of 2002. Among other things, this law has provisions that affect the assessment of user fees for product approvals and clearances. Given the recent enactment of this law, the effect of the law on us is unknown.

EMPLOYEES:

The company currently has only one full time employee and one part time executive employee. The company has a number of contractors in its R&D operations.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

OVERVIEW

On February 6, 2004, an agreement was reached whereby Tec Factory, Inc. would acquire from the various Interest holders HEARTSTAT Technology assets for use in continuing the HEARTSTAT operations for completing the development and commercialization of the first known practical system for monitoring blood flow perfusion (oxygen transport) and other cardiovascular and heart measures. Effective February 17, 2004 we changed our name to HEARTSTAT Technology, Inc., in an effort to reflect changes in our business focus to incorporate the new acquisition. The Company is proceeding forward with its new business plan focusing on the HEARTSTAT technology.

This acquisition was accounted for as an acquisition of assets as opposed to a reverse merger due to the fact that there was no current company that owned or operated this business or technology in the past 2 years (FOR MORE

INFORMATION ON THE ACCOUNTING POLICIES USED PLEASE CONSULT THE NOTES TO THE FINANCIAL STATEMENTS). The technology assets had a number of interest holders besides Mr. Ted Russell the inventor and all interest holders have agreed to exchange their interest in the technology and future operations for a proportionate share of restricted 144 stock in the HEARTSTAT Technology, Inc. as per the provisions of the Agreement for the Purchase of Assets attached as an exhibit hereto.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to impairment of long-lived assets. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions; however, we believe that our estimates, including those for the above-described items, are reasonable.

IMPAIRMENT OF LONG-LIVED ASSETS.

Our long-lived assets include property, equipment and goodwill. We assess impairment of long-lived assets whenever changes or events indicate that the carrying value may not be recoverable. In performing our assessment we must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the respective assets. If these estimates change in the future we may be required to record impairment charges against these respective assets.

RESULTS OF OPERATIONS

FISCAL YEARS ENDED DECEMBER 31, 2003 AND 2002.

HEARTSTAT Technology operated as Tec Factory, Inc. for fiscal 2003 and fiscal 2002 in which the company had negligible operations during these two years as it looked for an acquisition and business direction.

Operating expenses consisted of payroll and related expenses for executive, finance and administrative personnel, recruiting, professional fees and other general corporate expenses as well as payroll and related expenses for development personnel and consultants. Operating expenses were $21,000 for each of the years ended December 31, 2003 and 2002 respectively.

Net loss was $21,000 or ($0.002 per share) for the years ended December 31, 2003 and 2002.

On December 31, 2003, the Company had a working capital deficit of $42,000 compared to a working capital deficit of $21,000 on December 31, 2002. The Company had no cash balance as of December 31, 2003.

The Company has incurred operating losses and negative cash flows from its minimal operations for fiscal years ending December 31, 2002 and 2003.

FOR THE SIX MONTHS ENDED JUNE 30, 2004

Company operations increased somewhat in the first and second quarter of 2004 and, as reflected in the interim statements, in the first quarter the Company completed its acquisition of the HEARTSTAT technology system and assets which affected our financial statement assets by $408,000 pursuant to the assumption of $370,000 of debt and issuance $38,000 of capital stock reflecting 38,000,000 shares issued to the interest holders at $0.001 per share.

On March 18, 2004 the Company completed the acquisition and began its monthly operations to commercialize and bring to market products based on the HEARTSTAT Technology.

Operating expenses consist of payroll and related expenses for executive, finance and administrative personnel, recruiting, professional fees and other general corporate expenses as well as payroll and related expenses for development personnel and consultants. Operating expenses were $46,829 for the six months ended June 30, 2004.

Net loss was $46,829 ($0.0033 per share) for the six months ended June 30, 2004.

On June 30, 2004, the Company had a working capital deficit of $458,829, as compared to a working capital deficit of $42,000 on December 31, 2003. The Company had no cash balance as of June 30, 2004, but maintains a agreement with Diamond WorldWide, Inc. a related company, to continue to finance operations by issuing short term debt.

The Company has continued to incur operating losses for the six months ended June 30, 2004, mostly due to its expanding operations related to ramping up the commercialization of the HEARTSTAT technology. Continued losses are anticipated to occur through the remainder of 2004 and 2005 because of product development and administrative operating expenses that will be required by the Company before initial product shipments that are anticipated by the second quarter of 2006.

The Company has been funded and continues to be funded by Diamond WorldWide, Inc. which under an arrangement will continue to fund the operating and development expenses of the company. All monies advanced to HEARTSTAT by Diamond WorldWide will be accruing interest at 8% per annum. Diamond WorldWide, Inc. is a related company. (Discuss and disclose)

PLAN OF OPERATION

HEARTSTAT Technology, Inc. has refocused its operations after completing its acquisition of the technology. Upon the completion of the acquisition with the interest holders, the Company began the process of completing a financing and implementing the final commercialization of the HEARTSTAT Technology. The Company plans a private placement capital financing approximately of $5,000,000 which will be used for development, clinical trials for FDA clearance, as well as the launch of manufacturing and marketing and distribution of products using the HEARTSTAT Technology.

The Company concluded an employment contract with its President and Chief Technology Officer, Ted Russell, who is preparing to hire necessary product development personnel to begin the final phase of the development and commercialization of this technology. The Company plans to lease and commence operations of its R&D offices near Huntington, NY in the fourth quarter of 2004 and anticipates being fully operational by January of 2005.

ITEM 3. DESCRIPTION OF PROPERTY

HEARTSTAT Technology, Inc. currently has its principal executive offices located at 530 Wilshire Blvd, Suite 304, Santa Monica, CA 90401. This space represents a portion of the 670 square feet of office space and is subleased from Diamond WorldWide, Inc. The Company plans to lease a new research and development center in Long Island, New York, by the end of January 2005.

ITEM 4. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table provides certain information as to the officers and directors individually and as a group, and the holders of more than 5% of the Common Stock of the Company, as of September 30, 2004:

NAME AND ADDRESS OF BENEFICIAL OWNER (1)	AMOUNT AND NATURE OF