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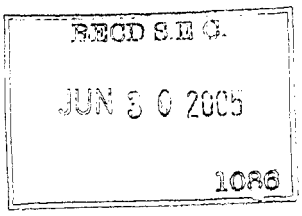


ARIS

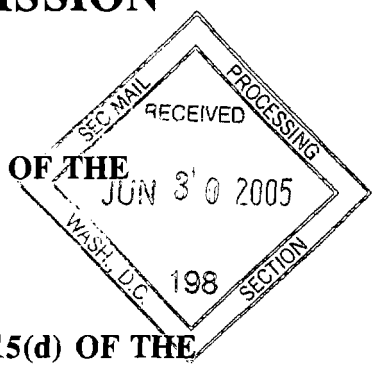
ANNUAL REPORT

2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K



(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the fiscal year ended December 31, 2004.

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the transition period from to .

Commission File Number: 000-27956

Physiometrix, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**77-0248588**
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
101 Billerica Ave., N. Billerica, MA	**01862**
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: (978) 670-2422

Securities registered pursuant to Section 12(b) of the Act: None

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

Common Stock, $0.001 par value
(Title of class)

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 preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Item 1—Yes ☒ No ☐ Item 2—Yes ☒ No ☐

Indicate by check mark if disclosures of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☐ No ☒

The aggregate value of voting stock held by non-affiliates of the Registrant was approximately $12,349,965 as of February 28, 2005, based upon the average of the high and low prices of the Registrant's Common Stock reported for such date on the NASDAQ SmallCap Market. Shares of Common Stock held by each executive officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status is not necessarily a conclusive determination for other purposes. As of February 28, 2005, the Registrant had outstanding 13,701,366 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information is incorporated into Part III of this report by reference to the Proxy Statement for the Registrant's 2005 annual meeting of stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K.

Physiometrix, Inc.

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PART I

Item 1. BUSINESS

Forward Looking Statements

This Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that involve certain risks and uncertainties. Actual events or results may differ materially from those projected in the forward-looking statements as a result of the factors described herein in the "Risk Factors" and in the documents incorporated herein by reference. These statements typically may be identified by the use of forward-looking words or phrases such as "believe," "expect," "intend," "anticipate," "should," "planned," "estimated," and "potential," among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our businesses include, but are not limited to, statements concerning (i) business strategy; (ii) products under development; (iii) other products; (iv) marketing and distribution, including statements related to distribution plans and arrangements and future marketing, sales and distribution strategies; (v) research and development; (vi) manufacturing; (vii) competition; (viii) government regulation especially as it relates to Food and Drug Administration ("FDA") approvals; (ix) third-party reimbursement (x) operating and capital requirements: (xi) clinical trials; and (xii) other factors that might be described from time to time in periodic filings with the Securities and Exchange Commission and include those set forth in this Annual Report on Form 10-K as "Risk Factors".

Introduction

Physiometrix, Inc. (also referred to herein as "Physiometrix," "Company," "we," "us," and "our") designs, develops, manufactures and markets noninvasive, advanced medical products incorporating proprietary materials, electronics technology and software for use in neurological monitoring applications during surgical and diagnostic procedures. We sell our products for use in hospitals, clinics and physicians' offices domestically and internationally. Our current principal product focus is our Patient State Analyzer ("PSA 4000"), an innovative system for monitoring brain activity during anesthesia. The PSA 4000 and disposable PSArray2 and, when introduced, the PSA 5000, are our primary products and most important to our success. We believe that the success of generating revenues as well as raising additional working capital, are the most critical components to our ability to continue as a going concern. Our cash, cash equivalents, and short-term investments, which aggregated $2.6 million as of December 31, 2004, will be sufficient to conduct operations only until the beginning of the third quarter of 2005, at which time, we will be unable to meet our working capital requirements. Our plan for the remainder of 2005 is to raise additional working capital, support the activities of our partner, Baxter Healthcare Corporation ("Baxter"), in the commercialization of the PSA 4000 with the PSArray2, and to launch the PSA 5000. We are aware of one other company with similar products to the PSA 4000. We do not believe we will be at a significant disadvantage in marketing our products against this company.

Our initial products, which were commercially introduced in 1994, are our *e*-Net headpiece and disposable HydroDot biosensors, which are based upon our proprietary HydroGel technology, and its custom electronics. These products are packaged as the HydroDot NeuroMonitoring System, which was developed and is sold for brain monitoring applications, such as clinical electroencephalograph ("EEG") procedures. The system is marketed and sold as a safer, lower cost alternative to current

EEG data collection technology. The system connects and interfaces to the standard input on all conventional EEG instruments currently in use worldwide, yet offers reduced patient setup time, more reliable data readings, and enhanced patient comfort and safety. The sale of these products are not a significant component of our operating plan and we do not consider the expected revenues from the HydroDot NeuroMonitoring System business to be significant to our financial success and liquidity.

Patient State Analyzer. The PSA 4000, which received initial 510(k) clearance from the Food and Drug Administration in June 2000, provides a simplified, user-friendly analysis of patient brain activity during surgical procedures involving general anesthesia. Currently, such monitoring conducted by EEG instruments is used only in a small percentage of all such procedures on a worldwide basis. Traditional EEG devices require a neurologist to interpret their data output. As a result, anesthesiologists are reluctant to use EEG monitoring during other surgical procedures, despite the potential benefits offered by brain monitoring, such as improved patient safety, shorter patient recovery times, and lower overall costs per procedure. On February 10, 2004, we received clearance from the FDA for commercial distribution of our PSA 5000 next generation monitor. The PSA 5000 is a new state of the art monitor that is more powerful, cost effective and offers improved ergonomics as compared to the PSA 4000. We anticipate launch of the product in mid 2005 and we will continue our effort to sell the remaining PSA 4000's.

We have shown in clinical studies that monitoring patients' brain activity during surgery with the PSA 4000 will improve patient safety and lower costs per surgical procedure by better controlling the amount of anesthesia administered during surgeries. This will reduce the amount of post-operative recovery time required, and eliminate the requirement of a neurologist or specialized technologist to interpret EEG results during surgery. We believe that these benefits create the opportunity for the PSA 4000 to become the standard of care during surgical interventions using general anesthesia. We market the PSA 4000 in the United States and Canada through Baxter, our exclusive distributor.

Since the third quarter of 2000, substantially all of our sales were to Baxter under a distribution agreement, which provides Baxter with exclusive distribution rights to our PSA 4000 in the United States and Canada. The agreement extends through termination and is cancelable by either party upon six months notice. Under the terms of the agreement, as amended in February 2003, if Baxter fails to meet minimum purchase commitments, we have the option to convert their distribution agreement into a non-exclusive relationship for the operating room ("OR") market segment. In 2003 and 2004, Baxter failed to meet minimum purchase requirements, however, we have not enforced our right to change the terms of the agreement, including Baxter's exclusivity rights. We may enter into additional distribution arrangements with other parties, enter into negotiations with Baxter to amend or modify our agreement or elect to enforce this right to change the terms of the existing agreement with Baxter.

In October 2002, we received 510(k) clearance from the FDA for the PSArray2, a new frontal-only disposable array sensor for use with the PSA 4000 system, and are currently shipping this new sensor to Baxter, our exclusive distributor in the United States and Canada. This new frontal array headpiece is designed to be easier to affix to the head during surgical procedures than our previous headpiece. We believe, based on our market research and feedback, that the availability of this new frontal headpiece has enhanced the attractiveness of the PSA 4000.

The table below summarizes the principal products currently offered by us, the markets served by these products and their present development and/or commercialization status:

Product	Description	Development/ Commercialization Status	% of Total Revenue (greater than 15%)		
			2002	2003	2004
Patient State Analyzer	Intraoperative EEG monitoring system	Commercial sales	59%	49%	38%
PSArray2—Frontal array for use with Patient State Analyzer	Easier to use headpiece for use with Patient State Analyzer	Commercial sales	4%	21%	35%

Industry Overview

There are more than 40 million surgical interventions performed annually worldwide under general anesthesia according to Frost and Sullivan. This represents a large market opportunity for the PSA 4000. We have developed the PSA 4000 to address this market. Currently, anesthesiologists measure heart, breathing rates, as well as other physiological changes, to monitor the effect of anesthesia on patients. However, the brain, the organ which anesthetic drugs affect the earliest, is generally not directly monitored. Nevertheless, in several types of surgical procedures, including high-risk cardiology and vascular surgical procedures, brain monitoring is recognized by clinicians as particularly important. Routine monitoring of brain functions during surgery can result in earlier detection of abnormalities that, if left undetected, could result in serious surgical and post surgical complications. Such monitoring can also potentially reduce costs and postoperative recovery times by enabling a reduction in the amount of anesthesia used during the surgical procedure, which would enable patients to emerge from the effects of the anesthesia and be ambulatory more quickly following the procedure. In addition, anesthesiologists are typically not familiar with conventionally produced EEG test results, and a neurologist must therefore be on hand to interpret EEG test information. We believe that the availability of a low cost, easy to use monitoring device such as the PSA 4000 could substantially increase brain monitoring during surgical procedures involving general anesthesia.

EEG Market

An EEG procedure measures neurophysiological activity by measuring the intensity and pattern of electrical signals generated by the brain. Undulations in the recorded electrical signals are called brain waves, and the entire record of electrical rhythms and other electrical activity (ongoing background signals and event related transients) of the brain is an EEG. EEGs are widely used to assist in the diagnosis of epilepsy, brain tumors, physiological disorders and other brain abnormalities. Because the electrical waves produced by an injured or abnormal brain will differ in predictable ways from waves produced by a normal brain, an EEG exam should disclose and help diagnose brain abnormalities and injuries.

Although EEG based brain monitoring has been performed for over 70 years, it is only recently that medical professionals have begun to recognize the benefits of EEGs as a broad based diagnostic tool. This should be contrasted with the field of cardiac monitoring in which medical professionals have long been aware of the benefits of such monitoring, and have integrated electrocardiogram ("ECG") procedures into both preventive and diagnostic health care. As a result, medical device and instrument companies have concentrated on, and provided improved technology for, the cardiac monitoring market. However, EEG technology has remained virtually unchanged since its inception.

The Physiometrix Solution

We believe that the availability of a low-cost, easy to use monitoring device such as the PSA 4000 could substantially increase brain monitoring during surgery and has the potential to become the standard of care in brain monitoring during the administration of general anesthesia. The PSA 4000 was developed to provide patient brain activity during surgical procedures involving general anesthesia. The PSArray2, which attaches to and is used with the PSA 4000, is a disposable frontal headpiece that attaches to a patient's forehead to collect EEG data for analysis by the PSA 4000. During surgical procedures involving general anesthesia, the PSA 4000 will constantly monitor data and alert the anesthesiologists as to a patient's state of consciousness and provide the anesthesiologist with a readout regarding a patient's ideal anesthetized state. We believe that monitoring a patient's brain activity during surgery will improve patient safety and lower costs per surgical procedure by better controlling the amount of anesthesia administered during surgeries.

On February 10, 2004, we received clearance from the FDA for commercial distribution of our PSA 5000 next generation monitor. The PSA 5000 is a new state of the art monitor that is more powerful, cost effective and offers improved ergonomics as compared to the PSA 4000. We anticipate launch of this product in mid 2005 and we will continue our effort to sell the remaining PSA 4000's.

Current Financial Condition

Since inception, we have incurred cumulative net losses of approximately $66.0 million, including losses of approximately $6.3 million during 2004. For the year ended December 31, 2004, we used $5.0 million in cash flows from operating activities, and at December 31, 2004 had cash, cash equivalents and short-term investments of approximately $2.6 million.

Our principal source of liquidity at December 31, 2004 consisted of cash, cash equivalents and short-term investments, which aggregated $2.6 million. We anticipate that our existing cash, cash equivalents, and short-term investments will be sufficient to conduct operations only until the beginning of the third quarter of 2005, at which time we will be unable to meet our working capital requirements. As a result, there is substantial doubt about our ability to continue as a going concern. We plan to raise capital through equity and/or debt issuance when, and if, such capital is available to us. We are engaged in negotiations and discussions with potential sources of new capital, and at this stage, we cannot assure you that we will be able to raise additional capital on acceptable terms, or at all. If additional amounts cannot be raised and we are unable to substantially reduce our expenses, we would suffer material adverse consequences to our business, financial condition and results of operations and would likely be required to seek other alternatives up to and including the sale of our technology, filing for protection under the United States bankruptcy laws or cessation of operations.

Business Strategy

Our objective is to become the leader in the design, development and commercialization of anesthesia monitoring technology. Key elements of our strategy include the following:

- *Design and Develop Innovative, Proprietary Products for the Neurology, Intensive Care Unit and Surgical Markets.* Physiometrix plans to capitalize on the growing recognition among medical professionals of easy to use and reliable methods of brain monitoring. We intend to remain focused on the development and marketing of products for surgery and the intensive care unit including products that are designed to expand the use of neurological monitoring. We have substantial design and development expertise in the neurological monitoring field and will seek to position ourselves at the forefront of innovation in this industry.
- *Diversify Product Offerings to Increase Market Penetration.* We seek to offer a range of products, including hardware and disposable products designed to encourage broader use of EEG

monitoring. Toward this end, we developed and received FDA 510(k) clearance for the PSArray2, a frontal headpiece for use with the PSA 4000 system in October 2002 and for the PSA 5000 next generation monitor in February 2004. We plan to commercially introduce the PSA 5000 during 2005.

- *Broaden Marketing Channels.* We have established a strategic relationship with Baxter for distribution of our PSA 4000 in the United States and Canada. We will seek to secure additional partners for distribution in major markets, principally the U.S., Europe and Japan. We intend to commercially introduce the PSA 5000 through either a direct sales force, which we would build following raising additional capital, or through new distribution partners or both.
- *Outsource Manufacturing to Control Costs.* We outsource many manufacturing processes to qualified contract manufacturers to control costs, maintain quality and reduce capital investment, while retaining control over key proprietary processes for certain components of our products.

Products and Technology

PSA 4000. We developed the PSA 4000 for brain monitoring in the operating room and in the intensive care unit. The PSA 4000 uses a single use disposable appliance to record EEG for continuous analysis. The PSA 4000 was designed to extract data known to be sensitive to the functional level of each region of the brain, the adequacy of blood supply and the interaction of each region with neighboring regions on the opposite side of the brain. Based on such measurements, statistical procedures will be used to deliver an analysis of the data into a measurement for monitoring the effects of anesthesia. During intraoperative procedures, the PSA 4000 will constantly monitor data and alert the anesthesiologist as to changes in the patient's state of consciousness. The PSA 4000 will provide the anesthesiologist with a readout regarding the patient's ideal anesthetized state.

Traditionally, the anesthesiologist has had three objectives:

- put the patient to sleep
- prevent patient response to pain
- ensure that the patient does not move during surgery

Typically, a combination of drugs is used to accomplish this, including analgesics to block pain, drugs to induce unconsciousness and muscle relaxants to immobilize the patient. However, current anesthesia practice is not always successful. Cases of surgical awareness are reported each year and, while fewer in number, deaths during general anesthesia also occur. Other known issues related to overmedication include nausea and exceptionally long recovery times.

Brain monitoring with traditional EEG techniques involves lengthy setups, the use of flammable materials, and cumbersome equipment. Traditional EEG devices also require a neurologist to interpret their data output. As a result, anesthesiologists are generally reluctant to use EEG monitoring, despite the potential benefits offered by brain monitoring such as improved patient safety and shorter patient recovery times. Our PSA 4000 provides a simple automated resolution of the difficulties of EEG use and interpretation in the operating room.

We believe that monitoring a patient's brain activity during surgery will improve patient safety and lower costs per surgical procedure by better controlling the amount of anesthesia administered during surgeries. This will reduce the amount of postoperative recovery time required.

There is also a market opportunity for the use of awareness monitoring during the administration of sedation to patients in recovery rooms and during certain diagnostic and therapeutic procedures which are performed outside the operating room. We are ready to adapt our technology to any modular monitoring system now in use in operating rooms around the world.

The PSA 4000 consists of EEG hardware with a single use disposable sensor and an 8-channel preamplifier input. The PSA 4000 functions include testing electrode impedance, amplifier calibration, EEG collection, quantitative analysis after artifact removal (brain wave abnormalities resulting from external stimulation, eye blinking or muscle movement), display and storage.

The PSA 4000 represents a revised approach for brain monitoring during surgery. Market acceptance of this product will be dependent upon, among other things, the willingness of physicians, EEG technicians and others to adopt these products. Market acceptance will also be dependent upon our ability to convince potential users of the cost and efficacy advantages of this product. Since commercial introduction of the PSA 4000 in 2000, we have ascertained that the lack of a frontal headpiece for use in capturing signals from the brain has affected market acceptance. Accordingly, we developed and received regulatory approval for such a headpiece. The PSArray2 frontal headpiece, which received FDA 510(k) approval in October 2002, is attached only to the patient's forehead and is therefore easier to attach than our original headpiece. We believe, based on our market research and feedback, that the availability of the PSArray2 frontal headpiece has enhanced the attractiveness of the PSA 4000.

PSA 5000. On February 10, 2004, we received clearance from the FDA for commercial distribution of our PSA 5000 next generation monitor. The PSA 5000 is a new state of the art monitor that is more powerful, cost effective and offers improved ergonomics as compared to the PSA 4000. We anticipate launch of the product in mid 2005 and we will continue our effort to sell the remaining PSA 4000's.

Other Products:

We have several products that we sell including the e-Net and disposable biosensors and related accessories, which provide a small revenue stream to us. We maintain our current customer base and do not actively promote these products. The following is a brief description of these products.

e-Net. The *e*-Net is a headpiece designed to position and hold the HydroDot disposable biosensors symmetrically against the scalp during an EEG study. The *e*-Net is manufactured from a proprietary elastic material and positions 20 biosensors according to the internationally recognized 10-20 System (defined below) on head sizes varying from 48 to 62 centimeters in circumference. The 10-20 System is a standard, universal methodology for marking and measuring the patient's scalp for electrode placement in EEG procedures.

HydroDot Disposable Biosensors. The HydroDot biosensors are disposable and are used in lieu of conventional cup electrodes to acquire EEG signals from a patient. The biosensors are packaged in ready-to-use sealed trays of 24 sensors. Minimal skin preparation and no collodion are required when the sensors are inserted into the sockets on the *e*-Net.

HydroSpot. We developed the HydroSpot biosensor for those technicians who want the benefits of the HydroDot biosensors, but do not wish to use the *e*-Net because they prefer a procedure setup similar to that used with conventional cup electrodes. The HydroSpot is a hydrogelled disposable biosensor attached to a reusable lead wire and will be offered as an alternative to the conventional cup electrodes typically employed in EEG procedures.

Marketing and Distribution

We selected Baxter, a major medical products company with substantial experience and capabilities in sales of capital equipment to hospitals, anesthesiologists and other potential users of brain monitoring systems, as our exclusive distribution partner in the United States and Canada for the PSA 4000. We currently intend to increase our sales, marketing and clinical support force to market the PSA 4000 and PSA 5000 in conjunction with Baxter and to secure additional partners for distribution in

major markets, principally the U.S., Europe and Japan. We may sell and market the PSA 5000, through Baxter, with a direct sales force which we would develop in conjunction with a new financing or through other partners.

In May 2000, we entered into a distribution arrangement with Baxter for the exclusive distribution of our PSA 4000 in the United States and Canada. The agreement was amended on February 12, 2003. Under the terms of the amended agreement, and in order to maintain exclusivity, Baxter is required to make quarterly minimum purchases under the contract. The contract is cancelable by either party with six months notice.

Research and Development

Research and development activities are performed by our internal research and development staff, whose activities are augmented by the use of outside consultants for particular projects and areas of specialization. We have retained consultants for hardware and software design and clinical evaluation and development of the PSA 4000 and PSA 5000. Our future research and development efforts are expected to be focused on continued development of the PSA 4000 and PSA 5000 technology and related product enhancements and extensions.

Research and development expenses for the years ended December 31, 2002, 2003 and 2004 were $2,229,736, $1,567,155 and $1,812,893 respectively, none of which was customer funded.

Manufacturing

We manufacture our products at our facilities in North Billerica, Massachusetts. Production occurs in approximately 5,000 square feet of space utilizing standard production equipment for most processes and proprietary equipment for several specialized operations. Our production area includes a segregated area where temperature can be controlled and maintained for the production of the HydroDot biosensors. We intend to increase outsourcing of manufacturing to contract manufacturers for certain components in order to reduce cost and capital requirements and improve quality, while retaining control over certain proprietary manufacturing processes.

We manufacture our products in conformance with FDA's Good Manufacturing Practices (GMPs). We are ISO 13485 certified and Certified Europe (CE)-marked both of which are required for the sale of our products in Europe. Any failure by us to remain in compliance with the GMPs or comply with ISO/European Norm ("EN") standards could have a material adverse effect on our business, financial condition and results of operation.

We purchase components from various suppliers and rely on single source suppliers for several parts. To date, we have not experienced any significant adverse effects resulting from shortages of components. Delays associated with any future component shortages, particularly as we scale up our manufacturing activities, would have a material adverse effect on our business, financial condition and results of operations. We actively monitor inventory positions of all critical parts and purchase required materials in order to prevent productions delays. This, however, is not a guarantee that shortages will not occur.

We currently manufacture our PSA 4000 products as well as our HydroDot NeuroMonitoring Systems, and beginning in mid 2005, our PSA 5000 products, in limited quantities. We do not have experience in manufacturing our products in commercial quantities. Manufacturers often encounter difficulties in scaling up production of products, including problems involving production yields, quality control and assurance, component supply and lack of qualified personnel. Difficulties encountered by us in scaling up manufacturing could have a material adverse effect on our business, financial condition and results of operations.

Competition

We believe that the primary competitive factors in the market for neurological monitoring devices are the ability to provide products that can improve clinical efficacy, reduce patient setup time, and contribute to improvement of laboratory operating efficiencies. We believe that the innovations we have developed in the field of neurology monitoring can potentially afford us a competitive advantage. There is currently one other company, Aspect Medical, that has a commercial product for brain monitoring during anesthesia similar to the PSA 4000. The PSA 5000, which received FDA 510(k) clearance in February 2004, was developed to be more powerful, cost effective and ergonomic than the PSA 4000.

Patents and Proprietary Rights

Our policy is to protect our proprietary position by, among other methods, filing United States and foreign patent applications to protect technology, inventions and improvements that are important to our business. The patent positions of medical device companies, including ours, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application either can be denied or significantly reduced before or after the patent is issued. Consequently, there can be no assurance that any patent applications will result in the issuance of patents, or that our issued or any future patents will provide significant protection or commercial advantage or will not be circumvented by others. Since patent applications are secret for 18 months after filing, or longer if permitted under applicable regulation, in the United States or corresponding applications are published in international countries, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file patent applications for such inventions. There can be no assurance that patents held by or licensed to us or any patents that may be issued as a result of our pending or future patent applications will be of commercial benefit, afford us adequate protection from competing products or technologies or will not be challenged by competitors or others or declared invalid. Also, there can be no assurance that we will have the financial resources to defend our patents from infringement or claims of invalidity.

In the event a third party has also filed a patent application relating to an invention claimed in one of our patent applications, we may be required to participate in an interference proceeding declared by the United States Patent and Trademark Office ("US PTO") to determine priority of invention, which could result in substantial uncertainties and costs to us, even if the eventual outcome is favorable to us. There can be no assurance that any patents issued to us would be held valid by a court of competent jurisdiction.

We rely upon trade secret protection for certain unpatented aspects of other proprietary technology. There is no assurance that others will not independently develop or otherwise acquire substantially equivalent proprietary information or techniques, others will not otherwise gain access to our proprietary technology or disclose such technology, or we can meaningfully protect our trade secrets.

We typically require our employees and consultants to execute appropriate confidentiality and proprietary information agreements upon the commencement of employment or consulting relationship with us. These agreements generally provide that all confidential information developed or made known to the individual by us during the course of the individual's relationship with us, is to be kept confidential and not disclosed to third parties, except in specific circumstances. The agreements generally provide that all inventions conceived by the individual in the course of rendering services to us shall be the exclusive property of ours, however, certain of our agreements with consultants, who typically are employed on a full time basis by academic institutions or hospitals, do not contain assignment of invention provisions. There can be no assurance, however, that these agreements will

provide meaningful protection or adequate remedies for us in the event of unauthorized use, transfer or disclosure of such information or inventions.

Government Regulation

United States

Our PSA 4000, PSA 5000, PSArray2, HydroDot NeuroMonitoring System, including its family of *e*-Nets, and HydroDot biosensors, HydroSpot, and other potential products are and will be regulated in the United States as medical devices by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDC Act") and require premarket clearance or approval by the FDA prior to commercialization. In addition, certain material changes or modifications to medical devices also are subject to FDA review and clearance or approval. Pursuant to the FDC Act, the FDA regulates the research, testing, manufacture, safety, labeling, storage, record keeping, advertising, distribution and production of medical devices in the United States. Noncompliance with applicable requirements can result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance or premarket approval for devices, and criminal prosecution. Medical devices are classified into one of three classes, Class I, II or III, on the basis of the controls deemed by FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls (*e.g.*, labeling, premarket notification and adherence to Good Manufacturing Practices ("GMP"). Class II devices are subject to general controls and to special controls (*e.g.*, performance standards, postmarket surveillance, patient registries, and FDA guidelines). Generally, Class III devices are those which must receive premarket approval by the FDA to ensure their safety and effectiveness (*e.g.*, life sustaining, life supporting and implantable devices, or new devices which have not been found substantially equivalent to legally marketed devices), and require clinical testing to ensure safety and effectiveness and FDA approval prior to marketing and distribution. The FDA also has the authority to require clinical testing of Class I and Class II devices. A premarket approval ("PMA") application must be filed if the proposed device is not substantially equivalent to a legally marketed predicate device or if it is a Class II device for which the FDA has called for such applications.

If human clinical trials of a device are required and if the device presents a "significant risk," the manufacturer or the distributor of the device is required to file an investigational device exemption ("IDE") application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal and, possibly, mechanical testing. If the IDE application is approved by the FDA, human clinical trials may begin at a specific number of investigational sites with a maximum number of patients, as approved by the agency. Sponsors of clinical trials are permitted to sell those devices distributed in the course of the study provided such costs do not exceed recovery of the costs of manufacture, research, development and handling. The clinical trials must be conducted under the auspices of an independent institutional review board ("IRB") established pursuant to FDA regulations.

Generally, before a new device can be introduced into the market in the United States, the manufacturer or distributor must obtain FDA clearance of a 510(k) notification or approval of a PMA application. If a medical device manufacturer or distributor can establish that a device is "substantially equivalent" to a legally marketed Class I or Class II device, or to a Class II device for which the FDA has not called for a PMA, the manufacturer or distributor may seek clearance from the FDA to market the device by filing a 510(K) notification. The 510(k) notification may need to be supported by appropriate data establishing the claim of substantial equivalence to the satisfaction of the FDA. The FDA recently has been requiring a more rigorous demonstration of substantial equivalence.

Following submission of the 510(k) notification, the manufacturer or distributor may not place the device into commercial distribution until an order is issued by the FDA. No law or regulation specifies

the time limit by which the FDA must respond to a 510(k) notification. At this time, the FDA typically responds to the submission of a 510(k) notification within 90 days. An FDA order may declare that the device is substantially equivalent to another legally marketed device and allow the proposed device to be marketed in the United States. The FDA, however, may determine that the proposed device is not substantially equivalent or require further information, including clinical data, to make a determination regarding substantial equivalence. Such determination or request for additional information could delay market introduction of the products that are the subject of the 510(k) notification.

If a manufacturer or distributor of medical devices cannot establish that a proposed device is substantially equivalent to a legally marketed device, the manufacturer or distributor must seek premarket approval of the proposed device through submission of a PMA application. A PMA application must be supported by extensive data, including preclinical and clinical trial data, as well as extensive literature to prove the safety and effectiveness of the device. Following receipt of a PMA application, if the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will "file" the application. Under the FDC Act, the FDA has 180 days to review a PMA application, although the review of such an application more often occurs over a protracted time period, and generally takes approximately two years or more from the date of filing to complete.

The PMA application approval process can be expensive, uncertain and lengthy. A number of devices for which premarket approval has been sought have never been approved for marketing. The review time is often significantly extended by the FDA, which may require more information or clarification of information already provided in the submission. During the review period, an advisory committee likely will be convened to review and evaluate the application and provide recommendations to the FDA as to whether the device should be approved. In addition, the FDA will inspect the manufacturing facility to ensure compliance with the FDA's GMP requirements prior to approval of an application. If granted, the approval of the PMA application may include significant limitations on the indicated uses for which a product may be marketed.

We received clearance of 510(k) premarket notification from the FDA to market the PSA 4000, PSA 5000, PSArray2, HydroDot NeuroMonitoring System, HydroSpot and Equinox EEG System for EEG monitoring and the EP System for certain external defibrillation applications and Radio Frequency ("RF") return during electrosurgical procedures where a combination of defibrillation and RF return indications is required.

We are also required to register as a medical device manufacturer with the FDA and state agencies and to list our products with the FDA. As such, we will be inspected by both FDA and state agencies for compliance with the FDA's GMP and other applicable regulations. These regulations require that we manufacture our products and maintain our documents in a prescribed manner with respect to manufacturing, testing and control activities. Further, we are required to comply with various FDA requirements for design, safety, advertising and labeling.

We are required to provide information to the FDA on death or serious injuries alleged to have been associated with the use of our medical devices, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. In addition, the FDA prohibits an approved device from being marketed for unapproved applications. If the FDA believes that a company is not in compliance with the law, it can institute proceedings to detain or seize products, issue a recall, enjoin future violations and assess civil and criminal penalties against the company, its officers and its employees. Failure to comply with the regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

The advertising of most FDA regulated products is subject to both FDA and Federal Trade Commission jurisdiction. We also are subject to regulation by the Occupational Safety and Health Administration and by other governmental entities.

Regulations regarding the manufacture and sale of our products are subject to change. We cannot predict what impact, if any, such changes might have on our business, financial condition or results of operations.

International

International sales of our products are subject to the regulatory agency product registration requirements of each country. The regulatory review process varies from country to country. We have obtained necessary regulatory approvals in certain European countries and Canada and will continue to seek approval in Japan in connection with future marketing and sales efforts.

In connection with future sales in the European market, we implemented policies and procedures which allowed our manufacturing and quality assurance processes to receive ISO13485:1996 certification. These standards for quality operations have been developed to ensure that companies know, on a worldwide basis, the standards of quality to which they will be held. The European Union has promulgated rules which require that medical products receive the CE mark, an international symbol of quality and compliance with applicable European medical device directives. We received our EC certificate for electroencephalograph products to market the PSA 4000 and PSA 5000 in the European community.

Third Party Reimbursement

In the United States, health care providers, such as hospitals and physicians, that purchase medical devices such as our products, generally rely on third party payors, principally federal Medicare, state Medicaid and private health insurance plans, to reimburse all or part of the cost of therapeutic and diagnostic catheterization procedures. Reimbursement for neurophysiological monitoring procedures performed using devices that have received FDA clearance or approval has generally been available in the United States. We anticipate that in a capitated payment system, such as the Diagnostically Related Group ("DRG") system utilized by Medicare and many managed care systems used by private health care payors, the cost of our products will be incorporated into the overall cost of the procedure and that there will be no separate, additional reimbursement for our products.

Internationally, future market acceptance of our products may be dependent in part upon the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country. The main types of health care payment systems in international markets are government sponsored health care and private insurance. There can, however, be no assurance that reimbursement for procedures performed using our products will be available in international markets under either governmental or private reimbursement systems.

We could be adversely affected by changes in reimbursement policies of governmental or private health care payors, particularly to the extent any such changes affect reimbursement for procedures in which our products are used. Failure by physicians, hospitals and other users of our products to obtain sufficient reimbursement from health care payors for procedures in which our products are used, or adverse changes in governmental and private third party payors' policies toward reimbursement for such procedures, would have a material adverse effect on our business, financial condition and results of operations.

Product Liability and Insurance

Our business involves the risk of product liability claims. We have not experienced any product liability claims to date. Although we maintain product liability insurance with coverage limits of $2 million per occurrence and an annual aggregate maximum of $3 million, there can be no assurance that product liability claims will not exceed such insurance coverage limits, which could have a material adverse effect on us, or that such insurance will be available on commercially reasonable terms or at all.

Employees

As of December 31, 2004, we had 45 full time employees. Of these employees, 10 were engaged in research and development activities, 15 in manufacturing and manufacturing engineering, 7 in quality assurance and regulatory affairs, 7 in sales and marketing, and 6 in general and administrative functions. No employees are covered by collective bargaining agreements, and we believe we maintain good relations with our employees.

General Information

Physiometrix was incorporated in Delaware in 1996. Our headquarters location and mailing address is 101 Billerica Ave. Bldg 5, N. Billerica, Massachusetts 01862, and the telephone number at that location is (978) 670-2422. Our Common Stock trades on the Nasdaq SmallCap Market under the symbol "PHYX." Our website is located at http://www.physiometrix.com. We make our periodic and current reports that are filed with the Securities and Exchange Commission ("SEC"), including reports on Form 10-K, Form 10-Q and Form 8-K, available, free of charge, on our website as soon as reasonably practicable after such materials are electronically filed with, or furnished to, the SEC. In addition, the public may read and copy any materials filed with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington DC 20549. Information about the SEC's Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. All reports and information electronically filed by us with the SEC may also be obtained on the SEC's website located at http://www.sec.gov.

Risk Factors

You should carefully consider the risks described below before making an investment decision. We believe that the risks and uncertainties described below are the principal material risks facing us as of the date of this Form 10-K. In the future, we may become subject to additional risks that are not currently known to us. If any of the following risks actually occur, our business, financial condition and operating results could be seriously harmed. As a result, the trading price of our common stock could decline, and you could lose all or part of the value of your investment.

We will need additional funds, and such funds may not be available on commercially reasonable terms when we need them, and as a result, there is substantial doubt about our ability to continue as a going concern.

We anticipate that our current cash, cash equivalents and short-term investments are adequate to maintain our current and planned operations only until the beginning of the third quarter of 2005, at which time, we will be unable to meet our working capital requirements. As a result, there is substantial doubt about our ability to continue as a going concern. We plan to raise capital through equity and/or debt issuance when, and if, such capital is available to us. There is no assurance, however, that we will be able to raise additional capital on acceptable terms, or at all. If we cannot raise additional capital, we would suffer material adverse consequences to our business, financial condition and results of operations and would likely be required to seek other strategic alternatives up

to and including the sale of our technology, filing for protection under the United States bankruptcy laws or ceasing operations.

We plan to continue to expend substantial funds for obtaining regulatory approvals, continuing sales and marketing activities and research and development. We may be required to expend greater than anticipated funds if unforeseen difficulties arise in the course of obtaining necessary regulatory approvals or in other aspects of our business. Our future liquidity and capital requirements will depend upon numerous factors, including actions relating to regulatory matters, and the extent to which the PSA 4000 and PSA 5000 gain market acceptance. Any additional financing, if required, may not be available on satisfactory terms or at all. Future equity financings may result in dilution to the holders of our common stock. Future debt financing may require us to pledge assets and to comply with financial and operational covenants.

We are dependent upon the PSA 4000, and if we are unable to introduce and successfully commercialize this product, our business will be seriously harmed.

Our business is completely dependent upon the PSA 4000. If we are unable to achieve widespread market acceptance for the PSA 4000, we will not be able to sustain or grow our business. In this event, our business and operating results would be seriously harmed and our stock price would likely decline.

During 2001, we began development of the PSArray2, which is a frontal-only disposable array sensor that attaches to and is used with our PSA 4000 consciousness-monitoring system. The PSArray2 was developed in an effort to improve market acceptance of the PSA 4000. We received FDA 510(k) clearance for the PSArray2 in October 2002. The introduction and successful commercialization of this product is critical to our future success. We began shipments of this product to Baxter, our exclusive distribution partner in the U.S. and Canada, during the fourth quarter of 2002. Initial commercialization efforts for this product have only recently begun, and we are not currently able to predict as to when or whether this product will achieve commercial acceptance.

We are significantly dependent on our distributor, Baxter, for sale of inventories of our principle product, the PSA 4000.

Our current agreement with Baxter provides Baxter with exclusive distribution rights for the PSA 4000 in the U.S. and Canada, making us significantly dependent upon Baxter for successful commercialization of this product. There is no assurance that this will occur. The agreement extends through termination and is cancelable by either party upon six months notice. Under the terms of the agreement, as amended in February 2003, if Baxter fails to meet minimum purchase commitments, we have the option to convert their distribution agreement into a non-exclusive relationship for the operating room market segment. In 2003 and 2004, Baxter failed to meet minimum purchase requirements, however, we have not enforced our right to change the terms of the agreement, including Baxter's exclusivity rights. We may enter into additional distribution arrangements with other parties, enter into negotiations with Baxter to amend or modify our agreement or elect to enforce this right to change the terms of the existing agreement with Baxter. There can be no assurance that we will obtain a new distribution partner for the PSA 4000 on terms that are mutually acceptable or that Baxter will continue to support the PSA 4000 at current levels, which would cause our business and results of operations to be materially and adversely affected.

We will not be able to achieve revenue growth or profitability if hospitals and anesthesia service providers do not buy and use the PSA 4000, our current principal product, in sufficient quantities.

Our revenue growth and prospects will depend on customer acceptance and usage of the PSA 4000. Customers may determine that the cost of the PSA 4000 exceeds cost savings in drugs, personnel and post-anesthesia care recovery resulting from use of the PSA 4000. In addition, hospitals and

anesthesia providers may not accept the PSA 4000 as an accurate means of assessing a patient's level of consciousness during surgery if patients regain consciousness during surgery while being monitored with the PSA 4000, or if the PSA 4000 is determined not to be a clinically reliable measuring system for other reasons. If hospitals and anesthesia providers do not accept the PSA 4000 as cost-effective, accurate or reliable, they will not buy and use the PSA 4000 in sufficient quantities to enable us to be profitable. In this event, our business, operating results and long-term prospects would be seriously harmed. Our stock price would also likely decline.

As a result of market feedback, we concluded that we needed to introduce a simpler headpiece for use with the PSA 4000. Therefore, the PSArray2 was developed, and we received FDA 510(k) clearance for the PSArray2 in October 2002. Even with FDA clearance for this headpiece, we cannot assure that introduction of the PSArray2 will improve market acceptance of the PSA 4000 or our results of operations. At this point, we are unable to accurately predict future demand for the PSA 4000, and we cannot assure you that the current economic environment and current product market environment will not continue.

Our ability to achieve future revenue growth or profitability will be dependent on the successful introduction of our newly developed product, the PSA 5000, and if we are unable to introduce and successfully commercialize this product, our business will be seriously harmed.

In February 2004, we received clearance from the FDA for commercial distribution of our PSA 5000 next generation monitor. The PSA 5000 is a new state of the art monitor that is more powerful, cost effective and offers improved ergonomics as compared to the PSA 4000. We are currently developing our marketing, sales and distribution strategy for the PSA 5000, and anticipate launch of the product in the middle of 2005. Should we determine that the PSA 5000 can best be marketed through a distribution partner, there can be no assurance that we will be able to obtain a suitable distribution partner for the PSA 5000 on terms that are mutually acceptable. Further, we cannot assure that the introduction of the PSA 5000 will be accepted by customers, perform as anticipated or improve our results of operations or competitive position. As the PSA 5000 has not been released for commercial sale, there is no way to predict commercial viability or future demand of this product.

We expect to continue to incur losses in the future, and we cannot assure you that we will ever become profitable.

We have incurred net losses in each year since inception. We expect to continue to incur substantial research and development, sales and marketing and general and administrative expenses in future periods. We will spend these amounts before we receive any incremental revenue from these efforts. Therefore, our losses will be greater than the losses we would incur if we developed our business more slowly. In addition, we may find that these efforts are more expensive than we currently anticipate, which would further increase our losses. Failure to become and remain profitable may depress the market price of our common stock and our ability to raise capital and continue our operations.

We have a limited operating history that you may use to assess our prospects, and we have no operating experience or history related to the PSA 4000, our current principal product.

We have a limited history of operations. Since our inception in January 1990, we have been primarily engaged in research and development of neurophysiological monitoring products. To date, we have sold only a relatively small number of units of our HydroDot NeuroMonitoring System and these sales have generated only limited revenues. Furthermore, these products are not central to our core business, which relates to the development and commercialization of the PSA 4000, and in the future, the PSA 5000. We have had limited revenues from commercial sales of the PSA 4000 and have not yet released the PSA 5000 for commercial sale. Accordingly, our historical results of operations may be of

limited utility in evaluating our future prospects. In addition, we do not have experience in manufacturing, marketing or selling our products in quantities necessary for achieving profitability. Whether we can successfully manage the transition to a larger scale commercial enterprise will depend upon the successful development of our manufacturing capability, the development of our marketing and distribution network, obtaining U.S. FDA and foreign regulatory approvals for future products and other potential products and strengthening our financial and management systems, procedures and controls. With respect to our PSA 4000, and in the future with respect to the PSA 5000, we will need to develop a sales and marketing effort targeted towards anesthesiologists, rather than neurologists to whom we have previously marketed our products. Accordingly, due to the significant change in our business associated with the PSA 4000, our historical financial information is of limited utility in evaluating our future prospects, and we cannot assure that we will be able to achieve or sustain revenue growth or profitability.

We face intense competition and may not be able to compete effectively, which could harm the market for our products and our operating results.

We expect to face substantial competition from larger medical device companies that have greater financial, technical, marketing and other resources than we do. As our resources in these areas are extremely limited, any current or potential competitor of ours is likely to have greater resources in these areas. In particular, Aspect Medical markets an anesthesia monitoring system that competes with the PSA 4000. Aspect has received FDA clearance for this system and is marketing it in the U.S and internationally. We may not be able to compete effectively with Aspect or other potential competitors. Other companies may develop anesthesia-monitoring systems that perform better than the PSA 4000 and/or sell for less. Competition in the sale of anesthesia-monitoring systems could result in the inability of the PSA 4000 to achieve market acceptance, price reductions, fewer orders, reduced gross margins and inability to establish or erosion of market share. In addition, the PSA 5000 has not been released for commercial sale and by the time it is released, competition and new or enhanced technologies could result in the inability of the PSA 5000 to achieve market acceptance. Any of these events would harm our business and operating results and cause our stock price to decline.

We may not be able to keep up with new products or alternative techniques developed by competitors, which could impair our future growth and our ability to compete.

The medical industry in which we market our products is characterized by rapid product development and technological advances. Our current or planned products are at risk of obsolescence from:

- new monitoring products, based on new or improved technologies,
- new products or technologies used on patients or in the operating room during surgery in lieu of monitoring devices,
- electrical or mechanical interference from new or existing products or technologies,
- alternative techniques for evaluating the effects of anesthesia,
- significant changes in the methods of delivering anesthesia, and
- the development of new anesthetic agents.

We may not be able to improve our products or develop new products or technologies quickly enough to maintain a competitive position in our markets and continue to grow our business.

If we do not successfully develop and introduce new or enhanced products, we could lose revenue opportunities and customers.

As the market for anesthesia monitoring equipment matures, we need to develop and introduce new products for anesthesia monitoring or other applications. In particular, we are developing versions of the PSA 4000 for use in areas outside the traditional hospital operating room setting and the success of these efforts and acceptance of our products and technology in these additional settings will be critical to our future success. We face at least the following risks:

- we may not successfully adapt the PSA 4000 to function properly in the intensive care unit, for procedural sedation, when used with anesthetics we have not tested or with patient populations we have not studied, such as infants and young children, and
- our technology is complex, and we may not be able to develop it further for applications outside anesthesia monitoring.

In addition, we recently received FDA clearance for our new product, the PSA 5000. The PSA 5000 has not yet been released for commercial sale. Prior to its release, new or enhanced technologies could emerge, resulting in the inability of the PSA 5000 to achieve market acceptance. In addition, there is no assurance the PSA 5000 will perform as anticipated or that customers will accept or demand this technology. Further, we may not be able to successfully adapt the PSA 5000 to other applications.

If we do not successfully adapt the PSA 4000 and PSA 5000 for new products and applications both within and outside the field of anesthesia monitoring, then we could lose revenue opportunities and customers. In this event, our business and results of operations would be harmed.

We have experienced significant operating losses to date, and our future operating results could fluctuate significantly.

We have experienced significant operating losses since inception and as of December 30, 2004, had an accumulated deficit of approximately $66.0 million. The development and commercialization of the PSA 4000 and other new products, if any, will require substantial development, clinical, regulatory and other expenditures. We expect our operating losses to continue for at least the next two years as we continue to expend substantial resources to maintain marketing and sales activities, scale up manufacturing capabilities, continue research and development and support regulatory and reimbursement approvals. Results of operations may fluctuate significantly from quarter to quarter and will depend upon numerous factors, including actions relating to regulatory and reimbursement matters, market acceptance of the PSA 4000, and the future market acceptance of the PSA 5000. In addition, competition, availability of third party reimbursement, implementing a distribution strategy for the PSA 5000 and other factors may affect our future results of operations.

Our reliance on sole and limited source suppliers could harm our ability to meet customer requirements in a timely manner or within budget.

Some of the components that are necessary for the assembly of our PSA 4000 are currently provided to us by separate sole suppliers or a limited group of suppliers. We purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. We have experienced shortages and delays in obtaining some of the components of our PSA 4000 in the past, and we may experience similar delays or shortages in the future. The disruption or termination of the supply of components could cause a significant increase in the costs of these components, which could affect our profitability. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could lead to customer dissatisfaction and damage our reputation. Furthermore, if we are required to change the manufacturer of a key component of the PSA 4000, we may be required to verify that the new

manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could delay our ability to manufacture the PSA 4000 in a timely manner or within budget.

Our business depends on our intellectual property rights, and measures we take to protect those rights may not be sufficient.

The success of our business depends, in part, on our ability to obtain patents and maintain adequate protection of our intellectual property for our technologies and products in the U.S. and other countries. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U.S., and many companies have encountered significant problems in protecting their proprietary rights in these foreign countries. These problems can be caused by, for example, a lack of rules and processes allowing for a meaningful defense of intellectual property rights. If we do not adequately protect our intellectual property, competitors may be able to practice our technologies and erode our competitive advantage, and our business and operating results could be harmed.

The patent positions of technology companies, including our patent positions, are often uncertain and involve complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We apply for patents covering our technologies and products as we deem appropriate. However, we may not obtain patents on all inventions for which we seek patents, and any patents we obtain may be challenged and may be narrowed in scope or extinguished as a result of such challenges. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to offer research services and develop, manufacture and sell products, which compete directly with our research services and products. In that case, our revenues and operating results would decline.

In addition to patents, we rely on trade secrets and proprietary know how, which we seek to protect, in part, through appropriate confidentiality and proprietary information agreements. These agreements generally provide that all confidential information developed or made known to the individual by us during the course of the individual's relationship with us, is to be kept confidential and not disclosed to third parties, except in specific circumstances. The agreements generally provide that all inventions conceived by the individual in the course of rendering services to us are our exclusive property. However, some of our agreements with consultants, who typically are employed on a full time basis by academic institutions or hospitals, do not contain assignment of invention provisions. We cannot assure you that proprietary information or confidentiality agreements with employees, consultants and others will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known to or independently developed by competitors. Disclosure or misuse of our confidential information would harm our competitive position and could cause our revenues and operating results to decline.

We could become involved in litigation relating to intellectual property rights, and any such litigation, even if resolved favorably to us, will result in significant cost and diversion of management's time and effort.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. We cannot assure you that we will not in the future become subject to patent infringement claims and litigation or interference proceedings declared by the United States Patent and Trademark Office ("US PTO") to determine the priority of inventions. The defense and prosecution of intellectual property suits, US PTO interference

proceedings and related legal and administrative proceedings are both costly and time consuming. Litigation may be necessary to enforce patents issued to us, to protect trade secrets or know how owned by us or to determine the enforceability, scope and validity of the proprietary rights of others.

Any litigation or interference proceedings will result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties. Costs associated with licensing or similar arrangements that may be involved in statement of intellectual property disputes, including patent disputes, may be substantial and could include ongoing royalties. Furthermore, there can be no assurance that necessary licenses would be available to us on satisfactory terms if at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing, marketing and selling our products, which would seriously harm our business and operating results and would likely cause our stock price to decline.

Our business entails the risk of product liability claims, and these claims could harm our financial condition and our ability to maintain insurance coverage.

The manufacture and sale of our products expose us to product liability claims and product recalls, including those which may arise from misuse or malfunction of, or design flaws in, our products or use of our products with components or systems not manufactured or sold by us. Product liability claims or product recalls, regardless of their ultimate outcome, could require us to spend significant time and money in litigation or to pay significant damages. We currently maintain insurance; however, it might not cover the costs of any product liability claims made against us. Furthermore, we may not be able to obtain insurance in the future at satisfactory rates or in adequate amounts.

If we do not attract and retain skilled personnel, we will not be able to expand our business.

Our products are based on complex technology. Accordingly, we require skilled personnel to develop, manufacture, sell and support our products. In addition, as we move to continue commercialization of our products, we may require additional personnel skilled in the sales and marketing of medical device products. Our future success will depend largely on our ability to continue to hire, train, retain and motivate additional skilled personnel, particularly sales representatives and clinical specialists who are responsible for customer education and training and post-installation customer support. We continue to experience difficulty in recruiting and retaining skilled personnel because the pool of experienced persons is small and we compete for personnel with other companies, many of which have greater resources than we do. Consequently, if we are not able to attract and retain skilled personnel, we will not be able to expand our business.

Failure of users of the PSA 4000 and PSA 5000 to obtain adequate reimbursement from third party payers could limit market acceptance of the system, which could prevent us from growing our business.

Anesthesia providers are generally not reimbursed separately for patient monitoring activities, including any such activities that would involve use of the PSA 4000 and PSA 5000. Accordingly, potential users of the PSA 4000 and PSA 5000 may have to justify its use based on the clinical and cost benefits they believe use of the system provides. For hospitals and outpatient surgical centers, when reimbursement is based on charges or costs, patient monitoring with the PSA 4000 and PSA 5000 may reduce reimbursements for surgical procedures, because charges or costs may decline as a result of monitoring with the PSA 4000. Failure by hospitals and other users of the PSA 4000 and PSA 5000 to obtain adequate reimbursement from third-party payers, or any reduction in the reimbursement by third-party payers to hospitals and other users as a result of using the PSA 4000 and PSA 5000 could

limit market acceptance of the PSA 4000 and PSA 5000, which could prevent us from growing our revenues and our business.

Our stock price may fluctuate, which may cause your investment in our stock to suffer a decline in value.

The market price of our common stock has fluctuated significantly in the past and may fluctuate significantly in the future in response to factors which are beyond our control. In addition, the stock market in general has recently experienced extreme price and volume fluctuations. In particular, the market prices of securities of technology and medical device companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of your shares.

We may incur significant costs from securities class litigation due to our stock price volatility.

Our stock price may fluctuate for many reasons, including timing of regulatory actions relating to the PSA 4000 and PSA 5000, variations in our quarterly operating results and changes in market valuations of medical device companies. Recently, when the market price of a stock has been volatile as our stock price may be, holders of that stock have occasionally instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Our investments could lose market value and consequently harm our ability to fund continuing operations.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we maintain our portfolio of cash equivalents and short-term investments in a variety of securities, including government and corporate obligations and money market funds. These securities are generally classified as available for sale and consequently are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income (loss). The market values of these investments may fluctuate due to market conditions and other conditions over which we have no control. Fluctuations in the market price and valuations of these securities may require us to record losses due to an impairment in the value of the securities underlying our investment. This could result in future charges on our earnings. All securities are held in U.S. currency.

Investments in both fixed rate and floating rate interest earning instruments carry varying degrees of interest rate risk. Fixed rate securities may have their fair market value adversely impacted due to a rise in interest rates. In general, securities with longer maturities are subject to greater interest rate risk than those with shorter maturities. While floating rate securities generally are subject to less interest rate risk than fixed rate securities, floating rate securities may produce less income than expected if interest rates decrease. Due in part to these factors, our investment income may fall short of expectations or we may suffer losses in principal if securities are sold that have declined in market value due to changes in interest rates.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that stockholders may favor.

Provisions of our restated certificate of incorporation and amended and restated by-laws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders,
- requiring supermajority stockholder voting to effect certain amendments to our restated certificate of incorporation and amended and restated by-laws,
- eliminating the ability of stockholders to call special meetings of stockholders,
- prohibiting stockholder action by written consent, and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Item 2. PROPERTIES

We lease an approximately 16,810 square foot facility in North Billerica, Massachusetts. This facility includes manufacturing, laboratory and office space. The facility is leased through November 14, 2005, at which time we intend to renew our lease, if funds are available to us. We believe these facilities will be adequate to meet our current and reasonably anticipated future requirements.

Item 3. LEGAL PROCEEDINGS

We are not party to any legal proceedings.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our Common Stock has been traded on the Nasdaq SmallCap Market under the symbol PHYX. During 2001 and through October 29, 2002, our Common Stock was traded on the Nasdaq National Market under the same symbol. The number of record holders of our Common Stock at February 28, 2005 was 70. The number of record owners was determined from our stockholder records maintained by our transfer agent and does not include beneficial owners or our common stock whose shares are held in the names of various security holders, dealers and clearing agencies. We believe that the number of beneficial owners of our common stock held by others as or in nominee names exceeds 2,100 in number. We have not paid any dividends since our inception and do not intend to pay any dividends in the foreseeable future.

We completed an initial public offering of 2,000,000 shares of Common Stock in April 1996. Prior to the initial public offering, our Common Stock was not publicly traded.

On February 29, 2000, we closed a private placement of 2,080,340 shares of Common Stock.

On December 5, 2003, we completed a private placement of 4,957,487 shares of Common Stock for gross proceeds of approximately $8.2 million, and $7.5 million net of cash offering costs. The shares were sold at a price of $1.65 per share, based on the average closing bid prices for the five days ended December 1, 2003. The shares were purchased by a select group of investors. In conjunction with the placement of the shares of Common Stock, we issued to the investors warrants to purchase up to an aggregate of 4,957,488 shares of our Common Stock, fifty percent (50%) of which have an exercise price of $1.82 per share, and fifty percent (50%) of which have an exercise price of $2.48 per share. The net proceeds of this private placement are intended for general corporate purposes, including sales and marketing activities and research and development programs in the areas of neurological monitoring.

The sale of the shares of Common Stock and the warrants were exempt from registration under the Securities Act of 1933, as amended, pursuant to Section 4(2) thereof. A registration statement covering the shares of Common Stock issued, and the shares of Common Stock issuable upon exercise of the warrants, as part of the private placement completed in December 2003 was filed with the Securities Exchange Commission on Form S-3 on December 11, 2003, and declared effective on February 5, 2004. Roth Capital Partners, LLC and Musket Research Associates acted as placement agents for Physiometrix for this private placement. As placement agents for the transaction, Roth Capital Partners, LLC and Musket Research Associates each received warrants to purchase 247,874 shares of our Common Stock, for an aggregate of 495,748 shares, at an exercise price of $1.98 per share.

Quarterly high and low stock prices are as follows:

Quarter Ended	High	Low
March 31, 2004	$3.070	$1.650
June 30, 2004	$1.710	$1.170
September 30, 2004	$2.390	$1.300
December 31, 2004	$2.110	$0.880

Quarter Ended	High	Low
March 31, 2003	$0.900	$0.400
June 30, 2003	$1.750	$0.680
September 30, 2003	$2.780	$1.020
December 31, 2003	$3.500	$1.370

EQUITY COMPENSATION PLAN INFORMATION

The following table gives information about our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing equity compensation plans as of December 31, 2004, including the 1991 Incentive Stock Plan, the 1996 Director Option Plan, the 2000 Supplemental Stock Plan, and the 2001 Incentive Stock Plan.

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by securityholders(1)	1,664,052	$ 2.64	1,181,354
Equity compensation plans not approved by securityholders(2)	1,500	$ 5.50	98,500
Total	1,665,552		1,279,854

(1) Warrants to purchase an aggregate of 495,748 shares of Common Stock were issued to two placement agents in connection with a private placement transaction we completed in December 2003. These warrants have an exercise price of $1.98 per share and were approved by the shareholders at the February 20, 2004 special meeting of shareholders.

(2) Options to purchase 1,500 shares of Common Stock were issued pursuant to our 2000 Supplemental Stock Plan, which does not require the approval of and has not been approved by our stockholders. See description of the 2000 Supplemental Stock Plan below.

2000 Supplemental Stock Plan

On December 8, 2000, the Board of Directors approved the 2000 Supplemental Stock Plan (the "2000 Plan"). The 2000 Plan provides for the granting of non-qualified stock options to employees and consultants at the fair market value of our common stock as of the date of grant. Options granted under the 2000 Plan generally vest over a four year period with ⅛ vesting after six months and 1/48 vesting each month thereafter, however, the vesting schedule can change on a grant-by-grant basis. The 2000 Plan provides that vested options may be exercised for 3 months after termination of employment and for 12 months after termination of employment as a result of death or disability. We may select alternative periods of time for exercise upon termination of service. The 2000 Plan permits options to be exercised with cash, check, and certain other shares of our stock or consideration received by us under a "cashless exercise" program. In the event that we merge with or into another corporation, or sell substantially all of our assets, the 2000 Plan provides that each outstanding option will be assumed or substituted for by the successor corporation. If such substitution or assumption does not occur, each option will fully vest and become exercisable. There are 100,000 shares of common stock reserved under the Plan, and 98,500 shares remaining for future issuance.

Item 6. SELECTED FINANCIAL DATA

	Year ended December 31,				
	2000	2001	2002	2003	2004
Statements of Operations Data:					
Revenues	$ 2,466,595	$ 2,718,305	$ 1,017,164	$ 1,737,804	$ 1,891,112
Cost of products sold	2,957,652	6,627,461	1,151,344	2,096,347	1,942,529
Gross deficit	(491,057)	(3,909,156)	(134,180)	(358,543)	(51,417)
Costs and expenses:					
Research and development	2,775,324	3,850,155	2,229,736	1,567,155	1,812,893
Selling, general and administrative	2,595,554	4,987,845	3,276,932	3,218,964	3,486,182
	5,370,878	8,838,000	5,506,668	4,786,119	5,299,075
Operating loss	(5,861,935)	(12,747,156)	(5,640,848)	(5,144,662)	(5,350,492)
Change in fair value of warrant derivative	—	—	—	(2,929,131)	(1,046,080)
Interest income	1,139,802	752,106	117,225	23,540	59,110
Net loss	$(4,722,133)	$(11,995,050)	$(5,523,623)	$(8,050,253)	$(6,337,462)
Basic and diluted net loss per common share	$ (0.60)	$ (1.42)	$ (0.66)	$ (0.91)	$ (0.47)
Shares used in computing basic and diluted net loss per common share	7,812,544	8,420,667	8,422,560	8,836,118	13,594,751

	December 31,				
	2000	2001	2002	2003	2004
Cash, cash equivalents and short-term investments	$ 21,850,127	$ 10,727,991	$ 3,933,917	$ 7,626,049	$ 2,588,737
Working capital (deficit)	22,426,459	10,276,802	4,980,834	(3,721,478)	2,379,974
Total assets	25,096,179	12,808,656	5,808,011	8,772,201	3,196,216
Accumulated deficit	(34,084,391)	(46,079,441)	(51,603,064)	(59,653,317)	(65,990,779)
Total stockholders' equity (deficit)	22,983,557	10,897,930	5,348,285	(3,541,810)	2,483,692

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

The following discussion of the financial condition and results of operations of Physiometrix should be read in conjunction with the Financial Statements and related Notes thereto included elsewhere in this Form 10-K. This Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as "believe," "expect," "intend," "anticipate," "should," "planned," "estimated," and "potential," among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. Actual events or results may differ materially from those projected in the forward-looking statements as a result of the factors described herein in the Risk Factors section of Item 1 of this Report on Form 10-K and in the documents incorporated herein by reference. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our businesses include, but are not limited to, statements concerning (i) business strategy; (ii) products under development; (iii) other products; (iv) marketing and distribution, including statements related to distribution plans and arrangements and future marketing, sales and distribution strategies; (v) research and development; (vi) manufacturing; (vii) competition; (viii) government regulation especially as it relates to Food and Drug Administration ("FDA") approvals; (ix) third-party reimbursement; (x) operating and capital requirements; (xi) clinical trials; and (xii) other factors that might be described from time to time in periodic filings with the Securities and Exchange Commission and include those set forth in this Annual Report on Form 10-K as "Risk Factors".

Overview

Since our inception in January 1990, we have been engaged primarily in the design and development and more recently the manufacture and sale of noninvasive, advanced medical products. Our products, which incorporate proprietary materials and electronics technology, are used in neurological monitoring applications. Our principal product is the Patient State Analyzer ("PSA 4000"), a consciousness monitoring system. The PSA 4000 is used with the PSArray2, a frontal-only disposable array sensor which attaches to the PSA 4000. We received 510(k) clearance from the FDA for the PSArray2 in October 2002. The PSArray2 was developed in an effort to improve market acceptance of the PSA 4000.

We have a limited history of operations and have experienced significant operating losses since our inception. As of December 31, 2004, we had an accumulated deficit of approximately $66.0 million. We anticipate that our operating results will fluctuate on a quarterly basis for the foreseeable future due to several factors, including actions relating to regulatory and reimbursement matters, the extent to which our products gain market acceptance, the introduction of our new product, the PSA 5000, the introduction of alternative means for neurophysiological monitoring and competition. Results of operations will also be affected by the progress of clinical trials and in-house development activities, and the extent to which we establish distribution channels for our products domestically and internationally.

Since the third quarter of 2000, substantially all of our sales were to Baxter Healthcare Corporation ("Baxter") under a distribution agreement, which provides Baxter with exclusive distribution rights to our PSA 4000 in the United States and Canada. The agreement extends through termination and is cancelable by either party upon six months notice after December 31, 2003. Under

the terms of the agreement, as amended in February 2003, if Baxter fails to meet minimum purchase commitments, we have the option to convert their distribution agreement into a non-exclusive relationship for the operating room market segment. In 2003, Baxter failed to meet minimum purchase requirements, however, we have not enforced our right to change the terms of the agreement, including Baxter's exclusivity rights. We may enter into additional distribution arrangements with other parties, enter into negotiations with Baxter to amend or modify our agreement or elect to enforce this right to change the terms of the existing agreement with Baxter.

On February 10, 2004, we received clearance from the FDA for commercial distribution of our PSA 5000 next generation monitor. The PSA 5000 is a new state of the art monitor that is more powerful, cost effective and offers improved ergonomics as compared to the PSA 4000. We anticipate launch of this product in mid 2005. We do not believe that the PSA 5000 will result in the obsolescence of the PSA 4000.

Our principal source of liquidity at December 31, 2004 consisted of cash, cash equivalents and short-term investments, which aggregated $2.6 million. We anticipate that our existing cash, cash equivalents, and short-term investments will be sufficient to conduct operations only until the beginning of the third quarter of 2005, at which time, we will be unable to meet our working capital requirements. As a result, there is substantial doubt about our ability to continue as a going concern. We plan to raise capital through equity and/or debt issuance when, and if, such capital is available to us. We are engaged in negotiations and discussions with potential sources of new capital, and at this stage, we cannot assure you that we will be able to raise additional capital on acceptable terms, or at all. If additional amounts cannot be raised and we are unable to substantially reduce our expenses, we would suffer material adverse consequences to our business, financial condition and results of operations and would likely be required to seek other alternatives up to and including the sale of our technology, filing for protection under the United States bankruptcy laws or cessation of operations.

Critical Accounting Policies

Our significant accounting policies are described in Note 2 to the financial statements included in Item 15 of this Form 10-K. Management believes the most critical accounting policies are as follows:

Use of Estimates

We prepare our financial statements in accordance with U.S. generally accepted accounting principles. These principles require that we make estimates and use assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates are made in connection with determining the market value of inventory, if lower than cost, and establishing allowances for bad debts. Actual results could differ from those estimates.

Revenue Recognition

We recognize revenue for product sales upon shipment, net of allowances for discounts and estimated returns which are also provided for at the time of shipment in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements.*

Inventories

Inventories are recorded at the lower of cost (first-in, first-out) or market value. Provisions for excess inventory are primarily based on management's estimates of forecasted net sales levels. We believe that our net inventories included in our balance sheet at December 31, 2004 are fully realizable and are expected to be sold within the next twelve months. On February 10, 2004, we received

clearance from the Food and Drug Administration ("FDA") for commercial distribution of our PSA 5000 next generation monitor. The PSA 5000 is a new state of the art monitor that is more powerful, cost effective and ergonomic than it's predecessor the PSA 4000. We anticipate launch of the product through a new distribution partner in mid 2005 and will continue our effort to sell the remaining PSA 4000's.

At December 31, 2004, we had 350 PSA 4000 units on hand with 310 units on hand fully reserved for. In the event we sell in excess of 40 units up to 350 units, we would expect to recognize 100% gross margin on the shipments.

Warrant Derivative

We had a derivative liability from December 2, 2003 through February 5, 2004, which resulted from a potential cash settlement, which was required in the event we could not successfully register the shares underlying the warrants, issued in connection with our common stock financing completed in December 2003. We account for this warrant derivative in accordance with EITF 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. The warrants were included as a liability and valued at fair market value until we met the criteria under EITF 00-19 for equity. A registration statement covering the shares sold in the private placement, along with the shares underlying the warrants was filed with the Securities and Exchange Commission on Form S-3 on December 11, 2003, and declared effective on February 5, 2004. Therefore, the value of the warrants was reclassified as stockholders' equity in the first quarter of 2004 and there is no future cash requirement with respect to this liability on behalf of the Company.

Stock—Based Compensation

We apply the principles of Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*," and related interpretations in accounting for our Stock Plans. Under APB No. 25, compensation expense is measured as the difference, if any, between the option exercise price and the fair value of our common stock at the date of grant. We have historically granted options to employees and directors at exercise prices equal to the fair value of our common stock. Accordingly, no compensation expense has been recognized for our employee stock-based compensation plans.

We follow the disclosure-only provisions under SFAS No. 123, "*Accounting for Stock-Based Compensation*," as amended by SFAS No. 148, "*Accounting for Stock-Based Compensation—Transition and Disclosure*".

In December 2004, the FASB issued Statement No. 123(R), *Share-Based Payment* (SFAS No. 123(R)). SFAS No. 123(R) replaces SFAS No. 123, supersedes APB No. 25 and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values (i.e., pro forma disclosure is no longer an alternative to financial statement recognition). The provisions of SFAS No. 123(R) must be applied at the beginning of the first interim or annual period beginning after June 15, 2005. We are in the process of evaluating the impact of this new pronouncement on our financial statements.

Results of Operations

Years Ended December 31, 2004 and 2003

Revenues

Revenues increased 9% to $1,891,000 for the year ended December 31, 2004 from $1,738,000 for the year ended December 31, 2003. This increase was primarily due an increase in PSArray2 sales. We shipped 87,000 PSArray2 units for $653,000 during 2004 as compared to 48,000 units shipped for $360,000 in 2003. Additionally, we shipped 236 PSA 4000 units during the year ended December 30, 2004 compared to 225 PSA 4000 units shipped for the year ended December 30, 2003. Revenue for the PSA 4000 shipments was down slightly in 2004 compared to 2003 due to a reduction in the average selling price of the PSA 4000. Future PSA 4000 revenues are entirely dependent on the acceptance of the new PSArray2 by anesthesiologists, which was developed in 2002 in an effort to improve market acceptance of the PSA 4000. Our current agreement with Baxter provides Baxter with exclusive distribution rights for the PSA 4000 in the U.S. and Canada, making us significantly dependent upon Baxter for successful commercialization of this product. There is no assurance that this will occur. Sales of our HydroDot NeuroMonitoring products were relatively unchanged compared with the same period last year. We intend to launch the PSA 5000 in 2005 and we will continue our effort to sell the remaining PSA 4000's.

Cost of Products Sold

Cost of products sold decreased 7% to $1,943,000 for the year ended December 31, 2004 from $2,096,000 for the year ended December 31, 2003. This decrease was primarily due to the shipments of 111 PSA 4000 units in 2004, which were shipped at no cost due to being 100% reserved for in prior years based on uncertainty as to the saleability of the units.

Gross Deficit

The gross deficit incurred during the years ended December 31, 2004 and 2003, resulted from costs of the product incurred together with headcount and overhead costs required in our manufacturing group exceeding the reported revenues. The gross deficit decreased by $307,000 during the year ended December 31, 2004 compared to the same period in the prior year primarily due to the shipment of 111 PSA 4000 units which were shipped at no cost due to being 100% reserved for in prior years based on uncertainty as to the saleability of the units.

Research and Development Expenses

Research and development expenses, consisting principally of headcount related expenses, clinical study costs and consulting fees, increased 16% to $1,813,000 for the year ended December 31, 2004 from $1,567,000 for the year ended December 31, 2003. The increase is primarily due to an increase in costs associated with the development of the PSA 5000, slightly offset by a decrease in salary related expenses due to staff reductions undertaken during 2004. The PSA 5000 is a new state of the art monitor that is more powerful, cost effective and ergonomic than its predecessor the PSA 4000.

Selling, General and Administrative Expenses

Selling, general and administrative increased 8% to $3,486,000 for the year ended December 31, 2004 from $3,219,000 for the year ended December 31, 2003. This increase was primarily due to a small increase in headcount related expense, coupled with an increase in advertising costs, consulting expenses and auditing fees.

Change in Fair Value of Warrant Derivative

During the fourth quarter of 2003 and first quarter of 2004, we recorded a non-cash expense of $2,929,131 and $1,046,080, respectively, related to warrants issued in connection with our common stock financing in December 2003. In accordance with EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, warrants are included as a liability and valued at fair market value until the criteria under EITF 00-19 for equity are met. The warrants issued by the Company in the private placement transaction were classified as a derivative and recorded as a liability due to the possibility of the Company having to make a cash settlement, including penalties, in the event we failed to register the shares underlying the warrants under the Securities Act of 1933, as amended, within 90 days after the closing of the private placement transaction. We valued the warrant derivative using the Black-Scholes model using the following assumptions in 2003: risk-free interest rate of 3.27%, expected life of warrants of 5 years, expected stock volatility of 167% and no expected dividend yield. A registration statement covering the shares sold in the private placement, along with the shares underlying the warrants, was filed with the Securities and Exchange Commission on Form S-3 on December 11, 2003 and declared effective on February 5, 2004. Therefore, the value of the warrants was reclassified as equity in the first quarter of 2004. We valued the warrant derivative on February 5, 2004, using the following assumptions: risk-free interest rate of 3.16%, expected life of warrants of 4.83 years, expected stock volatility of 157% and no expected dividend yield.

Interest Income

Interest income increased to $59,000 for the year ended December 31, 2004 from $24,000 for the year ended December 31, 2003. This increase was due to higher average cash balances available for investment in 2004 due to the private equity financing completed in December 2003, which raised net proceeds of approximately $7.5 million.

Income Taxes

We have experienced operating losses since inception and therefore have not paid any federal income taxes since our inception. We account for income taxes under Statement of Financial Accounting Standards No. 109 ("SFAS 109"). Realization of deferred tax assets is dependent on future earnings, if any, the timing and amount of which are uncertain. Accordingly, valuation allowances, in amounts equal to the net deferred tax assets as of December 31, 2004 and 2003, were established in each period to reflect these uncertainties.

Years Ended December 31, 2003 and 2002

Revenues

Revenues increased 71% to $1,738,000 for the year ended December 31, 2003 from $1,017,000 for the year ended December 31, 2002. This increase is primarily due to an increase in the number of PSA 4000 units shipped during 2003. We did not ship any PSA 4000 units during 2002 as compared to 225 units shipped in 2003. Revenue of $600,000 recognized in 2002 represented the removal of an acceptance contingency on units shipped to Baxter during 2001. The improved revenues in 2003 were also due to the introduction of the PSArray2, which received FDA 510(k) clearance on October 7, 2002. Shipments to Baxter of the PSArray2 during 2003 accounted for revenue of $360,000 as compared to revenue of $38,000 for 2002.

Future PSA 4000 revenues are entirely dependent on the acceptance of the new PSArray2 by anesthesiologists. There is no assurance that this will occur. Sales of our HydroDot NeuroMonitoring products decreased 9% to $311,000 for the year ended December 31, 2003 from $343,000 for the year ended December 31, 2002.

Cost of Products Sold

Cost of products sold increased 82% to $2,096,000 for the year ended December 31, 2003 from $1,151,000 for the year ended December 31, 2002. This increase was primarily due to the increased volume of PSA 4000 and PSArray2 units shipped in 2003 compared to 2002.

Gross Deficit

The gross deficit incurred during the years ended December 31, 2003 and 2002 resulted from costs of the product incurred together with headcount and overhead costs required in our manufacturing group exceeding the reported revenues. At December 31, 2003, we had 575 PSA 4000 units on hand with 450 units on hand fully reserved for. In the event we sell in excess of 125 PSA 4000 units up to 575 units, we will recognize 100% gross margin on these shipments.

Research and Development Expenses

Research and development expenses consisting principally of headcount related expenses, clinical study costs, and consulting fees, decreased 30% to $1,567,000 for the year ended December 31, 2003 from $2,230,000 for the year ended December 31, 2002. This decrease was primarily due to a decrease in outside consulting costs associated with development of the PSA 4000, as well as staff reductions and other discretionary expense reductions undertaken in the second quarter of 2002.

Selling, General and Administrative Expenses

Selling, general and administrative decreased 2% to $3,219,000 for the year ended December 31, 2003 from $3,277,000 for the year ended December 31, 2002. There were no significant changes in these expenses for the year ended December 31, 2002 compared to the year ended December 31, 2003.

Change in fair value of warrant derivatives

During the fourth quarter of 2003, we recorded a non-cash expense of $2,929,131 related to warrants issued in connection with our common stock financing completed in December 2003. In accordance with EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, the warrants are included as a liability and valued at fair market value until the Company meets the criteria under EITF 00-19 for equity. The warrants were classified as derivatives and recorded as a liability due to the possibility of the Company having to pay out certain cash penalties in the event we failed to register the shares underlying the warrants under the Securities Act of 1933, as amended within 90 days after the closing of the private placement transaction. We valued the warrant derivative using the Black-Scholes model. A registration statement covering the shares sold in the private placement, along with the shares underlying the warrants, was filed with the Securities and Exchange Commission on Form S-3 on December 11, 2003, and declared effective on February 5, 2004.

Therefore, the value of the warrants will be reclassified as equity in the first quarter of 2004. We expect to incur a non-cash charge in the first quarter of 2004 for the change in the fair value of the derivative up to the date the derivative is transferred into equity.

Interest Income

Interest income decreased to $24,000 for the year ended December 31, 2003 from $117,000 for the year ended December 31, 2002. This decrease was due to lower average cash balances available for investment in 2003, along with lower interest rates.

Income Taxes

We have experienced operating losses since inception and therefore have not paid any federal income taxes since our inception. We account for income taxes under Statement of Financial Accounting Standards No. 109 ("SFAS 109"). Realization of deferred tax assets is dependent on future earnings, if any, the timing and amount of which are uncertain. Accordingly, valuation allowances, in amounts equal to the net deferred tax assets as of December 31, 2003 and 2002, were established in each period to reflect these uncertainties.

Selected Quarterly Financial Data:

	Quarter Ended							
	March 31, 2003	June 30, 2003	September 30, 2003	December 31, 2003(1)	March 31, 2004(1)	June 30, 2004	September 30, 2004	December 31, 2004
Revenues	$ 238,744	$ 200,524	$ 609,095	$ 689,441	$ 197,194	$ 831,123	$ 437,791	$ 425,004
Cost of products sold.	340,116	331,130	657,332	767,769	330,126	708,965	510,085	393,353
Gross margin (deficit)	(101,372)	(130,606)	(48,237)	(78,328)	(132,932)	122,158	(72,294)	31,651
Operating loss	(1,199,712)	(1,300,263)	(1,125,790)	(1,518,897)	(1,452,962)	(1,197,590)	(1,523,657)	(1,176,283)
Net loss	(1,189,469)	(1,294,429)	(1,124,253)	(4,442,102)	(2,479,999)	(1,182,535)	(1,510,828)	(1,164,100)
Basic and diluted net loss per share	$ (0.14)	$ (0.15)	$ (0.13)	$ (0.49)	$ (0.19)	$ (0.09)	$ (0.11)	$ (0.09)

(1) During the fourth quarter of 2003 and first quarter of 2004, we recorded a non-cash expense of $2,929,131, and $1,046,080 respectively, related to a warrant derivative issued in connection with our common stock financing completed in December 2003, which raised net proceeds of approximately $7.5 million.

Liquidity And Capital Resources

At December 31, 2004, our cash, cash equivalents and short-term investments were $2,589,000 as compared to $7,626,000 at December 31, 2003.

Our operating activities used cash of $4,975,000 in the year ended December 31, 2004 as compared to $3,798,000 in the year ended December 31, 2003. The operating activities for 2004 and 2003 included a non-cash expense of $1,046,080 and $2,929,131 respectively, related to the derivative accounting treatment of free-standing unregistered warrants issued in connection with our private placement completed in December 2003. The $1,176,000 increase in net cash used in operating activities in 2004 compared to 2003 was a result of a large decrease in accounts payable and accrued expenses due to professional fees accrued in 2003 and paid in 2004 associated with the common stock financing completed in December 2003. Also contributing to the increase in net cash used in operating activities was a smaller decrease in inventory during 2003 than during 2004 as a result of PSA 4000 units being reserved for during 2002 and 2003.

Net cash provided by investing activities in the year ended December 31, 2004 was $2,470,000, as compared with $2,319,000 used in the year ended December 31, 2003. The increase was due primarily to a decrease in the purchase of short-term investments combined with an increase in the proceeds from maturities of short-term investments due to cash becoming available to invest in 2003 as a result of the private equity financing completed in December 2003 which raised net proceeds of approximately 7.5 million.

Our financing activities used cash of $25,000 in the year ended December 31, 2004 as compared to $7,527,000 of cash provided in the year ended December 31, 2003. During the fourth quarter of 2003, we completed a private placement of common stock and warrants to purchase common stock that raised approximately $7.5 million in net proceeds. The 2004 financing activities represented the exercise of employee stock options coupled with costs associated with the private placement of our common stock that occured in December 2003.

Our principal source of liquidity at December 31, 2004 consisted of cash, cash equivalents and short-term investments, which aggregated $2.6 million. Our net working capital at December 31, 2004 was approximately $2.4 million. We had a net working capital deficit of approximately $3.7 million at December 31, 2003, which was due primarily to warrant derivatives issued in connection with our common stock financing during December 2003, which raised net proceeds of approximately $7.5 million. The warrants were classified as derivatives due to the possibility of the Company having to make a cash settlement, including penalties, in the event we failed to complete the registration of the shares underlying the warrants under the Securities Act of 1933, as amended, within 90 days after the closing of the private placement transaction. A registration statement covering the shares sold in the private placement, along with the shares underlying the warrants, was filed with the Securities and Exchange Commission on Form S-3 on December 11, 2003, and declared effective on February 5, 2004. Therefore, the value of the warrants was reclassified as equity in the first quarter of 2004 and there is no future cash requirement with respect to this liability on behalf of the Company.

We anticipate that our existing cash, cash equivalents and short-term investments, and other current assets on hand at December 31, 2004 will be sufficient to conduct operations only until the beginning of the third quarter of 2005, at which time, we will be unable to meet our working capital requirements. As a result, there is substantial doubt about our ability to continue as a going concern. We will need to raise capital through equity and/or debt issuance when, and if, such capital is available to us. We are engaged in negotiations and discussions with potential sources of new equity capital, and at this stage, we can not assure you that we will be able to raise additional capital on acceptable terms, or at all. Future equity financings may result in dilution to the holders of our common stock. Future debt financings may require us to pledge assets and to comply with financial and operational covenants. If additional amounts can not be raised at acceptable terms and we were unable to substantially reduce our expenses, we would suffer material adverse consequences to our business, financial condition and results of operations and would likely be required to seek other alternatives up to and including protection under the United States bankruptcy laws or cessation of operations.

We are significantly dependent on our distributor, Baxter, for sale of inventories of our principal product, the PSA 4000.

The Company believes that the success of generating revenues as well as raising additional working capital are the most critical components to the Company's ability to continue as a going concern. The Company's plan for the remainder of 2005 is to support the activities of its partner, Baxter, in the commercialization of the PSA 4000 with the PSArray2 and to launch the PSA 5000 next generation monitor. The Company will make every attempt to conserve its cash resources and continue as a business. Although management and the current investors of the Company do not have any intention of liquidating the business, the Company would consider a sale of the technology or other strategic alternatives if the Company's cash constraints will not allow it to execute its plan. The Company is aware of one other company with similar products to the PSA 4000. The Company does not believe it will be at a significant disadvantage in marketing its products against this company.

At December 31, 2004, we had tax net operating loss carryforwards of approximately $52.4 million available to offset federal taxable income, which expire in varying amounts through 2024, and $31.7 million to offset state taxable income, which expire in varying amounts through 2009. We also have research and development tax credit carryforwards of approximately $1.6 million available to offset federal income taxes, which expire in varying amounts through 2024. In accordance with Section 382 of the Internal Revenue Code, the use of the above carryforwards may be subject to annual limitations based upon ownership changes of our stock which have occurred. The annual limitation may result in the expiration of net operating loss and tax credit carryforwards before full utilization.

Recent Accounting Pronouncements

In December 2004, the FASB issued Statement No. 123(R), *Share-Based Payment* (SFAS No. 123(R)). SFAS No. 123(R) replaces SFAS No. 123, supersedes APB No. 25 and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values (i.e., pro forma disclosure is no longer an alternative to financial statement recognition). The provisions of SFAS No. 123(R) must be applied at the beginning of the first interim or annual period beginning after June 15, 2005. We are in the process of evaluating the impact of this new pronouncement on our financial statements.

Off Balance Sheet Financing

We have not entered into any off-balance sheet financing arrangements and have not established any special purpose entities as of December 31, 2004.

Overview of Contractual Obligations

Contractual Obligations		Payments Due by Period			
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Leases	$184,714	$175,781	$ 8,933	—	—

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that an increase in prevailing interest rates may cause the principal amount of the investment to decrease. To minimize this risk in the future, we maintain our portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, money market funds and government and non-government debt securities. Due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. As of December 31, 2004, 100% of our total portfolio will mature in one year or less.

In connection with our private placement transaction completed in 2003, we issued warrants to purchase an aggregate of 4,957,488 shares of common stock. The terms of the private placement required the Company to register with the Securities and Exchange Commission the shares sold in the private placement, including the shares underlying the warrants, and provided for the possibility of the Company having to pay out certain cash penalties in the event we failed to register such shares underlying the warrants within 90 days after the closing of the private placement transaction. Accordingly, this resulted in a derivative contract in accordance with EITF 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock.* The warrants are included as a liability and valued at fair market value until we meet the criteria under EITF 00-19 for permanent equity. We value the derivative warrant using the Black-Scholes model. The derivative was valued at the date of the transaction in the amount of $8.4 million and then revalued at $11.3 million on December 31, 2003. A registration statement covering the shares underlying the warrants, was filed with the Securities and Exchange Commission on Form S-3 on December 11, 2003, and declared effective on February 5, 2004. The warrants were revalued on February 5, 2005 at $12.4 million and were reclassified as stockholders' equity in the first quarter of 2004. The relevant assumptions included in the calculation in 2003 were a term of 5 years, an interest rate of 3.27% and a volatility of 1.67. The relevant assumptions included in the calculation in 2004 were a term of 4.83 years, an interest rate of 3.16% and a volatility of 1.57.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Report of Independent Registered Public Accounting Firm, Financial Statements and Notes to Financial Statements begin on page F-1.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Changes in internal controls over financial reporting. There was no significant change in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Report on Form 10-K in that the Registrant will file a definitive proxy statement within 120 days after the end of its fiscal year pursuant to Regulation 14A with respect to the 2005 Annual Meeting of Stockholders (the "Proxy Statement") to be held June 2, 2005 and certain information included therein is incorporated herein by reference.

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this item relating to directors is incorporated by reference to the information under the caption *"Proposal No. 1 Election of Directors"* in the Proxy Statement.

The executive officers of the Registrant, who are elected by the board of directors, are as follows:

Name	Age	Position
John A. Williams	57	President, Chief Executive Officer and Director
Daniel W. Muehl	42	Vice President of Finance & Administration and Chief Financial Officer

John A. Williams joined the Company in December 1993 and has served as a member of the Board of Directors and as the Company's President and Chief Executive Officer. Prior to that time, Mr. Williams served as President of Bruel and Kjaer Medical, a medical device company, from 1990 to 1993. Mr. Williams was Vice President of Sales and Marketing at Medtronic/AMI, a medical device company, from 1988 to 1990 and Vice President of Sales and Marketing, Worldwide at Merrimack Laboratories from 1983 to 1987.

Daniel W. Muehl joined the Company in February 1998 as Vice President of Finance & Administration and Chief Financial Officer. Previously, Mr. Muehl was Chief Operating Officer and Chief Financial Officer at Number Nine Visual Technology from 1995 to 1998 and served in various finance positions at Powersoft Corporation and Medical Care America from 1991 to 1995. Mr. Muehl is a Certified Public Accountant and served his public accountancy with Ernst & Young LLP and Laventhol and Horwath from 1985 to 1991.

The information required by this item relating to our code of ethics is incorporated in by reference to the information under the heading "Code of Ethics" in the Proxy Statement.

Item 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the information under the caption "Executive Compensation" in the Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item is incorporated by reference to the information under the caption "Record Date and Stock Ownership" in the Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference to the information under the caption "Certain Transactions" in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required by Item 14 is incorporated herein by reference to the Section entitled "Independent Public Accountants" of the Company's definitive proxy statement which will be filed no later than 120 days after December 31, 2004.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) 1. Financial Statements

The following Financial Statements of Physiometrix, Inc. and Report of Ernst & Young LLP, Independent Registered Public Accounting Firm are in this Form 10-K.

	Page
Report of Independent Registered Public Accounting Firm.	F-1
Balance Sheets at December 31, 2003 and 2004.	F-2
Statements of Operations for the Years Ended December 31, 2002, 2003 and 2004.	F-3
Statements of Cash Flows for the Years Ended December 31, 2002, 2003 and 2004.	F-4
Statements of Stockholders' Equity (Deficit) for the Years Ended December 31, 2002, 2003 and 2004.	F-5
Notes to Financial Statements.	F-6

2. Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or the notes thereto.

3. Exhibits

Refer to (c) below.

(b) Reports on Form 8-K

We furnished a Current Report on Form 8-K dated March 3, 2005, attaching our fourth quarter ended December 31, 2004 earnings release dated March 3, 2005.

We furnished a Current Report on Form 8-K dated February 28, 2005, attaching a Notice of failure to satisfy a continued Nasdaq listing rule.

We furnished a Current Report on Form 8-K dated November 4, 2004, attaching our third quarter ended September 30, 2004 earnings release dated November 4, 2004.

We furnished a Current Report on Form 8-K dated July 28, 2004, attaching our second quarter ended June 30, 2004 earnings release dated July 28, 2004.

(c) Exhibits

Exhibit No.	Description
3.1(1)	Restated Certificate of Incorporation of the Company.
3.2(1)	Bylaws of the Company, as amended.
4.1(1)	Specimen Common Stock Certificate.
4.2(1)	Form of Warrant Agreement between the Company and Cruttenden Roth Incorporated, with form of Warrant attached.
10.1(1)	Form of Indemnification Agreement between the Company and each of its directors and officers.
10.2(1)	1991 Incentive Stock Plan and Form of Stock Option Agreement thereunder.
10.3(2)	1996 Director Option Plan.

Exhibit No.	Description
10.4(2)	1996 Employee Stock Purchase Plan and forms of agreements thereunder.
10.5(1)	Lease dated October 11, 1994 between the Company and Yvon Cormier, Trustee of YCEE Investment Trust, for a facility located at Five Billerica Park, 101 Billerica Avenue, North Billerica, Massachusetts 01862.
10.6(1)	Restated Shareholder Rights Agreement dated June 24, 1994 between the Company and certain holders of the Company's securities.
10.7(3)	Stock Purchase Agreement dated February 29, 2000 between the Registrant and the purchasers of common stock of the Registrant named therein, including form of Stock Purchase Warrant and other exhibits thereto.
10.8(4)	Strategic Alliance and Exclusive Distribution Agreement dated May 31, 2000 by and between the Company and Baxter Healthcare Corporation.
10.9(6)	Amendment A to Strategic Alliance and Exclusive Distribution Agreement dated May 31, 2000.
10.10(6)	Amendment B to Strategic Alliance and Exclusive Distribution Agreement dated May 31, 2000.
10.11(5)	2000 Supplemental Stock Plan.
10.12(5)	2001 Stock Option Plan.
10.13(7)	Amendment C to Strategic Alliance and Exclusive Distribution Agreement dated May 31, 2000.
10.14(8)	Stock Purchase Agreement dated December 02, 2003 between the Registrant and the purchasers of common stock of the Registrant named therein, including form of Stock Purchase Warrant and other exhibits thereto.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to page 39.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15(d)-14(a) promulgated under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15(d)-14(a) promulgated under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Filed as an Exhibit to the Company's Registration Statement on Form S-1 (File No. 3302138) and incorporated herein by reference.

(2) Filed as an Exhibit to the Company's Registration Statement on Form S-8 (File No. 33316525) and incorporated herein by reference.

(3) Filed as an Exhibit to the Company's Registration Statement on Form S-3 (File No. 33333660) and incorporated herein by reference.

(4) Filed as an Exhibit to the Company's Form 10-Q, Q3 2000 and incorporated herein by reference.

(5) Filed as an exhibit to the Company's Registration Statement on Form S-8 (File No. 333-69106) and incorporated by reference.

(6) Filed as an Exhibit to the Company's Form 10-K, 2000 and incorporated herein by reference.

(7) Filed as an Exhibit to the Company's Form 10-K, 2002 and incorporated herein by reference.

(8) Filed as an Exhibit to the Company's Registration Statement on Form S-3 (File No. 333-111102) and incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PHYSIOMETRIX, INC.

By: /s/ JOHN A. WILLIAMS
John A. Williams
President and Chief Executive Officer

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John A. Williams and Daniel W. Muehl, jointly and severally, his or her attorneys in fact, and each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys in fact, or his or her substitute or substitutes, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the date indicated.

Signature	Title	Date
/s/ JOHN A. WILLIAMS John A. Williams	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2005
/s/ DANIEL W. MUEHL Daniel W. Muehl	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2005
/s/ THOMAS BARUCH Thomas Baruch	Director	March 31, 2005
/s/ JAMES SAALFIELD James Saalfield	Director	March 31, 2005
/s/ CHRISTOPHER MITCHELL Christopher Mitchell	Director	March 31, 2005

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Physiometrix, Inc.

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

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Physiometrix, Inc. at December 31, 2003 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring operating losses, and has a significant accumulated deficit. Additionally, the Company believes its cash, cash equivalents and short-term investments on hand at December 31, 2004 are sufficient to conduct its operations only until the beginning of the third quarter of 2005, at which time the Company will be unable to meet its working capital needs. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts
February 11, 2005

PHYSIOMETRIX, INC.
BALANCE SHEETS

	December 31, 2003	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,099,155	$ 1,569,291
Short-term investments	3,526,894	1,019,446
Accounts receivable, net of allowance for doubtful accounts of $4,341 in 2003 and $2,136 in 2004	304,392	255,222
Inventories	560,294	150,443
Prepaid expenses	101,798	98,096
Total current assets	8,592,533	3,092,498
Equipment, net	179,668	103,718
Total assets	$ 8,772,201	$ 3,196,216
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 147,762	$ 172,753
Accrued expenses	823,519	539,771
Warrant derivative contract	11,342,730	—
Total current liabilities	12,314,011	712,524
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock: $.001 par value; 10,000,000 shares authorized: none issued or outstanding	—	—
Common stock: $.001 par value, 50,000,000 shares authorized; 13,380,481 shares in 2003 and 13,701,366 shares in 2004 issued and outstanding	13,380	13,701
Additional paid-in capital	56,098,127	68,461,448
Unrealized loss on available-for-sale securities	—	(678)
Accumulated deficit	(59,653,317)	(65,990,779)
Total stockholders' equity (deficit)	(3,541,810)	2,483,692
Total liabilities and stockholders' equity (deficit)	$ 8,772,201	$ 3,196,216

See accompanying notes.

PHYSIOMETRIX, INC.
STATEMENTS OF OPERATIONS

	Year ended December 31,		
	2002	2003	2004
Revenues	$ 1,017,164	$ 1,737,804	$ 1,891,112
Cost of products sold	1,151,344	2,096,347	1,942,529
Gross deficit	(134,180)	(358,543)	(51,417)
Costs and expenses:			
Research and development	2,229,736	1,567,155	1,812,893
Selling, general and administrative	3,276,932	3,218,964	3,486,182
	5,506,668	4,786,119	5,299,075
Operating loss	(5,640,848)	(5,144,662)	(5,350,492)
Other income (expense):			
Change in fair value of warrant derivative	—	(2,929,131)	(1,046,080)
Interest income	117,225	23,540	59,110
	117,225	(2,905,591)	(986,970)
Net loss	$(5,523,623)	$(8,050,253)	$ (6,337,462)
Basic and diluted net loss per common share	$ (0.66)	$ (0.91)	$ (0.47)
Shares used in computing basic and diluted net loss per common share	8,422,560	8,836,118	13,594,751

See accompanying notes.

PHYSIOMETRIX, INC.
STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2002	2003	2004
Operating activities:			
Net loss	$ (5,523,623)	$(8,050,253)	$(6,337,462)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	244,457	221,764	112,677
Change in fair value of warrant derivative	—	2,929,131	1,046,080
Stock-based compensation in connection with issuance of stock options to consultants	(21,978)	49,320	—
Changes in operating assets and liabilities:			
Accounts receivable	(29,426)	(243,186)	49,170
Inventories	7,239	771,141	409,851
Prepaid expenses	73,403	12,204	3,702
Accounts payable and accrued expenses	(1,451,000)	511,555	(258,757)
Net cash used in operating activities	(6,700,928)	(3,798,324)	(4,974,739)
Investing activities:			
Purchase of equipment	(89,102)	(33,981)	(36,727)
Purchase of short-term investments	(3,270,823)	(3,526,909)	(669,231)
Proceeds from maturity of short-term investments	10,019,784	1,241,530	3,176,001
Net cash provided by (used in) investing activities	6,659,859	(2,319,360)	2,470,043
Financing activities:			
Private placement cash offering costs	—	—	(87,756)
Proceeds from issuance of common stock and warrants	651	7,526,797	62,588
Net cash provided by (used in) financing activities	651	7,526,797	(25,168)
Net increase (decrease) in cash and cash equivalents	(40,418)	1,409,113	(2,529,864)
Cash and cash equivalents at beginning of year	2,730,460	2,690,042	4,099,155
Cash and cash equivalents at end of year	$ 2,690,042	$ 4,099,155	$ 1,569,291
Non-cash financing activities:			
Issuance of warrant derivative contract in connection with private placement of Common Stock	—	$ 8,413,599	—

See accompanying notes.

PHYSIOMETRIX, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Additional	Deferred	Unrealized Gain (loss) on Available for	Accumulated	Total Stockholders' Equity
	Shares	Amount	Paid-in Capital	Compensation	Sale Securities	Deficit	(Deficit)
Balance at December 31, 2001	8,421,952	$ 8,422	$56,997,319	$(35,425)	$ 7,055	$(46,079,441)	$ 10,897,930
Issuance of common stock upon exercise of options	1,042	1	650				651
Adjustment of value to options issued to consultants			(52,934)	52,934			—
Stock compensation				(21,978)			(21,978)
Components of comprehensive net loss:							
Net loss						(5,523,623)	(5,523,623)
Change in unrealized gain on available-for-sale securities					(4,695)		(4,695)
Comprehensive net loss							(5,528,318)
Balance at December 31, 2002	8,422,994	8,423	56,945,035	(4,469)	2,360	(51,603,064)	5,348,285
Issuance of common stock pursuant to private placement offering, net of cash offering costs	4,957,487	4,957	7,521,840				7,526,797
Issuance of warrant derivative contract, including placement agent warrants			(8,413,599)				(8,413,599)
Adjustment of value to options issued to consultants			44,851	(44,851)			—
Stock compensation				49,320			49,320
Components of comprehensive net loss:							
Net loss						(8,050,253)	(8,050,253)
Change in unrealized gain on available-for-sale securities					(2,360)		(2,360)
Comprehensive net loss							(8,052,613)
Balance at December 31, 2003	13,380,481	13,380	56,098,127	—	—	(59,653,317)	(3,541,810)
Issuance of common stock upon exercise of options and warrants	320,885	321	62,267				62,588
Warrant derivative contract reclassified as equity			12,388,810				12,388,810
Private placement cash offering costs			(87,756)				(87,756)
Components of comprehensive net loss:							
Net loss						(6,337,462)	(6,337,462)
Change in unrealized loss on available-for-sale securities					(678)		(678)
Comprehensive net loss							(6,338,140)
Balance at December 31, 2004	13,701,366	$13,701	$68,461,448	$ —	$ (678)	$(65,990,779)	$ 2,483,692

See accompanying notes.

PHYSIOMETRIX, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2004

1. The Company and Going Concern

The Company

Physiometrix, Inc. (the "Company") is engaged in the development, manufacturing and marketing of medical devices for use in neurodiagnostic monitoring in health care. The Company's principal product is the Patient State Analyzer ("PSA 4000") with the PSArray2, which is the frontal-only disposable array sensor which attaches to and is used with the Company's PSA 4000 consciousness-monitoring system. The Company's initial products were its e-Net headpiece and disposable HydroDot Biosensors and custom electronics, which are packaged as the HydroDot NeuroMonitoring System.

Going Concern

The Company is subject to numerous risks and uncertainties, including the need to raise additional capital to fund operations, research and development efforts and commercialize its products. Since its inception, the Company has incurred cumulative losses of approximately $66.0 million including losses of approximately $6.3 million during 2004, $8.1 million during 2003, and $5.5 million during 2002. The Company's principal source of liquidity at December 31, 2004 consists of cash, cash equivalents and short-term investments, which aggregate $2.6 million. The Company's net working capital at December 31, 2004 was $2.4 million. The Company had a net working capital deficit of $3.7 million at December 31, 2003, which was due primarily to a warrant derivative issued in connection with its common stock financing completed in December 2003, which raised net proceeds of approximately $7.5 million.

The Company believes its cash, cash equivalents and short-term investments on hand at December 31, 2004 are sufficient to conduct its operations only until the beginning of the third quarter of 2005, at which time the Company will be unable to meet its working capital needs. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is actively pursuing several sources of additional financing to address this uncertainty. There can be no assurances that management can secure additional financing under terms that are acceptable to the Company or at all. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company believes that the success of generating revenues as well as raising additional working capital are the most critical components to the Company's ability to continue as a going concern. The Company's plan for 2005 is to support the activities of its partner, Baxter, in the commercialization of the PSA 4000 with the new PSArray2, support the introduction of the PSA 5000, and raise additional working capital. The Company will make every attempt to conserve its cash resources and continue as a business. Although management and the current investors of the Company do not have any intention of liquidating the business, the Company would consider a sale of the technology if its cash constraints will not allow it to execute its plan. The Company is aware of one other company with similar products to the PSA 4000. The Company does not believe it will be at a significant disadvantage in marketing its products against this company.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in accordance with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash Equivalents and Short-Term Investments

Cash equivalents consist principally of United States Treasury bills and certificates of deposit with maturities of three months or less at the date of purchase. In addition, the Company has certain investments in commercial paper, U.S. government agencies and debt securities, which do not meet the definition of cash equivalents and have been classified as available-for-sale securities, and mature within one year.

Concentration of Credit Risk

One customer accounted for 89% and 87% of accounts receivable at December 31, 2004 and 2003, respectively, and 83% of 2004 revenues and 78% of 2003 revenues. The Company has specifically evaluated the creditworthiness of its major customer as well as other customers prior to shipment and establishes its allowance for doubtful accounts. The Company does not require collateral for its accounts receivable.

The Company purchases components from various suppliers and relies on single source suppliers for several parts. To date, the Company has not experienced any significant adverse effects resulting from shortages of components. The Company actively monitors inventory positions of all critical parts and purchases required materials in order to prevent productions delays.

Equipment

Equipment is recorded at cost and is depreciated using the straight-line method over its estimated useful life of three to five years.

Revenue Recognition

The Company recognizes revenue for product sales upon shipment, net of allowances for discounts and estimated returns which are also provided for at the time of shipment.

Stock-Based Compensation

The Company applies the principles of Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*," and related interpretations in accounting for its Plans. Under APB No. 25, compensation expense is measured as the difference, if any, between the option exercise price and the fair value of the Company's common stock at the date of grant. The Company has historically granted options to employees and directors at exercise prices equal to the fair value of the Company's

2. Summary of Significant Accounting Policies (Continued)

common stock. Accordingly, no compensation expense has been recognized for its employee stock-based compensation plans.

SFAS No. 123, "*Accounting for Stock-Based Compensation*," establishes a fair value based approach for valuing stock options. The Company follows the disclosure-only alternative afforded by SFAS No. 123, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure.* Had compensation costs for stock options issued to employees and directors been determined based on the estimated fair value at the grant dates as calculated in accordance with SFAS No. 123, the Company's reported net loss and basic and diluted net loss per common share for the years ended December 31, 2004, 2003 and 2002 would have been adjusted to the pro forma amounts indicated below:

	For the years ended December 31,		
	2002	2003	2004
Net Loss			
As reported	$(5,523,623)	$(8,050,253)	$(6,337,462)
Pro forma compensation expense	(656,863)	(624,921)	(558,553)
Pro forma net loss	$(6,180,486)	$(8,675,174)	$(6,896,015)
Basic and diluted loss per share			
As reported	$ (0.66)	$ (0.91)	$ (0.47)
Pro forma	$ (0.73)	$ (0.98)	$ (0.51)

The average estimated fair value of options granted during fiscal years 2002, 2003 and 2004, was $1.22, $0.48, and $2.17, respectively, and was estimated using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	2002	2003	2004
Dividend yield	None	None	None
Volatility	122%	127%	134%
Risk-free interest rate	4.10%	3.21%	3.16%
Expected life (years)	5.5	5.5	5.5

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

Net Loss Per Share

Basic net loss per share represents net loss divided by weighted average shares outstanding. Diluted net loss per share and basic net loss per share are the same since the Company has generated a net loss in 2002, 2003 and 2004. Therefore, the Company has excluded all common stock equivalents

2. Summary of Significant Accounting Policies (Continued)

from the calculation of diluted weighted average shares outstanding. As of December 31, 2004, 1,169,804 potential additional common shares were outstanding upon the exercise of stock options with a weighted average exercise price of $2.93 per share, but not included in the above calculation as their effect would have been anti-dilutive.

Recent Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 46, *Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin ("ARB") No. 51* ("FIN 46"). FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after December 15, 2003. The Company adopted FIN 46, as required, with no material impact to its consolidated financial position or results of operations.

In December 2004, the FASB issued Statement No. 123(R), *Share-Based Payment* (SFAS No. 123(R)). SFAS No. 123(R) replaces SFAS No. 123, supersedes APB No. 25 and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values (i.e., pro forma disclosure is no longer an alternative to financial statement recognition). The provisions of SFAS No. 123(R) must be applied at the beginning of the first interim or annual period beginning after June 15, 2005. The Company is in the process of evaluating the impact of this new pronouncement on its financial statements.

Financial Instruments

Financial instruments principally consist of cash equivalents, accounts receivable, accounts payable and warrant derivative. The estimated fair values of these financial instruments approximate their carrying values.

Warrant Derivative

The Company had a derivative liability associated with warrants issued in connection with its private placement transaction completed in December 2003 due to the possibility of the Company having to make a cash settlement, including penalties, in the event the Company failed to register the shares underlying the warrants under the Securities Act of 1933, as amended, within 90 days after the closing of the private placement transaction. The Company accounted for this warrant derivative in accordance with EITF 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock.* The warrants were included as a liability and valued at fair market value until the Company met the criteria under EITF 00-19 for permanent equity. The Company valued the derivative warrant using the Black-Scholes model. A registration statement covering the shares sold in the private placement, along with the shares underlying the warrants, was filed with the

2. Summary of Significant Accounting Policies (Continued)

Securities and Exchange Commission on Form S-3 on December 11, 2003 and was declared effective on February 5, 2004. Therefore, the value of the warrants was reclassified as equity in the first quarter of 2004 and there is no future cash settlement requirement on behalf of the Company.

Impairment of Long-lived Assets

The Company follows Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS No. 144)*, which requires that long-lived assets be measured at the lower of carrying amount of fair value less cost to sell.

Income Taxes

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes.* The Company uses the asset and liability accounting method whereby deferred tax assets and liabilities are recognized based on temporary differences between the financial statements and tax bases of assets and liabilities using current statutory tax rates. A valuation allowance against net deferred tax assets is recorded if, based on the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Management evaluates on a quarterly basis the ability to recover the deferred tax assets and the level of the valuation allowance. At such time as it is more likely than not that deferred tax assets are realizable, the valuation allowance will be appropriately reduced.

3. Inventories

Inventories are recorded at the lower of cost (first-in, first-out) or market, and consist of the following at December 31:

	2003	2004
Purchased components	$512,179	$111,921
Work in process	19,752	24,297
Finished units	28,363	14,225
	$560,294	$150,443

Provisions for excess inventory are primarily based on management's estimates of forecasted net sales levels.

4. Equipment

Equipment consists of the following at December 31:

	2003	2004
Computer equipment	$ 708,106	$ 737,222
Machinery and equipment	652,854	660,465
	1,360,960	1,397,687
Accumulated depreciation	(1,181,292)	(1,293,969)
	$ 179,668	$ 103,718

5. Accrued Expenses

Accrued expenses consist of the following at December 31:

	2003	2004
Payroll	$288,149	$331,722
Professional fees	411,778	92,079
Other	123,592	115,970
	$823,519	$539,771

6. Leases

The Company leases its administrative and manufacturing facility under a non-cancelable operating lease which expires in November 2005. Total rent expense was approximately $218,000 in 2002 and in 2003 and $187,000 in 2004. Future minimum operating lease payments as of December 31, 2004 are $175,781 in 2005, and $8,933 in 2006.

7. Warrant Derivative Liability

The Company had a derivative liability associated with warrants issued in connection with its private placement transaction completed in December 2003 due to the possibility of the Company having to make a cash settlement, including penalties, in the event the Company failed to register the shares underlying the warrants under the Securities Act of 1933, as amended within 90 days after the closing of the private placement transaction. The Company accounted for this warrant derivative in accordance with EITF 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock.* The warrants were included as a liability and valued at fair market value until the Company met the criteria under EITF 00-19 for permanent equity. The Company valued the derivative warrant using the Black-Scholes model. The derivative was valued at the date of the transaction in the amount of $8.4 million and then revalued at $11.3 million and $12.4 million on December 31, 2003 and February 5, 2004 respectively. The relevant assumptions included in the calculation in 2003 were a term of 5 years, an interest rate of 3.27% and a volatility of 1.67. The relevant assumptions included in the calculation in 2004 were a term of 4.83 years, an interest rate of 3.16% and a volatility of 1.57. A registration statement covering the shares sold in the private placement, along with the shares underlying the warrants, was filed with the Securities and Exchange

7. Warrant Derivative Liability (Continued)

Commission on Form S-3 on December 11, 2003 and was declared effective on February 5, 2004. Therefore, the value of the warrants was reclassified as equity in the first quarter of 2004 and there is no future cash settlement requirement on behalf of the Company.

8. Stockholders' Equity

Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock, $.001 par value, in one or more series, each of such series to have such rights and preferences, including voting rights, dividends rights, conversion rights, redemption privileges and liquidation preferences, as shall be determined by the Board of Directors. To date, no shares of preferred stock have been issued or are outstanding.

Common Stock and Warrants to Purchase Common Stock

On December 2, 2003, the Company entered into a definitive agreement for a private placement of public equity. The agreement was for the sale of 4,957,487 shares of Common Shares of the Company at $1.65 per share and the issuance of warrants to purchase up to 4,957,448 shares of Common Stock. Specifically, the warrants allow for the purchase of up to 2,478,724 shares of Common Stock at $1.82 per share and 2,478,724 shares of Common Stock at $2.48 per share. The Company also issued warrants to the placement agents for the purchase of up to 495,748 shares of Common Stock at $1.98 per share. All warrants expire December 5, 2008. As of December 31, 2004, the Company had 5,301,721 warrants outstanding at a weighted average exercise price of $2.14.

Stock Option Plans

The Company's 1991 Incentive Stock Plan (the 1991 Plan) provides for the issuance of incentive and non-statutory common stock options to employees, officers and consultants. The 1991 Plan provides for the granting of options to purchase up to 1,500,000 shares of the Company's common stock. Except for non-statutory options, the exercise price of the options granted under the Plan may not be less than 100% of the fair market value of the common stock subject to the option on the date of grant as determined by the Board of Directors. Generally, options granted under the 1991 Plan vest over a four-year period and expire ten years from the date of grant.

The Company's 1996 Director Option Plan (the Director Plan) provides that each non-employee director who becomes a director will be granted a non-statutory option to purchase 15,000 shares of common stock at its then fair market value. Annually thereafter, each non-employee director will be granted a non-statutory option to purchase 5,000 shares of common stock at its then fair market value. All options will vest ratably over four years and expire ten years after date of grant. The Director Plan provides for the granting of non-statutory options to purchase up to 150,000 shares of the Company's common stock.

The Company's 2000 Supplemental Stock Plan provides for the granting of non-statutory options to purchase up to 100,000 shares of the Company's common stock. The exercise price of the options granted under this plan may not be less than 100% of the fair market value of the common stock

8. Stockholders' Equity (Continued)

subject to the option on the date of grant as determined by the Board of Directors. Generally, options granted under this plan vest over a four-year period and expire ten years from the date of grant.

The Company's 2001 Incentive Stock Plan (the 2001 Plan) provides for the issuance of incentive and non-statutory common stock options to employees, officers and consultants. The 2001 Plan provides for the granting of options to purchase up to 1,500,000 shares of the Company's common stock. Except for non-statutory options, the exercise price of the options granted under the Plan may not be less than 100% of the fair market value of the common stock subject to the option on the date of grant as determined by the Board of Directors. Generally, options granted under the 2001 Plan vest over a four-year period and expire ten years from the date of grant.

A summary of option activity for the four plans is as follows:

	2002	Weighted Average Exercise Price	2003	Weighted Average Exercise Price	2004	Weighted Average Exercise Price
Outstanding at beginning of year	1,142,936	$3.61	1,312,144	$2.46	1,321,144	$2.44
Granted	320,000	1.22	15,000	0.55	197,500	2.43
Canceled	(149,750)	8.75	(6,000)	1.82	(68,052)	3.26
Exercised	(1,042)	.63	—	—	(280,788)	.22
Outstanding at end of year	1,312,144	$2.46	1,321,144	$2.44	1,169,804	$2.93
Exercise price range at end of year	$.04-$24.00		$.04-$24.00		$.55-$24.00	
Exercisable at end of year	828,389	$2.23	1,003,050	$2.52	852,514	$3.37
Available for grant at end of year	1,418,302		1,409,302		1,279,854	

The following table presents weighted average price information about significant option groups outstanding at December 31, 2004:

Exercise Price	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price
$ .55-$ .76	432,221	4.63	$ 0.71	386,576	$ 0.71
$ .82-$ 2.00	355,000	6.73	$ 1.35	239,739	$ 1.45
$ 2.15-$12.88	320,083	7.48	$ 4.64	164,011	$ 6.74
$15.69-$24.00	62,500	5.65	$18.40	62,188	$18.41
	1,169,804	6.10	$ 2.93	852,514	$ 3.37

The weighted average contractual life of options outstanding at December 31, 2004 was 6.1 years. The Company has reserved 2,449,658 shares for issuance under the Company's stock options plans and 5,301,721 shares for issuance upon exercise of warrants.

9. 401(k) Savings Plan

The 401(k) Savings Plan ("Savings Plan") allows all employees that have attained the age of 21 to make annual, tax-deferred contributions of up to 15% of their eligible compensation. Annually, the Company may make discretionary matching contributions based upon a percentage of the employees' contributions. The Company made no such contributions to the Savings Plan in 2002, 2003 or 2004.

10. Income Taxes

Since the Company has incurred only losses since inception, and due to the degree of uncertainty related to the use of the loss carryforwards, the Company has fully reserved its deferred tax assets. At December 31, 2004, the Company had tax net operating loss (NOL) carryforwards of approximately $52.4 million available to offset federal taxable income, which expire in varying amounts through 2024, and $31.7 million to offset state taxable income, which expire in varying amounts through 2009. The Company also has research and development tax credit carryforwards of approximately $1.6 million available to offset federal income taxes, which expire in varying amounts through 2024. In accordance with Section 382 of the Internal Revenue Code, the use of the above carryforwards may be subject to annual limitations based upon ownership changes of the Company's stock which may have occurred.

Significant components of the Company's deferred income taxes are as follows as of December 31:

	2003	2004
Net operating loss carryforwards	$18,463,000	$20,831,000
Research and development costs	2,401,000	2,141,000
Research and development tax credits	1,789,000	1,944,000
Inventory allowances	808,000	649,000
Other	7,000	6,000
	23,468,000	25,571,000
Valuation allowance	(23,468,000)	(25,571,000)
Net deferred tax asset	$ —	$ —

A reconciliation of the effective rate with the federal statutory rate is as follows:

	2002	2003	2004
Federal statutory rate	-34.00%	-34.00%	-34.00%
State income taxes, net of federal benefit	-6.00%	-6.00%	-6.00%
Permanent differences	0.00%	14.60%	6.60%
Change in valuation allowance	40.00%	25.40%	33.40%
Effective tax rate	0.00%	0.00%	0.00%

The valuation allowance increased by $2,103,000 in 2004 and $2,345,000 in 2003 due primarily to the fact that the Company has not benefited its current year net operating losses due to uncertainty regarding future taxable income.

During 2003 and 2004, approximately $4.8 million and $3.5 million, respectively, of the Company's state NOL carryforwards expired and will not be available to offset future state taxable income, if any.

10. Income Taxes (Continued)

If unused, the Company's state NOL carryforwards expire after five years of the period in which they are generated. At December 31, 2004, the Company had $31.7 million of state NOL carryforwards available, which, if unused, will expire according to the following schedule:

Amount of NOL Carryforward	Year NOL Generated	Year NOL Expires
$ 3,935,000	2000	2005
8,401,000	2001	2006
6,757,000	2002	2007
6,339,000	2003	2008
6,276,000	2004	2009
$31,708,000		

The Company's federal NOL carryforwards expire at various dates through 2024; however, significant portions of the federal NOL carryforwards begin to expire in 2009. Due to the uncertainty surrounding the realizability of the NOL carryforwards, the Company has fully reserved these deferred tax assets.

11. Distribution Agreement

The Company has a distribution agreement with Baxter Healthcare Corporation ("Baxter"), which provides Baxter with exclusive distribution rights to The Company's PSA 4000 in the United States and Canada. The agreement extends through termination, but is cancelable by either party upon six months notice after December 31, 2003. Under the terms of the agreement, as amended in February 2003, if Baxter fails to meet minimum purchase commitments, the Company has the option to convert their distribution agreement into a non-exclusive relationship for the OR market segment. In 2003 and 2004, Baxter failed to meet minimum purchase requirements, however, the Company has not enforced its rights to change the terms of the agreement, including Baxter's exclusivity rights.

12. Related Party Transactions

The Company had a loan outstanding to an officer in the amount of $84,000 at December 31, 2001. During 2002, the loan was forgiven and recorded as compensation expense.

13. Segment Information

The Company is focused on one business segment related to medical devices for use in neurodiagnostic monitoring in healthcare. All of the Company's revenues in 2002, 2003 and 2004 have been to customers located within the United States. All of the Company's assets and operations are located within the United States.

14. Valuation and Qualifying Accounts

A rollforward of the Company's allowance for doubtful accounts is as follows:

Year Ended	Balance at Beginning of year	Additions	Write-offs	Balance at End of year
December 31, 2002	$5,453	—	$ (659)	$4,794
December 31, 2003	$4,794	—	$ (453)	$4,341
December 31, 2004	$4,341	—	$(2,205)	$2,136

Officers
John A. Williams
President and
Chief Executive Officer

Daniel W. Muehl
Vice President, Finance & Administration
and Chief Financial Officer

Directors
John A. Willliams
President and
Chief Executive Officer

Thomas R. Baruch
Chairman of the Board
General Partner,
CMEA

Christopher D. Mitchell
Partner
Wilson, Sonsini, Goodrich & Rosati, P.C.

James A. Saalfield
Managing General Partner
Still River Mgt. Company, Inc.

Corporate Information

Corporate Headquarters
101 Billerica Ave.
No. Billerica, MA 01862
Phone: (978) 670-2422
Fax: (978) 670-2817

Legal Counsel
Wilson, Sonsini, Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304

Form 10-K Annual Report
A copy of Physiometrix, Inc. Annual Report on Form 10-K as filed with the Securities and Exchange Commission, is available without charge. Please direct your request to:
Investor Relations
Physiometrix, Inc.
101 Billerica Ave.
No. Billerica, MA 01862

Transfer Agent
American Stock Transfer & Trust Company
59 Maiden Lane
New York, NY 10038

Independent Accountants
Ernst & Young, LLP
200 Clarendon Street
Boston, MA 02116

Annual Meeting
The Annual Meeting of Shareholders will be held on July 28, 2005 at 10:00 am, at
Physiometrix, Inc.
101 Billerica Ave., North Billerica, MA 01862

Stock Profile and Activity
Physiometrix' common stock is traded on NASDAQ under the symbol PHYX.

As of December 31, 2004, there were 70 registered holders of the Company's common stock. The Company has not paid dividends on its common stock since inception and does not anticipate paying any cash dividends in the near future

Year Ended December 31, 2004	High	Low
First Quarter	$3.070	$1.650
Second Quarter	$1.710	$1.170
Third Quarter	$2.390	$1.300
Fourth Quarter	$2.110	$0.880