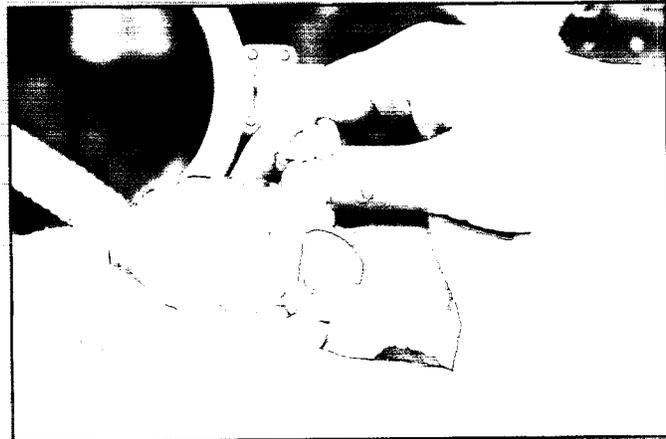


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Biosensor Solutions for Critical Care

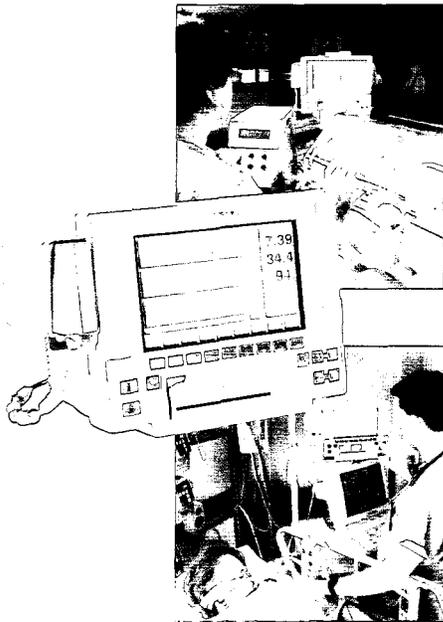
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FINANCIAL

2001 Annual Report
DIAMETRICS MEDICAL, INC.

CONTINUOUS MONITORING



Trendcare® with Neotrend® L Sensor

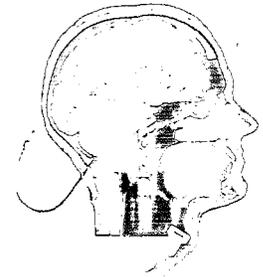
The Trendcare monitor and the Neotrend multi-parameter sensor is the first and only system for continuous monitoring of blood gases and temperature in critically ill newborns. The Neotrend system enables real-time availability of this information, aiding the prevention of life-long health complications these tiny patients can develop.

Trendcare® with Paratrend® 7 Sensor

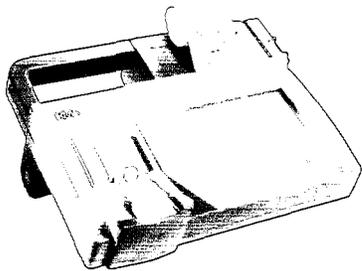
The Trendcare monitor and Paratrend intra-arterial sensor provide continuous, real-time respiratory and metabolic information for critically ill adult and pediatric patients. Trendcare provides a new and optimized way for delivering patient care, improving clinical management protocols, and reducing turnaround time for therapeutic intervention.

Neurotrend®

The Neurotrend Cerebral Tissue Monitoring System is the first commercially available product that can continuously measure four critical areas of brain metabolism - O₂, CO₂, pH and temperature. Information from the Neurotrend system can assist the physician's treatment plan by providing indications of ischemia and hypoxia in patients with closed head trauma or those undergoing surgery in the brain.



INTERMITTENT TESTING

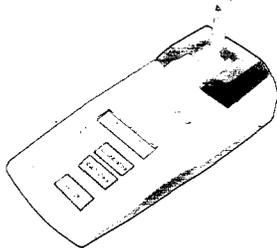


IRMA® SL Blood Analysis System

The IRMA SL Blood Analysis System delivers laboratory quality blood test results where they are needed most - at the patient's side. IRMA is intended for use in adult, pediatric, and neonatal intensive care; surgery, post-anesthesia, patient transport; and emergency department applications. Point-of-care diagnostic blood testing is designed to reduce turnaround time, improve clinical protocols and staff efficiency, and contribute to improved patient outcomes.

Cartridges

Diametrics' proprietary cartridges can be used on both the IRMA System and the Blood Analysis Portal System. Cartridges come in a variety of configurations supporting pH, PCO₂, pO₂, Na⁺, K⁺, Cl⁻, iCa, Glucose, BUN/Urea, and Hct measurements. Calculated and derived values are also supported.

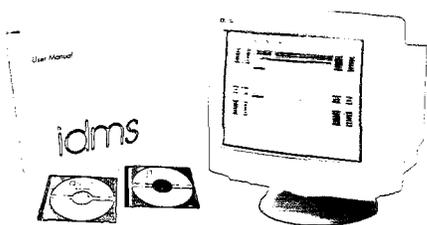


Blood Analysis Portal System

The Blood Analysis Portal System provides a completely new and optimized way of delivering patient care. The system is designed for use with Philips' CMS and V24/V26 monitors in all acute care settings, integrating biochemical and physiological information needed to optimize patient care.



DATA MANAGEMENT



Integrated Data Management System (idms™)

The Integrated Data Management System allows for biochemical data and device integration. Information is uploaded through various connectivity options into the idms system, which is the central command station for applications needed to manage the customer's point-of-care diagnostic program.

Diametrics Medical, Inc. develops and manufactures critical care blood and tissue analysis systems that provide immediate or continuous diagnostic results at the point-of-patient care. Diametrics' blood and tissue analysis systems consist of two biosensor technology platforms. The first platform includes intermittent blood testing products based upon electrochemical technology, consisting of the IRMA® SL Blood Analysis System and the Philips' Blood Analysis Portal System. The second platform includes continuous monitoring products based upon fiberoptic technology, consisting of the Trendcare® continuous blood gas monitoring systems and the Neurotrend® Cerebral Tissue Monitoring System.

The IRMA and Portal systems feature portability and measurement integration, allowing caregivers immediate turn-around of biochemical information from blood samples injected into single use disposable cartridges. Results are viewed, printed, and/or transmitted for blood gases, electrolytes, glucose, blood urea nitrogen and hematocrit. The Philips' Blood Analysis Portal System integrates seamlessly with the Philips' CMS acute care patient monitoring system and V24/V26 intermediate care patient monitors. Both systems use standard Diametrics' cartridges and deliver results in approximately 90 seconds at the patient's bedside. Complementing both the IRMA and Portal systems is the Integrated Data Management System ("idms"), an advanced software application specially designed to receive, manage and transmit data captured from point-of-care diagnostic instruments. The Integrated Data Management System manages point-of-care test results and information from multiple devices; provides convenient sorting, viewing and analysis capabilities for trending, reporting and archiving data; and is the central command station for managing the point-of-care diagnostics program.

The Trendcare system, including Paratrend® 7 and Neotrend® applications, provides immediate and continuous information on blood gases and temperature in adult, pediatric and neonatal patients via a small fiberoptic sensor placed through the patient's arterial catheter. Neurotrend continuously monitors oxygen, carbon dioxide, acidity and temperature through sensor placement directly in brain tissue or fluids, providing critical information that can guide clinicians and surgeons in treating patients with head trauma or those requiring surgical intervention in the brain.

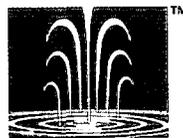
Intermittent blood testing products and Trendcare continuous monitoring systems are distributed by Philips Medical Systems. The Company's Neurotrend Cerebral Tissue Monitoring System is distributed through CODMAN, a Johnson & Johnson company.

Partnerships



PHILIPS

Let's make things better.



COOK®
GROUP
INCORPORATED

Codman
a Johnson & Johnson company

tyco

Healthcare

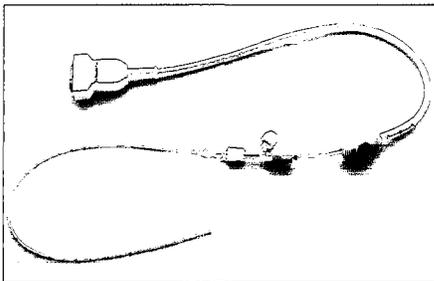
LIFESCAN

a Johnson & Johnson company

The year 2001 was a challenging one for Diagnostics. While we made impressive progress in strengthening our blood and tissue analysis product portfolio during the year, market penetration of our existing products remains a significant challenge for us and our corporate partners. During the year our employees again demonstrated that they have the skills, loyalty and endurance to stay the course and ultimately deliver the exciting upside our company offers to all of its stakeholders.

Continuous Monitoring

For Diagnostics' continuous monitoring biosensor technology platform, Tyco and Cook, market leaders in their respective fields, have launched access devices which enhance use of our sensors. Diagnostics' new Neotrend® L sensor is compatible with Tyco's Argyle® umbilical artery catheters, thereby expanding the potential market for Philips



Medical Systems ("Philips") commercialization of this product. Correspondingly, in the adult and pediatric market, Cook's uniquely differentiated kink resistant catheter affords improved access and ease of use with Diagnostics' Paratrend® 7 sensor, and provides assurance that the data stream

produced by our sensor will not be interrupted on its way to the monitor screen.

Diagnostics' continuous monitoring development activities in 2001 were centered around the development of a continuous blood monitoring system for integration with critical care patient monitors and other medical devices. This system will integrate with other technologies to facilitate monitor display of both continuous biochemical and physiological information at the patient's bedside, and to direct therapy. Products from

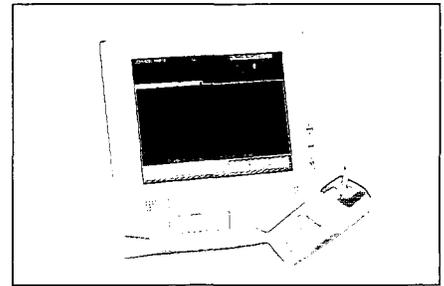


this program, which also includes a new calibrator and monitor, are scheduled to begin market introduction during 2003. The potential for further miniaturization and integration of Diagnostics' continuous sensor technology holds great promise for future application to "closed loop" therapy management systems.

Intermittent Testing

Diagnostics' system miniaturization and integration goals were achieved for our intermittent testing products through a joint development program with Philips to produce the Blood Analysis Portal System ("Portal"). Shipments of Portal began in February 2002 with

early indications that Philips' customer base has a high degree of interest in this device



for the benefits afforded by the integration of biochemical and physiological measurements on the patient monitor screen.

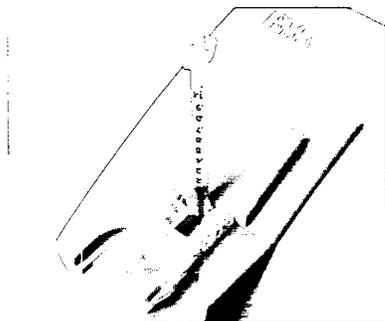
During 2001 and early 2002 Diagnostics introduced exciting new enhancements to its Integrated Data Management System ("idms"), resulting in an advanced software application specially designed to receive, manage and transmit data captured from point-of-care diagnostic instruments and to serve as the central command station for managing the point-of-care diagnostics program. The Integrated Data Management System manages point-of-care



test results and information from multiple devices and provides a variety of functions for displaying, reporting and storing patient results. It also provides capabilities which address quality control and regulatory requirements. The Integrated Data Management System

supports both the IRMA and the new Blood Analysis Portal systems.

Other significant developments for the intermittent testing product line included the receipt of FDA clearance to market tests for glucose and lactate for use with the Company's IRMA® SL Blood Analysis System. The "GL" cartridge panels glucose with sodium, potassium and chloride, and is scheduled for market release in the second quarter 2002. The lactate



test will be incorporated on a future cartridge panel. In the critical care setting, glucose testing is used to monitor diabetic patients as well as patients undergoing surgical procedures. Lactate testing is used to detect, treat and monitor decreased tissue oxygenation, primarily associated with shock, hypovolemia, and heart failure; as well as to monitor certain metabolic conditions.

With an enriched product portfolio, partnerships with Philips Medical Systems and Johnson & Johnson Codman, and continued research and development emphasis on taking full advantage of our proprietary position in electro-chemical and fiberoptic

biosensor technologies, Diametrics intends to be a market leader in bringing biosensor based solutions to the care of critically ill patients.

We thank you, our shareholders, for your support over the past year. We will work diligently with our corporate partners to further raise the quality of our execution during 2002, and will not rest as we pursue the upside and value resident in the assets of this company. We look forward to further communicating with you during the course of the year.

Yours very truly,

David T. Giddings
Chief Executive Officer &
President

André de Bruin
Chairman of the Board

THE VOICE OF THE CUSTOMER

"The ability to observe real-time blood gas changes in the very small or very sick newborn with the **Neotrend** system fundamentally changes the way we think about therapy. It's not just what we see now, it's what we missed previously."

Mark Mammel, MD

*Director Research and Education,
Associate Director of Newborn Medicine,
Children's Healthcare, St. Paul, Minnesota, USA*

"We have used **Paratrend 7** monitoring in over one hundred critically ill children. Every child requiring high frequency oscillatory ventilation is monitored with this product. We believe that using continuous blood gas analysis for this subset of patients is a clinical necessity."

Joseph Britto, MD

Consultant and Hon. Senior Lecturer in Paediatric Intensive Care, Department of Paediatrics, Imperial College School of Medicine at St. Mary's Hospital, London, UK

"I have over five years of experience with the **Neurotrend** system for monitoring brain tissue oxygenation and metabolism, and find it useful in helping influence management of patients with severe brain injury. We are planning to use Neurotrend monitoring as a standard of care in the severe head injured patients that are admitted to our Neurointensive Care Unit as part of our multi-modal brain monitoring system."

Dr Arun K Gupta, MBBS MA FRCA

*Director of Neuro Critical Care and
Consultant in Anaesthesia, Addenbrooke's Hospital,
Associate Lecturer, University of Cambridge,
Cambridge, UK*

"We have been using the **IRMA** system for over five years. The IRMA provides fast, accurate and reliable results, and also enables the user to define levels of security, amount of data captured, reportable tests, and quality control lockout settings necessary to ensure regulatory compliance."

Dave Colard, MT(ASCP)

*Point of Care Testing Coordinator, Clinical Pathology
St. Luke's Hospital, Kansas City, Missouri, USA*

Shareholder and Corporate Information

EXECUTIVE OFFICERS

David T. Giddings
President and Chief Executive Officer

Roy S. Johnson
Executive Vice President and
President and Managing Director of
Diametrics Medical, Ltd.

Laurence L. Betterley
Senior Vice President and Chief Financial Officer

STOCK LISTING

The Company's common stock is traded on The
Nasdaq National Market under the symbol DMED.

STOCK TRANSFER AGENT

American Stock Transfer & Trust Company
40 Wall Street
New York, NY 10005
Phone: (800) 937-5449

FORM 10-K

A copy of the Company's annual report on Form 10-K
as filed with the Securities and Exchange Commission
is available to shareholders free of charge by writing to
Diametrics Medical, Inc.

ANNUAL MEETING

The annual meeting of Diametrics Medical, Inc. share-
holders will be held May 22, 2002 at 3:30 p.m. at the
Company's corporate headquarters. All shareholders
and other interested parties are invited to attend.

INVESTOR INQUIRIES

Please direct all inquiries to Laurence L. Betterley,
Senior Vice President and Chief Financial Officer, at
the Company's corporate headquarters.

DIRECTORS

André de Bruin (1)
Chairman of the Board of Diametrics Medical, Inc. and
Chairman of the Board of QUIDEL Corporation

Gerald L. Cohn (1) (2)
Consultant and Private Investor

David T. Giddings

Carl S. Goldfischer, M.D. (2)
Private Investor and Limited Partner of Bay City Capital

Roy S. Johnson

Mark B. Knudson, Ph.D. (1) (2)
Chairman and CEO of Venturi Group, LLC,
President and CEO of Pi Medical, Inc. and
Chairman and Founder of HeartStent Corporation

(1) Member of the Compensation Committee of the Board of Directors

(2) Member of the Audit Committee of the Board of Directors

CORPORATE HEADQUARTERS

Diametrics Medical, Inc.
2658 Patton Road
St. Paul, Minnesota 55113
Phone: (651) 639-8035
Website: www.diametrics.com

INTERNATIONAL SUBSIDIARY

Diametrics Medical, Ltd.
5 Manor Court Yard, Hughenden Ave.
High Wycombe, Bucks. HP13 5RE
England
Phone: +44 (0) 1494 446651
Website: www.dmladmin.co.uk

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

FORM 10-K

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

For the fiscal year ended December 31, 2001

or

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

Commission file number 0-21982

DIAMETRICS MEDICAL, INC.

(Exact name of registrant as specified in its charter)

MINNESOTA
(State or other jurisdiction of
incorporation or organization)

41-1663185
(IRS Employer
Identification Number)

2658 Patton Road
Roseville, Minnesota
(Address of principal executive offices)

55113
(Zip Code)

Registrant's telephone number, including area code: (651) 639-8035

Securities registered pursuant to Section 12(b) of the Act: None
Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$.01 par value

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.

Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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.

As of February 28, 2002, 26,804,862 shares of Common Stock were outstanding, and the aggregate market value of the common shares (based upon the closing price on said date on The Nasdaq National Market) of DIAMETRICS MEDICAL, INC. held by non-affiliates was approximately \$112,600,000.

Documents Incorporated by Reference

Parts of the Registrant's definitive Proxy Statement for the 2002 Annual Meeting of Shareholders to be held on May 22, 2002 are incorporated by reference in Part III hereof.

PART I

Unless the context otherwise indicates, all references to the "Registrant," the "Company," or "Diametrics" in this Annual Report on Form 10-K are to Diametrics Medical, Inc., a Minnesota corporation, incorporated in January 1990, and where the context requires, its subsidiary, Diametrics Medical, Ltd. ("DML").

The following federally registered trademarks of the Company are used in this Annual Report on Form 10-K: Diametrics Medical, Inc.[®], IRMA[®]SL, Paratrend[®] 7, Neotrend[®], Neurotrend[®] and Trendcare[®]. SureStep[®]Pro is a registered trademark of LifeScan, a Johnson & Johnson company. Argyle[®] is a registered trademark of Tyco Ludlow.

Item 1. Business

Overview

The Company develops, manufactures and commercializes blood and tissue analysis systems that provide immediate or continuous diagnostic results at the point-of-patient care. Since its commencement of operations in 1990, the Company has transitioned from a development stage company to a full-scale development, manufacturing and marketing organization (primarily through distributors). The Company's goal is to be the world leader in critical care blood and tissue analysis systems. The Company markets and distributes its products primarily through two global distribution partnerships with Philips Medical Systems ("Philips"), a division of Royal Philips Electronics, and Codman & Shurtleff, Inc., a Johnson & Johnson company ("Codman").

Blood and tissue analysis is an integral part of patient diagnosis and treatment, and access to timely and accurate results is critical to effective patient care. The Company believes that its blood and tissue analysis systems will result in more timely therapeutic interventions by providing accurate, precise and immediate or continuous test results, thereby allowing faster patient transfers out of expensive critical care settings and reducing patient length of stay. In addition, point-of-care testing can save money for hospitals by reducing the numerous steps, paperwork and personnel involved in collecting, transporting, documenting and processing blood and tissue samples. Moreover, point-of-care blood and tissue analysis systems could ultimately eliminate the need for hospitals to maintain expensive and capital intensive stat laboratories.

The Company has two primary product platforms. The first platform includes intermittent blood testing products based primarily on electrochemical biosensor technology (the IRMA SL blood analysis system and the Blood Analysis Portal measurement module). The second platform includes continuous monitoring products based upon fiberoptic biosensor technology (the Trendcare continuous blood gas monitoring systems and the Neurotrend cerebral tissue monitoring system).

Since its inception in 1990, the Company has developed, manufactured and marketed the IRMA ("Immediate Response Mobile Analysis") System, an electrochemical-based blood analysis system that provides rapid and accurate diagnostic results at the point-of-patient care. The IRMA SL System consists of a portable, microprocessor-based analyzer that employs single-use, disposable cartridges to perform simultaneously several of the most frequently ordered blood tests in a simple 90-second procedure. The Company's first disposable electrochemical cartridge, introduced in May 1994, performs three of the most frequently ordered blood tests for critical care patients—the measurement of oxygen, carbon dioxide and acidity (the "blood gases"). In June 1995, the Company expanded the IRMA System test menu with the introduction of its electrolyte cartridge which measures inorganic compounds including sodium, potassium and ionized calcium. The Company further expanded its critical or "stat" test menu during the third quarter of 1996 with the release of the second-generation system, IRMA SL, and the addition of the measurement of hematocrit (i.e., the concentration of red blood cells in whole blood) to its electrolyte cartridge. With these measurements and associated calculated values, the IRMA SL System is able to perform the majority of the critical or stat tests performed annually in the United States, comprising an estimated \$1.2 billion annual market.

In 1997, the Company introduced its third-generation system, IRMA SL Series 2000, and a new combination cartridge. The combination cartridge is based upon the Company's "snapfit" cartridge design and gives clinicians the ability to perform all critical blood gas, electrolyte and hematocrit tests using one small blood sample and one single-use cartridge. During 1998, the Company expanded the test menu of the IRMA System by integrating the LifeScan (a Johnson & Johnson company) SureStepPro glucose strip testing module into the analyzer. In 2000, the Company introduced its H4 single-use cartridge, which adds both chloride and blood urea nitrogen ("BUN") to a test panel of sodium, potassium and hematocrit.

During the first quarter of 2002, the Company released its Blood Analysis Portal measurement module, which was co-developed with Philips and provides the analyte measurement capability of Philips' new Blood Analysis Portal System. The Blood Analysis Portal System incorporates the technology of the IRMA SL System and plugs directly into Philips' monitoring systems to allow for an integration of blood test and physiological measurements at the patient's bedside. Also scheduled for market release in the second quarter of 2002 is a new single-use cartridge which panels glucose with sodium, potassium and chloride electrolytes ("GL"). Under development are additional blood tests for lactate and creatinine, and a reusable version of the single-use disposable cartridge which the Company plans to integrate into its next generation analyzer.

In the fourth quarter of 1996, the Company established its second product platform with the introduction of a number of new products through the acquisition of Biomedical Sensors, Ltd. ("BSL"), a Pfizer company. With the acquisition of BSL (now known as Diametrics Medical, Ltd.), the Company acquired a world-class continuous monitoring fiberoptic biosensor technology platform, which complements the Company's existing intermittent testing electrochemical biosensor platform. This product line includes continuous monitoring systems, consisting of a monitor, calibrator and intravascular disposable sensors. Primary products include the Trendcare continuous blood gas monitoring systems, consisting of Paratrend 7, which provides direct continuous monitoring of blood gases and temperature in critically ill adult and pediatric patients, and Neotrend, which provides direct continuous monitoring of blood gases and temperature in critically ill newborn babies; and the Neurotrend cerebral tissue monitoring system, which measures oxygen, carbon dioxide, acidity and temperature in brain tissue and fluids as an indication of cerebral ischemia (i.e., deficient blood supply to the brain) and hypoxia (i.e., inadequate oxygenation of the blood) in patients with severe head injury and in patients undergoing surgical intervention in the brain.

The Company has obtained clearances under Section 510(k) of the Food Drug and Cosmetic Act (the "FDC Act") to market in hospital laboratories and at the point-of-patient care the IRMA SL System to test blood gases, electrolytes, glucose, lactate, BUN and hematocrit in whole blood, the Paratrend 7 and Neotrend to monitor blood gases and temperature, and the Neurotrend system to monitor oxygen, carbon dioxide, acidity and temperature in the brain. Additionally, in the first quarter of 1998, the Company received clearance from the United States Food and Drug Administration (the "FDA") to market the multi-use cartridge for its IRMA SL System. The multi-use cartridge is planned to be available on the Company's next generation analyzer, currently under development. The Company has also gained CE Mark approval under the applicable directives for the IRMA SL System and the Paratrend 7, Neotrend and Neurotrend continuous monitoring products, allowing these products to be marketed in Europe.

In October 1998, the Company entered into an exclusive distribution agreement with Codman for worldwide market development and distribution of the Company's Neurotrend monitoring system. The term of the agreement is for six years and is renewable for two years. If minimum sales levels and marketing expenditure levels are not achieved by Codman, certain payments will be due to the Company. Also, Codman has the right of first refusal to market new continuous monitoring products developed for the neuro market.

On June 7, 1999, the Company and Hewlett Packard Company ("HP") announced that HP had signed an exclusive worldwide distribution agreement to market, sell and distribute the Company's Trendcare continuous blood-gas monitoring systems and the IRMA SL point-of-care blood analysis system. Under the terms of the distribution agreement, the Company transferred full responsibility for marketing, sales and distribution of these

products to HP. The initial term of the distribution agreement is three and a half years, with the option for extensions. The distribution agreement also provides for minimum purchase commitments of the Company's products, market development commitments, research and development funding and royalty payments. In November 1999, HP assigned the distribution agreement, with all its related rights and obligations, to Agilent Technologies, Inc. ("Agilent"), a leading provider of test and measurement solutions and communications components. Agilent was formed as a new company and subsidiary of HP in November 1999. HP spun-off its ownership in Agilent to HP shareholders during 2000. In August 2001, Agilent completed the sale of its healthcare business to Royal Philips Electronics, including its equity investment in the Company. Also as part of this transaction, the distribution agreement between the Company and Agilent was assigned to Philips Medical Systems, a division of Royal Philips Electronics. The initial term of the distribution agreement ends on October 31, 2002, with the option for three three-year extensions. The Company is discussing various options for the possible continuation of a relationship with Philips following the end of the initial term, which could include a continuation of the distribution relationship with Philips under modified terms yet to be determined.

The Company's principal executive office is located at 2658 Patton Road, Roseville, Minnesota 55113, and its telephone number is (651) 639-8035.

Principal Products

Additional information regarding the Company's principal products is provided below:

IRMA SL Series 2000 Blood Analysis System. The IRMA SL Series 2000 ("IRMA SL System"), the third generation IRMA blood analysis system, was released in the third quarter 1997. The IRMA SL System is comprised of the IRMA SL analyzer and a variety of electrochemical-based disposable cartridges which perform select combinations of the most frequently ordered critical care diagnostic tests of blood gases, electrolytes, hematocrit and BUN in a simple 90-second procedure. The IRMA SL System also features electronic quality control, as an alternative to aqueous quality control measures, which eliminates the need for this costly and time-consuming process for many customers.

The IRMA SL analyzer is a battery or AC operated, portable, microprocessor-based instrument weighing approximately four pounds, and includes an on-board printer. The analyzer can be easily linked for data downloading purposes to a hospital's laboratory or information system.

In conjunction with a marketing alliance reached in 1997 with LifeScan, the Company incorporated blood glucose monitoring into the IRMA platform by integrating LifeScan's SureStepPro Glucose Module into the IRMA SL System. The Company began marketing the new integrated workstation during the first half of 1998. The Company also plans to release to the market in the second quarter 2002 a new single-use cartridge for use with the IRMA SL System which panels glucose with existing electrolytes, called the GL cartridge.

Blood Analysis Portal Measurement Module. The Blood Analysis Portal measurement module ("Portal measurement module"), released in the first quarter of 2002, was co-developed with Philips and provides the analyte measurement capability of Philips' new Blood Analysis Portal System ("Portal System"). The Portal System incorporates the technology of the IRMA SL System and is designed for use with Philips' monitoring systems, enabling similar benefits available with the IRMA SL System, and additionally providing for an integration of blood test and physiological measurements at the patient's bedside. The Portal System utilizes the same electrochemical-based disposable cartridges available with the IRMA SL System and delivers results in approximately 90 seconds for blood gases, electrolytes, hematocrit, chemistries and other calculated values. The Portal System also features electronic quality control, and requires aqueous quality control only before a new cartridge lot is put into use. The Portal System is designed for use with Philips' monitors in adult, pediatric, and neonatal intensive care, as well as operating room, post-anesthesia and emergency care settings.

The Integrated Data Management System—"idms". Initially released in 1996, the Integrated Data Management System (formerly referred to as "IDMS") is an advanced software application specially designed

to receive, manage and transmit data captured from point-of-care diagnostics instruments. The Integrated Data Management System integrates point-of-care test results and information from multiple devices, and provides convenient sorting, viewing and analysis capabilities for trending, reporting, and archiving data. An enhanced version, released in the second quarter of 2001, provides point-of-care program management tools to track operators and devices for quality control and regulatory purposes, and is language-enabled. The Integrated Data Management System was further enhanced with a new release in the first quarter 2002 that accommodates the device settings and information management needs of the new Blood Analysis Portal System, in addition to the IRMA SL System and other point-of-care diagnostic instruments. The Integrated Data Management System also seamlessly transfers point-of-care results to other laboratory, hospital, or clinical information systems.

Capillary Collection Device. The Capillary Collection Device was initially introduced in 1996 and was enhanced in the third quarter of 2000 with a new design. The Capillary Collection Device is a disposable component of the IRMA SL System and provides the capability to collect and inject a capillary blood sample. It is used with the IRMA SL System's single use cartridges to perform blood gas, electrolyte, hematocrit and BUN testing. The capillary collection device has applications in neonatal and pediatric intensive care units, and in other situations where a capillary sample is preferred over an arterial or venous sample.

Trendcare Continuous Blood Gas Monitoring System. The Trendcare continuous blood gas monitoring system ("Trendcare"), consists of a monitor, patient data module and calibration system which provides the platform for the Paratrend 7 and Neotrend intravascular disposable sensors (described below). The Trendcare monitor displays trended patient data which allows constant surveillance of the patient's condition, while the patient data module stores critical calibration and patient information which moves with the patient during transfers. The real-time patient information delivered by Trendcare can signal the onset of adverse events and immediately identifies the impact of ventilator and resuscitation therapy.

- **Paratrend 7.** Paratrend 7 is the Company's second generation sensor for its continuous monitoring products, and is the only multi-parameter sensor for in-vivo direct continuous monitoring of blood gases and temperature in critically ill adult and pediatric patients. Inserted via an arterial catheter, the sensor provides constant, precise measurement of vital blood gas parameters. The new technology uses a fluorescent optical sensor for monitoring oxygen, replacing the electrochemical version of its predecessor. The Company received FDA clearance in October 1997 to market the Paratrend 7 in the United States, and received CE Mark approval in May 1998, allowing the system to be marketed in Europe. During 2000, the Company released a modified version of this sensor, Paratrend 7+, which provides a dial-in introducer system as an alternative to the telescopic introducer of Paratrend 7. The dial-in introducer allows single-handed advancement of the sensor into an arterial line, facilitating ease of use.

- **Neotrend.** Based upon the fluorescent optical sensor technology introduced with the Paratrend 7, Neotrend is the only multi-parameter system for direct continuous monitoring of blood gases and temperature in critically ill newborn babies, delivering real-time respiratory and metabolic information at the point-of-care. The Company received FDA clearance in December 1997 to market Neotrend in the United States, and received CE Mark approval in May 1998, allowing the product to be marketed in Europe. In early 2001, the Company released a modified version of this sensor, Neotrend L, which is compatible with Argyle 3.7-Fr. and 5.0-Fr. umbilical artery catheters, offering the convenience of use with this widely accepted and utilized catheter brand. The Neotrend L will replace the former version of this sensor during 2002.

Neurotrend Cerebral Tissue Monitoring System. The Neurotrend cerebral tissue monitoring system ("Neurotrend") is designed for direct continuous monitoring of oxygen, carbon dioxide, acidity and temperature in brain tissue and fluids as an indication of cerebral ischemia and hypoxia in patients with severe head injury, and also for use during surgical intervention in the brain. Neurotrend continuously measures these parameters through a small fiberoptic sensor placed directly into the brain tissue or fluids. CE Mark approval was received in the second quarter 1998, allowing the system to be marketed in Europe, and the Company received clearance from the FDA in November 1999, allowing the system to be marketed in the United States.

Regulatory Status

Human diagnostic products are subject, prior to clearance for marketing, to rigorous pre-clinical and clinical testing mandated by the FDA and comparable agencies in other countries and, to a lesser extent, by state regulatory authorities. The Company and its products are regulated by the FDA under a number of statutes including the FDC Act. The FDC Act provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FDC Act, wherein the manufacturer gives the FDA a pre-market notification of the manufacturer's intention to commence marketing the product. The manufacturer must, among other things, establish that the product to be marketed is substantially equivalent to another legally marketed product. Marketing may commence when the FDA issues a letter finding substantial equivalence. A 510(k) clearance is subject to continual review, and later discovery of previously unknown problems may result in restrictions on the product's marketing or withdrawal of the product from the market. If a medical device does not qualify for the 510(k) procedure, the manufacturer must file a pre-market approval ("PMA") application. This procedure requires more extensive pre-filing testing than the 510(k) procedure and involves a significantly longer FDA review process.

The Company has obtained clearances under Section 510(k) of the FDC Act to market the IRMA SL System to test blood gases, electrolytes, hematocrit, glucose, lactate and BUN in whole blood in hospital laboratories and at the point-of-patient care. The multi-use cartridge, which allows multiple test panels to be performed on a single cartridge, received clearance during 1998. The multi-use cartridge is planned to be available on the Company's next generation analyzer, currently under development. Continuous monitoring products which have been cleared under Section 510(k) include the monitoring systems used with the Paratrend 7 sensor for direct continuous monitoring of blood gases and temperature in adults and pediatric patients, the Neotrend sensor for monitoring of blood gases and temperature in critically ill newborn babies, and the Neurotrend sensor designed for direct continuous monitoring of oxygen, carbon dioxide, acidity and temperature in brain tissue or fluids as an indication of cerebral ischemia and hypoxia in patients with severe head injury and also for use during surgical intervention in the brain.

Prior to clearance for marketing in Europe, the Company's products must also meet regulatory standards outlined in several directives administered by the European Union. Compliance with applicable directives and achievement of CE Mark approval is based upon conformity assessment to the essential requirements stated in the directive. In order for manufacturers to affix CE Mark to their products, allowing the products to be marketed in Europe, they must follow the conformity assessment procedures applicable to the classification of the product, and prepare a declaration of conformity. Once gained, the CE Mark requires updating when significant changes are made to the product, and the Company's full quality system is subject to annual audit by its notified body in the United Kingdom and in the United States.

The Company has gained CE Mark approval under the applicable directives for all of its marketed products that currently require it, including the Paratrend 7, Neotrend and Neurotrend continuous monitoring products, and the IRMA SL System.

The Company's long-term business strategy includes development of cartridges and sensors for performing additional blood and tissue chemistry tests, and any such additional tests will be subject to the same regulatory process. No assurance can be given that the Company will be able to develop such additional products or uses on a timely basis, if at all, or that the necessary clearances for such products and uses will be obtained by the Company on a timely basis or at all, or that the Company will not be subjected to a more extensive pre-filing testing and FDA approval process. The Company also markets its products in several foreign markets. Requirements vary widely from country to country, ranging from simple product registrations to detailed submissions such as those required by the FDA. Manufacturing facilities are also subject to FDA inspection on a periodic basis and the Company and its contract manufacturers must demonstrate compliance with current Quality System Regulations promulgated by the FDA.

The Company's intermittent testing products are affected by the Clinical Laboratory Improvement Act of 1988 ("CLIA") which is regulated by the Centers for Medicare and Medicaid Services. This law is intended to

assure the quality and reliability of all medical testing in the United States regardless of where tests are performed. The regulations require laboratories performing blood chemistry tests to meet specified standards in the areas of personnel qualification, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations have established three levels of regulatory control based on test complexity; "waived," "moderate complexity" and "high complexity." The tests performed by the Company's IRMA SL System have been categorized under CLIA as "moderately complex," which places this system in the same category as most other commercially available blood gas and blood chemistry testing instruments. The glucose strip test is categorized as a "waived" test, which places this test in the same category as most other commercially available point-of-care glucose testing systems. The Company's continuous monitoring products are not affected by CLIA.

Research and Development

The Company owns two complementary biosensor technology platforms; an electrochemical platform, on which the IRMA and Portal intermittent testing products are based, and a fiberoptic platform, on which the Paratrend 7, Neotrend and Neurotrend continuous monitoring products are primarily based. The Company is pursuing product line extensions from both of these core technology platforms.

The Company intends to continue to expand its cartridge and test menus available on the IRMA SL System and Blood Analysis Portal System. The GL single-use cartridge, which panels glucose with sodium, potassium and chloride electrolytes, is planned for market release in the second quarter 2002. The GL cartridge is intended for use by critical care centers to screen diabetic patients and patients undergoing surgical procedures. Additionally, a lactate cartridge is in development. In the critical care setting, lactate testing is used to detect, treat and monitor decreased tissue oxygenation, primarily associated with shock, hypovolemia, and heart failure; and to monitor certain metabolic conditions. Development also continues on a creatinine test, with plans to integrate this test into a panel configuration compatible with a next generation analyzer currently under development and expected to be released to the market in the 2004-2005 timeframe. The Company's multi-use cartridge, which incorporates the Company's sensor and calibration technologies into products that can perform multiple blood test panels on different patients over a period of days before disposal, is also expected to be available on the Company's next generation analyzer. The Company believes that the IRMA SL System and related core technologies provide a flexible platform which are capable of performing an even wider variety of blood chemistry tests.

Development efforts also include further enhancements to the Company's Integrated Data Management System. The Integrated Data Management System is an advanced data management software application that provides a comprehensive data management system for point-of-care technologies. The new version of the Integrated Data Management System, released in the first quarter of 2002, supports the device settings and information management needs of the Portal System and the IRMA SL System.

The Company plans to continually improve the IRMA SL System, and in collaboration with Philips, the Blood Analysis Portal System, through software upgrades, manufacturing process improvements and equipment design enhancements, based on the results of ongoing marketing studies and field experience.

Under joint development by the Company and Philips is the integration of the Company's continuous monitoring product line technology into Philips' patient monitoring platforms. The resulting product will miniaturize and consolidate certain functionalities and the technology of the Trendcare monitor and patient data module into one device which plugs directly into Philips' monitoring systems. This system will provide an integration of technologies which will create a communications interface that facilitates monitor display of both continuous biochemical and physiological information at the patient's bedside. In conjunction with this project, the Company is redesigning the Trendcare satellite monitor and calibrator systems, which will be compatible with the new patient data module. Market release for these products is scheduled for 2003.

Additionally, studies are underway to apply continuous monitoring technology to new neurological and tissue applications. The Company's future development plans also include further expansion of the blood and tissue analysis test menu available on the continuous monitoring platform.

The Company has incurred research and development expenses of approximately \$5,138,000, \$4,962,000 and \$4,847,000, net of funding from Philips of \$2.2 million, \$2 million and \$1.2 million for the years ended December 31, 2001, 2000 and 1999, respectively.

Sales and Marketing

The Company markets and distributes its products primarily through two global distribution partnerships with Codman and Philips. The Company also continues to sell direct to end-users and through regional distributors in the veterinary market, which is not subject to an exclusive distribution agreement. Additionally, the Company's marketing strategy is to pursue partnerships with market leaders who will help identify and promote future applications in continuous tissue monitoring.

Effective October 1, 1998, the Company entered into an exclusive distribution agreement with Codman for worldwide market development and distribution of the Company's Neurotrend cerebral tissue monitoring system. The Company's exclusive distribution agreement with Philips, initially entered into with Hewlett Packard Company on June 7, 1999, provides for worldwide market development and distribution of the Company's Trendcare continuous blood gas monitoring systems and intermittent blood testing products. Information concerning the Company's export sales is contained in note 15 to the consolidated financial statements included in Part II, Item 8 of this Form 10-K.

Prior to entering into the exclusive distribution agreements described above, the Company's marketing efforts for its blood analysis systems focused on acute care hospitals. Under the Company's new distribution agreements, near term end-user sales of the Company's products are expected to continue to come from hospital critical care departments where blood tests are frequently requested on a stat basis. The Company's distributors' objectives will also include penetration of smaller hospitals and alternate-site markets, such as emergency medical facilities, home healthcare agencies, outpatient clinics, skilled nursing homes and doctors' offices or clinics. The Company believes that the advantages of its blood analysis and monitoring systems will help overcome the possible reluctance of acute care hospitals to change standard operating procedures for performing blood and tissue analysis or incur additional capital expenses.

The Company's established arrangements with hospital systems, healthcare facilities and other influential healthcare buying groups that established the Company as a sole, preferred or dual source supplier of its blood analysis systems are now administered by Philips. The Company expects its distribution partners to continue to enter into arrangements with buying groups and customers with respect to purchases of its blood and tissue analysis systems.

Manufacturing

The Company's manufacturing facilities support its intermittent testing and continuous monitoring platforms and are located in Roseville, Minnesota and High Wycombe, United Kingdom, respectively. The Company manufactures its electrochemical thick-film cartridges used with the IRMA and Portal Systems in its Roseville, Minnesota facility. Components for the Company's continuous monitoring sensors used in the Paratrend 7, Neotrend and Neurotrend products are sourced from a variety of outside vendors, but the unique assembly and testing of the sensing elements is performed in the Company's High Wycombe facility. The sub-assembly of external plastic assemblies is sub-contracted to outside vendors. The Company uses external manufacturers to produce a range of hardware items, including the Trendcare and Neurotrend monitors and patient data module. The Company assembles in-house the IRMA SL analyzer and the Portal measurement module at its Roseville facility, and the continuous monitoring calibrator at its High Wycombe facility. These devices could be manufactured by a number of microelectronics assembly companies, using primarily off-the-shelf components. Software for the intermittent testing products is developed and maintained by the Company, and software for the continuous monitoring products is jointly developed with an external source, with acceptance and validation performed by the Company.

The majority of the raw materials and purchased components used to manufacture the Company's products are readily available. Most of the Company's raw materials are or may be obtained from more than one source. Some components are manufactured to the Company's specifications and supplied by a single source. Plans are ongoing to add additional second sourcing where appropriate. Components used to manufacture the Company's hardware products are subject to obsolescence. The Company monitors on an ongoing basis the need to make product design changes to accommodate new replacement components for obsolete parts and to transition its materials procurement to the replacement components as necessary.

The Company's manufacturing facilities include three clean rooms in Roseville which range from Class 1,000 to Class 100,000, and two clean rooms in High Wycombe, both rated as Class 10,000. The Company believes its current facilities, with ongoing additional investments in production equipment to increase automation and capacity, can support production of required cartridges and sensors for the foreseeable future.

The Company maintains a comprehensive quality assurance and quality control program, which includes complete documentation of all material specifications, operating procedures, maintenance and equipment calibration procedures, training programs and quality control test methods. To control the quality of its finished product, the Company utilizes ongoing statistical process control systems during the manufacturing process and comprehensive performance testing of finished goods.

The Company continues to successfully undergo required inspections of its manufacturing facilities by the FDA (most recently in May 2001 and October 1999 for Roseville and High Wycombe facilities, respectively), and by the British Standards Institution for the High Wycombe facility (most recently in October 2001). Additionally, the Roseville facility's quality systems have been ISO 9001 certified since 1997 by the Management Service division of TÜV America Inc. ("TUV"), a technical inspection association which provides testing and certification services. The Company successfully completed its most recent TUV audit in February 2002. As a result of these inspections, the Company's manufacturing facilities and documentation and quality control systems are deemed satisfactory and in compliance with the related quality regulations issued by these agencies.

Patents and Proprietary Rights

The Company has implemented a strategy of pursuing patent applications to provide both design freedom and protection from competitors. This strategy includes evaluating and seeking patent protection both for inventions most likely to be used in its blood and tissue analysis systems and for those inventions most likely to be used by others as competing alternatives.

For its intermittent testing platform, the Company currently maintains four patents issued for its calibration technology, four patents related to its sensor technology and four for companion technology. In addition, two patents have been issued and maintained covering the IRMA SL analyzer and disposable cartridge designs. Overseas, the Company has foreign patent applications pending, filed under the Patent Cooperation Treaty, designating various jurisdictions, including Canada, the major European countries, Brazil, Australia and Japan, corresponding to one or more U.S. applications. The Company maintains 26 foreign patents; three issued in the United Kingdom, three in Germany, three in France, eight in Canada, five in Japan and one each in Italy, the Netherlands, Spain and Australia.

As it relates to its continuous monitoring platform, the Company currently maintains four U.S. patents associated with the design and manufacture of its sensor technology platforms, and has filed six patent applications. These patents are at various patent process stages in the major European countries and Japan.

Material patents have expirations ranging from the year 2006 to 2018. The Company is not currently a party to any patent litigation.

The Company has federally registered the trademarks "IRMA," "Diametrics Medical, Inc.," "Diametrics Medical, Incorporated," "IRMA Data Management System (IDMS)," "Neocath," "Paratrend," "Tissutrak," "Paratrend 7," "Neotrend," "Neurotrend" and "Trendcare."

Competition

The Company believes that potential purchasers of point-of-care blood and tissue analysis systems will base their purchase decision upon a combination of factors, including the product's test menu, ease of use, accuracy, price and ability to manage the data collected. The Company is aware of one other company, i-STAT, that is marketing a bedside point-of-care blood analysis system. The Company believes that its intermittent blood analysis systems possess distinct competitive advantages over i-STAT's products including ease of use, closed instead of open handling of blood samples, and room temperature instead of refrigerated storage of reagents.

The Company also competes with companies that market near-patient multi-use blood analysis systems. These companies include Roche/AVL Scientific Corporation, Radiometer, Inc., Instrumentation Laboratories and Bayer. However, the Company believes that to be successful in the point-of-care market, a device must not only be able to perform a variety of commonly ordered blood chemistry tests, but also be very portable to facilitate ease of use at the patient's bedside.

The Company's blood analysis systems also compete with manufacturers providing traditional blood analysis systems to central and stat laboratories of hospitals. Although these laboratory-based instruments provide the same tests available with the Company's products, they are complex, expensive and require the use of skilled technicians. The Company believes that its blood analysis systems offer several advantages over these laboratory-based instruments including immediate or continuous results, ease-of-use, reduced opportunity for error and cost effectiveness. The Company believes that its multi-parameter continuous arterial blood gas and tissue monitoring systems are currently the only products of their kind commercially available.

The Company's products are competitively priced with other point-of-care product offerings and are lower in price than centralized testing labs when the full cost of implementation is considered (i.e., equipment, maintenance, facilities and trained lab personnel). Centralized testing labs also do not provide the convenience and fast turnaround time for test results that point-of-care products offer.

Many of the companies in the medical technology industry have substantially greater capital resources, research and development staffs and facilities than the Company. Such entities may be developing or could in the future attempt to develop additional products competitive with the Company's blood and tissue analysis systems. Many of these companies also have substantially greater experience than the Company in research and development, obtaining regulatory approvals, manufacturing and marketing, and may therefore represent significant competition for the Company. There can be no assurance that the Company's competitors will not succeed in developing or marketing technologies and products that will be more effective or less expensive than those being sold by the Company or that would render the Company's technology and products obsolete or noncompetitive.

Executive Officers

<u>Name</u>	<u>Age</u>	<u>Position</u>
David T. Giddings	58	President and Chief Executive Officer
Roy S. Johnson	49	Executive Vice President and President and Managing Director of Diametrics Medical, Ltd.
Laurence L. Betterley	48	Senior Vice President and Chief Financial Officer

Mr. Giddings has been President, Chief Executive Officer and a director of the Company since April 1996, and Chairman of the Board from April 1996 to December 2001. Mr. Giddings was formerly President and Chief Operating Officer of the United States operations of Boehringer Mannheim Corporation ("BMC"), a U.S. subsidiary of Corange Ltd., a private global healthcare corporation. He joined BMC in 1992 after a 26-year career with Eastman Kodak Company, where he held a number of senior management positions, including

General Manager and Vice President of Marketing and Sales, clinical products division. He also served as Vice President and General Manager of Kodak's imaging information system group and of its printing and publishing division.

Mr. Johnson joined the Company in November 1996 as an Executive Vice President, and the President and Managing Director of Diametrics Medical, Ltd. ("DML"), a subsidiary of the Company established in conjunction with the acquisition in November 1996 of Biomedical Sensors, Ltd. ("BSL"). DML develops, manufactures and markets the Company's continuous blood and tissue monitoring systems. Beginning in 1977, Mr. Johnson served in a number of management positions for the predecessors of the BSL business, most recently as President and Chief Executive Officer while it was a subsidiary of Orange Medical Instruments, Inc. and later when it was an operating unit of Pfizer Inc. Mr. Johnson started his career in 1974 with Burroughs Wellcome in pharmaceutical production management and was the head of manufacturing in Burroughs' Sydney, Australia subsidiary.

Mr. Betterley has been Senior Vice President of the Company since October 1996 and Chief Financial Officer since August 1996. Prior to this, he was with Cray Research, Inc. in various management and financial positions including Chief Financial Officer from 1994 to 1996, Vice President of Finance from 1993 to 1994 and Corporate Controller from 1989 to 1993. Cray Research developed, manufactured and sold high performance computing systems used for computational research.

Employees

As of December 31, 2001, the Company had a total of 166 full-time employees, including 51 persons engaged in research and development activities. None of the Company's employees are covered by a collective bargaining agreement and Diametrics believes it maintains good relations with its employees.

Forward-Looking Statements

This Annual Report on Form 10-K and the Company's financial statements, "Management's Discussion and Analysis of Results of Operations and Financial Condition" in Item 7 and other documents incorporated by reference contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements represent our expectations or beliefs, including, but not limited to, our current assumptions about future financial performance, anticipated problems, and our plans for future operations, which are subject to various risks and uncertainties. When used in this Form 10-K and in future filings by the Company with the Securities and Exchange Commission, in our press releases, presentations to securities analysts or investors, in oral statements made by or with the approval of an executive officer of the Company, the words or phrases "believes," "may," "will," "expects," "should," "continue," "anticipates," "intends," "will likely result," "estimates," "projects," or similar expressions and variations thereof are intended to identify such forward-looking statements. However, any statements contained in this Form 10-K that are not statements of historical fact may be deemed to be forward-looking statements. We caution that these statements by their nature involve risks and uncertainties, certain of which are beyond our control, and actual results may differ materially depending upon a variety of important factors, including those described in Exhibit 99 to this Form 10-K.

Item 2. Properties

The Company's principal properties are as follows:

<u>Location of Property</u>	<u>Use of Facility</u>	<u>Approximate Square Footage</u>	<u>Lease Expiration Date</u>
Roseville, Minnesota	Manufacturing, research and development, sales support, marketing and administration	43,300	February 2004
Malvern, Pennsylvania	Research and development	2,700	March 2007
High Wycombe, United Kingdom	Manufacturing, process engineering, purchasing and distribution	14,500	September 2005
High Wycombe, United Kingdom	Sales support, marketing and administration	5,500	January 2015(1)
High Wycombe, United Kingdom	Research and Development	6,000	April 2004(2)

(1) Lease can be terminated without penalty at the Company's sole discretion in January 2005.

(2) Lease can be terminated without penalty at the Company's sole discretion in April of 2003.

The Company believes that its facilities are sufficient for its projected needs through 2003.

Item 3. Legal Proceedings

The Company is currently not subject to any material pending or threatened legal proceedings.

Item 4. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of security holders during the fourth quarter of the year ended December 31, 2001.

PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters

The Company's Common Stock, \$.01 par value, trades on The Nasdaq National Market under the symbol "DMED." The following table sets forth, for the periods indicated, the high and low quarterly closing prices for the Common Stock as quoted on The Nasdaq National Market:

	2001	
	High	Low
First Quarter	\$ 7½	\$37⁄8
Second Quarter	4²⁄₂₅	2⁄₅
Third Quarter	4¹⁄₂₀	3¹³⁄₂₀
Fourth Quarter	5⁹⁄₁₀	3⁷⁄₂₀
	2000	
	High	Low
First Quarter	\$12⁵⁄₈	\$7⁵⁄₈
Second Quarter	10³⁄₈	5²¹⁄₃₂
Third Quarter	8¼	6¼
Fourth Quarter	9¼	5³⁄₈

There were 359 common shareholders of record and the Company estimates approximately 5,500 shareholders holding stock in "street name" accounts as of December 31, 2001. The Company has not paid any stock dividends on its common stock since its inception, and management does not anticipate paying cash dividends in the foreseeable future.

Item 6. Selected Financial Data

SELECTED FIVE-YEAR FINANCIAL DATA

(in thousands, except share and per share amounts)	Years ended December 31,				
	2001	2000	1999	1998	1997
Statement of Operations Data:					
Net sales	\$ 24,489	\$ 25,258	\$ 18,687	\$ 12,156	\$ 10,434
Operating loss	(3,578)	(2,743)	(10,044)	(17,175)	(20,737)
Net loss	(3,876)	(2,648)	(10,244)	(17,388)	(21,037)
Net loss per share (1), (2)	(0.14)	(0.10)	(0.41)	(0.79)	(1.13)
Weighted average shares outstanding . .	26,762,684	26,490,826	24,719,038	21,996,382	18,665,837
Balance Sheet Data:					
Working capital	\$ 11,876	\$ 14,334	\$ 15,009	\$ 11,415	\$ 12,509
Total assets	23,461	27,811	31,972	25,346	28,662
Long-term liabilities	8,533	7,886	7,823	8,345	8,969
Shareholders' equity	9,529	14,185	13,841	11,366	12,773

- (1) The Company has not paid any dividends since inception.
- (2) Basic and diluted net loss per share amounts are identical as the effect of potential common shares is antidilutive.

Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition

SUMMARY

Diametrics Medical, Inc., which began operations in 1990, is engaged in the development, manufacture and commercialization of critical care blood and tissue analysis systems which provide immediate or continuous diagnostic results at the point-of-patient care.

Since its commencement of operations in 1990, the Company has transitioned from a development stage company to a full-scale development, manufacturing and marketing organization (primarily through distributors). As of December 31, 2001, the primary funding for the operations of the Company has been approximately \$148 million raised through public and private sales of its equity securities and issuance of convertible promissory notes.

Distribution and commercialization of the Company's products primarily occurs through Philips Medical Systems ("Philips") and Codman & Shurtleff, a Johnson & Johnson company ("Codman"). Philips is the exclusive global distributor of the Company's critical care blood monitoring products, the IRMA[®]SL blood analysis system and the Trendcare[®] continuous blood gas monitoring systems, including Paratrend[®] and Neotrend[™]. Philips also is the exclusive global distributor of the Blood Analysis Portal System, co-developed by the Company and Philips. Codman is the exclusive worldwide distributor of the Neurotrend[™] cerebral tissue monitoring system.

The Codman distribution agreement was initiated in October 1998, has a term of six years and is renewable for two years. If minimum sales levels and marketing expenditure levels are not achieved by Codman, certain payments will be due to the Company. Also, Codman has the right of first refusal to market new continuous monitoring products developed for the neuro market. In addition, Johnson & Johnson Development Corporation has an equity investment of approximately \$4 million in the Company's Common Stock.

The distribution agreement with Philips was signed in June 1999, initially as an agreement between the Company and Hewlett Packard Company ("HP"). Under the terms of the distribution agreement, the Company transferred full responsibility for marketing, sales and distribution of the blood monitoring products described above to HP. The initial term of the agreement is three and a half years, with the option for extensions. Concurrently with the execution of the agreement, HP made a \$9.5 million equity investment in the Company. In addition to HP's equity investment, the agreement also provides for minimum purchase commitments of the Company's products, market development commitments, research and development funding and royalty payments, as well as funding of sales and marketing costs during a sales transition period in 1999. In late 1999, HP assigned the distribution agreement and its equity investment with the Company to Agilent Technologies, Inc. ("Agilent"), a leading provider of test and measurement solutions and communications components, which was formed as a new company and subsidiary of HP. HP spun off its ownership in Agilent to HP shareholders during 2000. In August 2001, Agilent completed the sale of its healthcare business to Royal Philips Electronics, including its equity investment in the Company. Also as part of this transaction, the distribution agreement between the Company and Agilent was assigned to Philips Medical Systems, a division of Royal Philips Electronics. The initial three-and-a half year term of the Company's distribution agreement with Philips ends on October 31, 2002, with the option for three three-year extensions. The Company is discussing various options for the possible continuation of a relationship with Philips following the end of the initial term, which could include a continuation of the distribution relationship with Philips under modified terms yet to be determined. The Company's sales to Philips in 2001 represented 90% of total sales, and the Company recognized in 2001 approximately \$2 million of funding from Philips as a reduction in research and development expenses. Sales to Philips include product purchases by Philips to meet sales demand of its end-user customers and to fulfill its internal product requirements associated with the sales process, as well as contractual purchase commitments and royalties under the distribution agreement. As a result, the level of the Company's sales to Philips during any period is not indicative of Philips' sales to its end-user customers during that period, which are estimated to be substantially less than the Company's sales to Philips in each of the last three years.

The Company's historical trend of achieving successive improvements in annual operating results was suspended in 2001 primarily due to the realization of uncertainties affecting revenues described in the

Company's 2000 Annual Report, including: 1) delayed sales due to the transition of the Company's distribution channel as a result of the sale of Agilent's healthcare business to Royal Philips Electronics, 2) the impact of new product introductions on hardware sales of the Company's existing product lines, and 3) the impact on sales of reduced capital spending in the healthcare sector after hospitals made investments to address Year 2000 date change requirements. Total revenues for the year were down 3% from the prior year. Revenue from product sales, which excludes non-product revenue such as royalties, grew 4% for the year. Gross profit was 27% of sales in 2001, a three percentage point reduction from the prior year, while operating expenses declined 2% year over year. The resulting net loss for the year increased 46% from the previous year. The decline in gross profit and increase in net loss were driven by a \$1.7 million reduction in non-product revenue, primarily royalties.

CRITICAL ACCOUNTING POLICIES

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., which require the Company to make estimates and assumptions in certain circumstances that affect amounts reported. In preparing these financial statements, management has made its best estimates and judgments of certain amounts, giving due consideration to materiality. The Company believes that of its significant accounting policies (more fully described in note 1 to the consolidated financial statements), the following are particularly important to the portrayal of the Company's results of operations and financial position and may require the application of a higher level of judgment by the Company's management, and as a result are subject to an inherent degree of uncertainty.

Revenue Recognition and Accounts Receivable. The Securities and Exchange Commission's Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition" provides guidance on the application of generally accepted accounting principles to selected revenue recognition issues, and the Company's revenue recognition policies are in compliance with SAB 101. The Company markets and distributes its products primarily through two global distribution partnerships with Philips and Codman. The Company also continues to sell direct to end-users and through regional distributors for a small volume of products and transactions that are not subject to the exclusive distribution agreements. The Company recognizes revenue upon shipment of product to its distributors and direct customers or, in the case of trial instruments and monitors placed directly with end-user customers, upon the customer's acceptance of the product. The Company's sales terms to its distributors and customers provide no right of return outside of the Company's standard warranty policy (see Note 1), and payment terms consistent with industry standards apply. Sales terms and pricing extended to the Company's distributors are governed by the respective distribution agreements, together with binding purchase orders for each transaction. Most of the Company's sales since 1999 (after the inception of the Company's distribution partnerships with Philips and Codman) have been to its distribution partners, totaling 94% of total sales in 2001, and 90% and 70% in 2000 and 1999, respectively. The Company's distribution partners purchase the Company's products to meet sales demand of their end-user customers as well as to fulfill their internal requirements associated with the sales process and contractual purchase requirements under the respective distribution agreements. Internal and other requirements include purchases of products by Philips (and to a lesser extent, Codman) for training, demonstration and evaluation purposes, clinical evaluations, product support, establishing inventories, meeting minimum purchase commitments, and for royalties primarily in 2000. As a result, the level of the Company's revenue during any period is not indicative of its distributors' sales to end-user customers during that period, which are estimated to be substantially less than the Company's sales to those distributors in each of the last three years. While this does not affect the Company's recognition of revenue for direct sales to its distributors or the collectibility of its receivables, the Company's future revenue growth may be impacted by its distributors' level of inventories of the Company's products, their sales to end-user customers and their internal product requirements.

As sales to the Company's two global distribution partners comprise most of the Company's revenues, the Company's accounts receivable balance at any point in time likewise reflects a concentration of amounts due from these parties. The Company maintains allowances for doubtful accounts for estimated losses from the inability of its customers to make required payments. While the Company believes that the quality of its

receivables from its distribution partners is high, if the financial condition of the Company's distribution partners were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

Inventories. Inventories are stated at the lower of cost or market using the first-in, first-out method. Reserves for slow moving and obsolete inventories are provided based upon current and expected future product sales and the expected impact of product transitions or modifications. While the Company expects its distributors' sales to grow, a reduction in its distributors' sales could reduce the demand for the Company's products, and additional inventory reserves may be required.

Recognition of Research and Development Funding. Research and development funds earned by the Company under the Philips distribution agreement are recorded as a reduction of the development costs incurred, and have totaled approximately \$2 million annually.

Foreign Currency Translation/Transactions. The financial position and results of operations of the Company's foreign subsidiary, DML, are measured using local currency as the functional currency. The financial statements of the Company's foreign subsidiary are translated in accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 52. Accordingly, assets and liabilities are translated using period-end exchange rates and statements of operations items are translated using average exchange rates for the period, with the resulting translation adjustments recorded as a separate component of shareholders' equity. Also recorded as translation adjustments in shareholders' equity are transaction gains and losses on intercompany balances for which settlement is not planned or anticipated in the foreseeable future. Other foreign currency transaction gains and losses are credited or charged against earnings. The Company's subsidiary has had negative cash flows since its acquisition by the Company in late 1996, and is expected to continue to have negative cash flows and require funding from the Company for the foreseeable future. As a result, settlement of the Company's net intercompany receivable balance with its subsidiary is not expected in the foreseeable future. As such, the Company records transaction gains or losses on intercompany balances in shareholders' equity in accordance with SFAS No. 52. The Company will continue to evaluate the potential for future settlement of intercompany balances. Settlement of intercompany balances on a near-term basis would require the Company to include transaction gains or losses on intercompany balances as credits or charges to current income (vs. shareholders' equity), potentially resulting in an increase in the volatility of the Company's Statements of Operations.

Impairment of Long-Lived Assets. Long-lived assets at December 31, 2001 consist of property and equipment and purchased software. The Company reviews its long-lived assets for impairment whenever events or business circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

RESULTS OF OPERATIONS

Sales

Sales of the Company's products were \$24,488,928 for 2001, compared to \$25,258,407 for 2000, and \$18,687,184 for 1999. The 35% increase in sales from 1999 to 2000 reflects a 32% growth in sales of instruments and a 9% increase in disposable cartridge and sensor sales. Unit sales in 2000 grew at a higher rate than the related revenues, at 42% for instruments and 28% for disposable cartridges and sensors. The reduced rate of revenue growth relative to units resulted from the impact of lower average sales prices under the Philips and Codman distribution agreements. The impact of reduced pricing was partially mitigated in 2000 by the recognition of royalty revenue under the Philips distribution agreement of \$2,260,000. Sales declined 3% in 2001 from 2000, driven by a reduction in non-product revenue, primarily royalties. Product revenues increased 4% during 2001, with a 10% increase in disposable cartridge and sensor sales and a 1% increase in instrument sales. Unit sales in 2001 also grew at a higher rate than the related revenues, at 20% for both instruments and

disposable cartridges and sensors. The favorable revenue impact of unit sales growth in 2001 was partially offset by lower average cartridge sales prices to Philips, resulting from volume price reductions, and a higher ratio of IRMA analyzer instrument sales, which have lower average sales prices, relative to total instrument sales. The Company's sales to Philips and Codman comprised approximately 94%, 90% and 70% of total sales in 2001, 2000 and 1999, respectively, and are expected to approximate 2001 levels as a percentage of total sales in 2002. Due to the significant purchases of the Company's products by its distributors for their internal use in the sales process and to meet minimum purchase commitments, the distributors' sales to their end-user customers over the last three years are estimated to be approximately 40% of the Company's product sales related to those distributors over that period. While expected to remain below the level of the Company's sales to the distributors in 2002, the distributors' sales to their end-user customers in 2002 are expected to increase as a percentage of the Company's product sales to those distributors compared to the last three years.

For the year ended December 31, 2001, both intermittent blood testing products revenue and continuous monitoring products revenue were comprised of 71% instrument related revenue and 29% disposable cartridge and sensor related revenue. Intermittent testing products represented 57%, 44% and 39% of sales in 2001, 2000 and 1999, respectively, with continuous monitoring products comprising the remaining sales in each year. The Company's revenues are affected principally by the number of instruments, both monitors and IRMA analyzers, sold to distributors, the extent to which the distributors sell these instruments to end-user customers, and the rate at which disposable sensors and cartridges are used in connection with these products. As of December 31, 2001, the Company has sold approximately 10,800 instruments. Unit sales in 2001 of both instruments and disposable sensors and cartridges increased approximately 20% from 2000. As the Company grows, it is expected that the growing end-user customer base will increase the usage and rate of usage of disposable products, with the result that overall disposable product sales will exceed that of instrument sales.

Cost of Sales

Cost of sales totaled \$17,984,341 for 2001, compared to \$17,738,103 for 2000 and \$15,779,694 for 1999. Cost of sales as a percentage of revenue was 73% in 2001, 70% in 2000 and 84% in 1999. The three percentage point increase in 2001 relative to 2000 was primarily caused by lower non-product revenue, primarily royalties. Excluding the impact of non-product revenues, cost of sales as a percentage of revenue improved by four percentage points from 2000 to 2001. The year-to-year improvements in the Company's cost of sales as a percentage of revenue, excluding the impact of non-product revenue, reflect lower disposable unit manufacturing costs resulting from increased unit sales volumes and improved cartridge and sensor yields, a reduction in instrument material costs, and the impact of operational efficiencies and process improvements. Partially offsetting the improvement in 2001 was the impact of lower average cartridge sales prices, resulting from volume price reductions. Improvements in 2000 and 1999 were partially offset by the impact of generally lower average sales prices resulting from the initiation in mid 1999 of the distribution agreement with Philips. Sales returns in 1999 from distributors that were displaced as a result of the Company's exclusive distribution agreement with Philips also partially offset the improvement in that year. The Company introduced a new intermittent testing hardware product in the first quarter of 2002, which will supplement but not replace the Company's existing hardware product line. It is not expected that the introduction of the new hardware product will increase obsolescence of existing hardware inventories.

Operating Expenses

Total operating expenses decreased \$181,000 or 2% from 2000 to 2001, following a decrease of \$2.7 million or 21% from 1999 to 2000. The significant decline in operating expenses from 1999 to 2000 is primarily the result of the transfer during 1999 of the Company's sales and marketing functions to Philips and the recognition in 2000 of a full year of research and development funding received from Philips as part of the distribution agreement.

Research and development expenses totaled \$5,137,974 for 2001, compared to \$4,962,348 in 2000 and \$4,847,463 in 1999. The year-to-year increases in expenses of 2% and 4% in 2000 and 2001, respectively, were

primarily due to increased investments to support new research and development projects, partially offset by the recognition of funding from Philips in the amounts of \$2.2 million in 2001, \$2 million in 2000 and \$1.2 million in 1999.

Selling, general and administrative expenses totaled \$4,944,599 for 2001, compared to \$5,300,918 in 2000 and \$8,103,826 in 1999. The significant decrease in expenses from 1999 to 2000 was primarily impacted by the transfer during 1999 of most of the Company's sales and marketing functions to Philips. The decrease in expenses from 2000 to 2001 was primarily due to a reduction in personnel.

Interest and Other Expense

The Company realized interest income of \$323,490 in 2001, compared to \$787,396 in 2000 and \$528,787 in 1999. The improvement in interest income from 1999 to 2000 reflects the impact of higher average cash and investment balances, primarily affected by the timing of the Company's financing activities, funding received from Philips and improved cash flows from operations. The decline in interest income from 2000 to 2001 reflects the impact of lower average cash and investment balances and lower average interest rates.

Interest expense totaled \$572,618 in 2001, compared to \$586,616 in 2000 and \$630,459 in 1999. The decline in expense from 1999 to 2000 primarily reflects the impact of lower average debt balances, while the decline from 2000 to 2001 reflects the impact of slightly lower average interest rates on comparable average debt balances.

Net other expense totaled \$48,785 in 2001, compared to \$105,435 in 2000 and \$98,076 in 1999. The change in net amounts from 2000 to 2001 was primarily due to a decrease in foreign currency transaction losses. Foreign currency transaction gains and losses were not material in any of the years presented.

Net loss

Net loss for the year ended December 31, 2001 was \$3,875,899, compared to \$2,647,617 in 2000 and \$10,243,547 in 1999. The improvement in net loss from 1999 to 2000 reflects revenue growth; improved margins, influenced by higher unit volumes, changes in product mix, royalty revenue and improved manufacturing yields; and reduced operating expenses due primarily to research and development funding received from Philips and the transfer of the Company's sales and marketing functions to Philips. The net loss in 2001 increased from 2000 primarily as a result of a reduction in non-product revenue, changes in product mix and lower interest income.

The Company anticipates that commercial success of its distribution partners should result in growth in disposable sensor and cartridge revenue in 2002. This growth is likely to be offset initially by a decline in instrument revenue due to the impact of a new hardware product introduction on average hardware sales prices and sales of existing hardware product lines as distributors reduce inventories of these products. Revenue and gross profit levels in 2002 will depend on the impact of the new product line introduction, revenue mix, and sales performance of the Company's distributors. As a result, the Company's financial performance for 2002 may not improve from or may be less favorable than that of 2001. If sales growth does occur in 2002, it is expected to be delayed to the later part of the year due to these factors.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2001, the Company had working capital of approximately \$11.9 million, a decrease of approximately \$2.4 million from the working capital of \$14.3 million reported at December 31, 2000. The net decrease primarily reflects the impact of the increase in net loss between years of \$1.2 million and a \$3.6 million decrease in proceeds from warrant exercises and employee stock plans, partially offset by a \$2.3 million reduction in purchases of property and equipment. Through December 31, 2001, the Company raised approximately \$148 million through the public and private sales of its equity securities and the issuance of convertible promissory notes.

Net cash provided by operating activities totaled \$1 million for the year ended December 31, 2001, compared to net cash used in operating activities of \$5.4 million and \$3 million for the same periods in 2000 and 1999, respectively. This was the result of net losses of \$3.9 million, \$2.6 million and \$10.2 million in 2001, 2000 and 1999, respectively, adjusted by changes in operating assets and liabilities, primarily accounts receivable, inventories, accounts payable, accrued expenses and deferred credits and revenue, discussed below.

Net accounts receivable decreased \$2.1 million for the year ended December 31, 2001, compared to a decrease of \$109,000 in 2000 and an increase of \$1.4 million in 1999. In spite of a significant increase in sales between 1999 and 2000, the accounts receivable balance decreased in 2000 primarily due to an improvement in days sales outstanding, impacted by the Company's distribution partnerships, and the timing of sales. The larger decline in accounts receivable during 2001 was primarily due to the timing of sales and an improvement in days sales outstanding.

Inventories decreased \$213,000 for the year ended December 31, 2001, after an increase of \$164,000 in 2000 and a decrease of \$651,000 in 1999. The decrease in 1999 and small increase in 2000 reflect a decrease in finished goods inventories in both years. The decline in finished goods inventory in 2000 was offset by an increase in work-in-process inventory to meet anticipated production and sales requirements in the first quarter of 2001. The decrease in 2001 reflects a decrease in continuous monitoring inventories of \$628,000 due to the production and shipment of products to the Company's distributors, partially offset by an increase in intermittent testing hardware inventories in preparation for shipment in the first quarter 2002 of initial sales of a new hardware product line as well as sales of existing hardware products. Each year's average inventory balance was positively impacted by successive improvements in inventory turnover, stemming from improved inventory management.

Accounts payable and accrued expenses decreased \$954,000 on a combined basis for the year ended December 31, 2001, after a decrease of \$647,000 in 2000 and an increase of \$405,000 in 1999. The increase in 1999 is primarily due to increased accruals for employee bonuses and costs to complete committed product upgrades. The declines in 2000 and 2001 were affected primarily by the timing of vendor payments and reductions in product upgrade accruals as upgrades were completed during 2000 and 2001 from the upgrade program which began in 1999.

Deferred credits and revenue increased \$750,000 during 2001, after a \$4.1 million decrease during 2000 and a \$5.1 million increase in 1999. The increase in 1999 primarily reflects the receipt of \$9.5 million of prepaid funding from Philips under the terms of the distribution agreement, partially offset by the recognition of approximately \$4.4 million of the funding as a reduction of 1999 expenses and royalty revenue. The decrease in 2000 represents the recognition of funding from Philips for research and development and royalties of \$4.3 million, partially offset by customer advance payments. The increase in 2001 primarily reflects the receipt of \$3 million of research and development funding from Philips, partially offset by the recognition of approximately \$2.2 million of the funding as a reduction of 2001 expenses.

Net cash provided by investing activities totaled \$4.4 million for the year ended December 31, 2001, following net cash provided by investing activities of \$1.6 million in 2000 and net cash used in investing activities of \$9.1 million in 1999. These year-to-year changes were primarily affected by the amounts and timing of equity funding, funding received from Philips and operating cash flow requirements, which all affected the amount of cash available for the purchase of marketable securities. Purchases of property and equipment also affected net cash provided by or used in investing activities, and totaled \$1.1 million for the year ended December 31, 2001, \$3.4 million in 2000 and \$1.7 million in 1999. Capital additions in each year consisted primarily of investments in production and development equipment, software and instruments for internal use in research and development. In 2002, the Company expects total capital expenditures and new lease commitments to approximate \$1.2 million for the year, primarily reflecting investments to support new product development and production.

Net cash provided by financing activities totaled \$191,000 for the year ended December 31, 2001, compared to \$3.6 million in 2000 and \$11.8 million in 1999. The year-to-year changes were due primarily to the amounts and timing of equity funding and the amount of proceeds from employee stock plans and warrant exercises in each of these years.

In late 1996 and throughout 1997, the Company entered into long-term debt obligations of approximately \$8.9 million. The original debt consisted of a \$7.3 million senior secured fixed rate loan note issued to Pfizer Inc. in connection with the Company's acquisition of DML and approximately \$1.6 million in notes payable for equipment financing. Proceeds from the issuance in August 1998 of \$7.3 million of Convertible Senior Secured Fixed Rate Notes, issued in conjunction with a private equity placement, were simultaneously used to retire the \$7.3 million Pfizer note. Repayments on the Company's contractual obligations, consisting of debt, capital leases and operating leases, are summarized below:

	Year ending December 31			
	2002	2003	Thereafter	Total
Long-term debt (1)	\$ 678,587	\$7,610,978	\$ —	\$ 8,289,565
Capital leases (1)	159,511	159,511	166,675	485,697
Operating leases	760,762	695,249	557,660	2,013,671
Total contractual obligations	<u>\$1,598,860</u>	<u>\$8,465,738</u>	<u>\$724,335</u>	<u>\$10,788,933</u>

(1) Amounts include principal and interest.

Effective March 31, 1998, the Company secured a \$1 million receivable-backed line of credit. The loan agreement requires the Company's accounts receivable collections to be applied to reduce the loan balance, including advances, interest and fees. At December 31, 2001, no advances were outstanding under the line of credit. The existing line of credit agreement will not be renewed upon its expiration in mid 2002; however, the Company plans to re-establish a line of credit agreement with an alternative source in 2002.

At December 31, 2001, the Company had U.S. net operating loss and research and development tax credit carryforwards for income tax purposes of approximately \$120.8 million and \$1.4 million, respectively. (See note 13 of Notes to Consolidated Financial Statements for further discussion).

The full principal balance of the Company's \$7.3 million Convertible Senior Fixed Rate Notes becomes due August 4, 2003, unless the note holders elect prior to that date to convert the notes into shares of the Company's Common Stock at a conversion price of \$8.40 per share. If the note holders do not exercise the conversion option or do not elect to extend the due date, the Company plans to refinance the notes with debt or equity to the extent cash flows from operations or partnering activities are not sufficient to retire the notes. There is no assurance that the Company will be able to refinance the notes or be able to refinance under favorable terms. The Company believes, however, that excluding the impact of retiring or refinancing the notes, currently available funds and cash generated from projected operating revenues, supplemented by proceeds from employee stock plans, warrant exercises, asset based credit and partnering activities will meet the Company's working capital and capital expenditure requirements. If the amount or timing of funding from these sources or cash requirements vary materially from those currently planned, the Company could require additional capital. The Company's long-term capital requirements will depend upon numerous factors, including the rate of market acceptance of the Company's products, the level of resources devoted to expanding the Company's business and manufacturing capabilities, and the level of research and development activities. While there can be no assurance that adequate funds will be available when needed or on acceptable terms, management believes that the Company will be able to raise adequate funding if needed.

EURO CONVERSION

The Company sells and distributes most of its products globally through distributors, with sales denominated in U.S. dollars. The Company's subsidiary, DML, conducts its operations from the U.K. The U.K. is one of three countries of the European Union ("EU") that has not adopted the euro as its legal currency; however, the U.K. may convert to the euro at a later date. The euro will be the sole official currency in participating EU countries on July 1, 2002.

While the Company will continue to evaluate the impact of the euro conversion over time, based upon currently available information, management does not believe that the conversion to the euro currency will have a material impact on the Company's financial condition or overall trends in results of operations.

NEW ACCOUNTING PRONOUNCEMENTS

In July 2001, The Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141 "Business Combinations," and SFAS No. 142 "Goodwill and Other Intangible Assets," which change the accounting for business combinations and goodwill. SFAS No. 141 requires that the purchase method of accounting be used for business combinations initiated after June 30, 2001. Use of the pooling-of-interests method is prohibited. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including goodwill recorded in past business combinations, will therefore cease upon adoption of the Statement, which for the Company will be January 1, 2002. The Company has evaluated SFAS No. 141 and SFAS No. 142, and has concluded that they do not have a material effect on its financial statements.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." This Statement supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of," and addresses significant issues related to the implementation of SFAS No. 121. SFAS No. 144 establishes a single accounting method under which long-lived assets to be disposed of by sale are measured, which is the lower of book value or fair value less costs to sell. Additionally, SFAS No. 144 expands the scope of discontinued operations to include all components of an entity with operations and cash flows that (1) can be distinguished from the rest of the entity and (2) will be eliminated from the ongoing operations of the entity in a disposal transaction. SFAS No. 144 is effective January 1, 2002 and its provisions are to be applied prospectively. The Company has evaluated SFAS No. 144 and has concluded that it does not have a material effect on its financial statements.

The Company's discussion and analysis of results of operations and financial condition, including statements regarding the Company's expectations about new and existing products, future financial performance, market risk exposure and other forward looking statements are subject to various risks and uncertainties, including, without limitation, demand and acceptance of new and existing products, technological advances and product obsolescence, competitive factors, stability of domestic and international financial markets and economies, the performance of the Company's distributors and the availability of capital to finance growth. These and other risks are discussed in greater detail in Exhibit 99 to this Form 10-K.

Item 7.a. Quantitative and Qualitative Disclosures About Market Risk

The Company's primary market risk exposure is foreign exchange rate fluctuations of the British pound sterling to the U.S. dollar as the financial position and operating results of the Company's U.K. subsidiary, DML, are translated into U.S. dollars for consolidation. The Company's exposure to foreign exchange rate fluctuations also arises from transferring funds to its U.K. subsidiary in British pounds sterling. Effective November 1, 1999, most of the Company's sales are made to distributors and denominated in U.S. dollars, thereby significantly mitigating the risk of exchange rate fluctuations on trade receivables. November 1, 1999 marked the completion of a sales transition period with Philips, the Company's exclusive global distributor of the IRMA SL blood analysis system and the Trendcare continuous blood monitoring products, which followed the completion of a distribution agreement in the fourth quarter 1998 with Codman, who is the exclusive global distributor of Neurotrend, a continuous cerebral tissue monitoring product.

The effect of foreign exchange rate fluctuations on the Company's financial results for the years ended December 31, 2001, 2000 and 1999 was not material. The Company does not currently use derivative financial instruments to hedge against exchange rate risk. Because foreign exchange exposure to these rate fluctuations increases as intercompany balances grow, the Company will continue to evaluate the need to initiate hedging programs to mitigate the impact on intercompany balances of changes in the exchange rate of the British pound sterling to the U.S. dollar.

The Company's exposure to interest rate risk is limited to borrowings under a \$1 million receivable backed credit line and a bank loan. Any advances under the line of credit bear interest on the unpaid principal amount at a fluctuating rate tied to the Prime Rate, while amounts outstanding under the bank loan bear interest at a fluctuating rate tied to the bank's base rate. The Company does not use derivative financial instruments to manage interest rate risk. Borrowings under the line of credit are limited to \$1 million and are generally repaid within a few months. The outstanding balance under the bank loan is less than \$50,000. Given the above, the Company's exposure to interest rate risk is not believed to be material. All other existing debt agreements of the Company bear interest at fixed rates, and are therefore not subject to exposure from fluctuating interest rates.

Item 8. Financial Statements and Supplementary Data

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All other schedules have been omitted because they are not applicable or not required, or because the required information is included in the consolidated financial statements or the notes thereto.

Independent Auditors' Report

The Board of Directors and Shareholders Diametrics Medical, Inc.:

We have audited the accompanying consolidated balance sheets of Diametrics Medical, Inc. and subsidiary as of December 31, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity and comprehensive loss and cash flows for each of the years in the three-year period ended December 31, 2001. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Diametrics Medical, Inc. and subsidiary as of December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States of America.

KPMG LLP

Minneapolis, Minnesota
January 29, 2002

DIAMETRICS MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,		
	2001	2000	1999
Net sales	\$ 24,488,928	\$ 25,258,407	\$ 18,687,184
Cost of sales	17,984,341	17,738,103	15,779,694
Gross profit	6,504,587	7,520,304	2,907,490
Operating expenses:			
Research and development	5,137,974	4,962,348	4,847,463
Selling, general and administrative	4,944,599	5,300,918	8,103,826
	<u>10,082,573</u>	<u>10,263,266</u>	<u>12,951,289</u>
Operating loss	(3,577,986)	(2,742,962)	(10,043,799)
Interest income	323,490	787,396	528,787
Interest expense	(572,618)	(586,616)	(630,459)
Other expense, net	(48,785)	(105,435)	(98,076)
Net loss	<u>\$ (3,875,899)</u>	<u>\$ (2,647,617)</u>	<u>\$ (10,243,547)</u>
Basic and diluted net loss per common share	<u>\$ (0.14)</u>	<u>\$ (0.10)</u>	<u>\$ (0.41)</u>
Weighted average common shares outstanding	<u>26,762,684</u>	<u>26,490,826</u>	<u>24,719,038</u>

The accompanying notes are an integral part of these consolidated financial statements.

DIAMETRICS MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2001	2000
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,654,845	\$ 2,431,704
Marketable securities	749,141	6,281,761
Accounts receivable, net of allowance for doubtful accounts of \$93,820 in 2001 and \$153,750 in 2000	4,556,865	6,682,129
Inventories	4,066,964	4,280,234
Prepaid expenses and other current assets	247,286	397,406
Total current assets	17,275,101	20,073,234
Property and equipment, net	6,178,805	7,336,283
Other assets, net	6,700	401,240
	\$ 23,460,606	\$ 27,810,757
 Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,562,569	\$ 2,398,987
Accrued expenses	1,796,390	1,914,409
Deferred credits and revenue	1,750,000	1,000,365
Current portion of long-term liabilities	289,686	425,775
Total current liabilities	5,398,645	5,739,536
Long-term liabilities:		
Long-term liabilities, excluding current portion	7,572,752	7,472,215
Other liabilities	960,300	414,115
Total liabilities	13,931,697	13,625,866
Shareholders' equity:		
Preferred stock, \$.01 par value: 5,000,000 shares authorized, none issued	—	—
Common stock, \$.01 par value: 45,000,000 shares authorized, 26,802,687 and 26,713,166 shares issued and outstanding at December 31, 2001 and 2000, respectively	268,027	267,132
Additional paid-in capital	147,517,078	147,291,259
Accumulated deficit	(135,887,470)	(132,011,571)
Accumulated other comprehensive loss	(2,368,726)	(1,361,929)
Total shareholders' equity	9,528,909	14,184,891
Commitments and contingencies (notes 9, 16, and 17)		
	\$ 23,460,606	\$ 27,810,757

The accompanying notes are an integral part of these consolidated financial statements.

DIAMETRICS MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE LOSS

	Common Stock	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total shareholders' equity	Total comprehensive income (loss)
Balance, December 31, 1998	\$233,916	\$130,477,220	\$(119,120,407)	\$ (225,165)	\$ 11,365,564	
Net loss	—	—	(10,243,547)	—	(10,243,547)	\$(10,243,547)
Foreign currency translation adjustment . .	—	—	—	(405,483)	(405,483)	(405,483)
Minimum pension liability	—	—	—	114,141	114,141	114,141
Comprehensive loss for the year ended December 31, 1999	—	—	(10,243,547)	(291,342)	—	\$(10,534,889)
Issued common stock	21,303	11,849,017	—	—	11,870,320	
Issued common stock under employee stock purchase plan	329	146,284	—	—	146,613	
Exercise of options to common stock	2,237	976,708	—	—	978,945	
Issued stock options in lieu of cash compensation	—	14,103	—	—	14,103	
Balance, December 31, 1999	<u>257,785</u>	<u>143,463,332</u>	<u>(129,363,954)</u>	<u>(516,507)</u>	<u>13,840,656</u>	
Net loss	—	—	(2,647,617)	—	(2,647,617)	\$ (2,647,617)
Foreign currency translation adjustment . .	—	—	—	(333,522)	(333,522)	(333,522)
Minimum pension liability	—	—	—	(511,900)	(511,900)	(511,900)
Comprehensive loss for the year ended December 31, 2000	—	—	(2,647,617)	(845,422)	—	\$ (3,493,039)
Issued common stock under employee stock purchase plan	190	107,743	—	—	107,933	
Exercise of options to common stock	3,134	1,332,694	—	—	1,335,828	
Exercise of warrants to common stock . . .	6,023	2,387,490	—	—	2,393,513	
Balance, December 31, 2000	<u>267,132</u>	<u>147,291,259</u>	<u>(132,011,571)</u>	<u>(1,361,929)</u>	<u>14,184,891</u>	
Net loss	—	—	(3,875,899)	—	(3,875,899)	\$ (3,875,899)
Foreign currency translation adjustment . .	—	—	—	(385,522)	(385,522)	(385,522)
Minimum pension liability	—	—	—	(621,275)	(621,275)	(621,275)
Comprehensive loss for the year ended December 31, 2001	—	—	(3,875,899)	(1,006,797)	—	\$ (4,882,696)
Issued common stock under employee stock purchase plan	360	106,575	—	—	106,935	
Exercise of options to common stock	535	119,244	—	—	119,779	
Balance, December 31, 2001	<u>\$268,027</u>	<u>\$147,517,078</u>	<u>\$(135,887,470)</u>	<u>\$(2,368,726)</u>	<u>\$ 9,528,909</u>	

The accompanying notes are an integral part of these consolidated financial statements.

DIAMETRICS MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,		
	2001	2000	1999
Cash flows from operating activities:			
Net loss	\$ (3,875,899)	\$ (2,647,617)	\$(10,243,547)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	2,408,285	2,157,034	2,224,519
Other	196,506	(102)	12,988
Changes in operating assets and liabilities:			
Receivables, net	2,125,264	108,544	(1,370,581)
Inventories	213,270	(163,886)	651,189
Prepaid expenses and other current assets	150,120	(112,070)	168,955
Accounts payable	(836,418)	(39,563)	(96,793)
Accrued expenses	(118,019)	(607,845)	501,842
Deferred credits and revenue	749,635	(4,104,849)	5,105,214
Net cash provided by (used in) operating activities . . .	1,012,744	(5,410,354)	(3,046,214)
Cash flows from investing activities:			
Purchases of property and equipment	(1,124,411)	(3,437,775)	(1,689,372)
Sale of evaluation and demonstration instruments	—	—	944,737
Purchases of marketable securities	(4,319,091)	(18,230,499)	(16,026,009)
Proceeds from maturities of marketable securities	9,851,711	23,287,747	7,663,443
Other	(1,100)	4,261	25,819
Net cash provided by (used in) investing activities . . .	4,407,109	1,623,734	(9,081,382)
Cash flows from financing activities:			
Principal payments on borrowings and capital lease obligations	(522,862)	(370,679)	(1,245,332)
Proceeds from borrowings	487,310	115,846	—
Net proceeds from issuance of common stock	226,714	3,837,274	12,995,878
Net cash provided by financing activities	191,162	3,582,441	11,750,546
Effect of exchange rate changes on cash and cash equivalents			
	(387,874)	(150,279)	(269,402)
Net increase (decrease) in cash and cash equivalents . .	5,223,141	(354,458)	(646,452)
Cash and cash equivalents at beginning of year	2,431,704	2,786,162	3,432,614
Cash and cash equivalents at end of year	\$ 7,654,845	\$ 2,431,704	\$ 2,786,162
Supplemental disclosures of cash flow information:			
Cash paid during the year for interest	\$ 572,618	\$ 586,616	\$ 630,459

The accompanying notes are an integral part of these consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of the Business. Diametrics Medical, Inc. along with its subsidiary ("the Company"), is a medical device company engaged in the development, manufacture and commercialization of critical care blood and tissue analysis systems which provide immediate or continuous diagnostic results at the point-of-patient care.

The Company markets its products to health care organizations primarily through distribution partnerships with Philips Medical Systems ("Philips") and Codman & Shurtleff, Inc., a Johnson & Johnson company ("Codman"), who have exclusive global distribution rights for the products they distribute. The Company also continues to sell direct to end-users and through regional distributors for a small volume of products and transactions that are not subject to the exclusive distribution agreements.

Principles of Consolidation. The accompanying consolidated financial statements include the accounts of Diametrics Medical, Inc. and Diametrics Medical, Ltd. ("DML"), its wholly-owned subsidiary. All material *intercompany accounts and transactions have been eliminated.*

Foreign Currency Translation/Transactions. The financial statements of the Company's foreign subsidiary are translated into U.S. dollars for consolidation. All assets and liabilities are translated using period-end exchange rates and statements of operations items are translated using average exchange rates for the period. The resulting translation adjustments are recorded as a separate component of shareholders' equity. Also recorded as translation adjustments in shareholders' equity are transaction gains and losses on intercompany balances for which settlement is not planned or anticipated in the foreseeable future. Other foreign currency transaction gains and losses are included in determining net income, but have not been material in any of the years presented.

Cash and Cash Equivalents. The Company considers highly liquid debt instruments purchased with an original maturity of 90-days or less to be cash equivalents. At December 31, 2001, cash and cash equivalents consist mainly of U.S. government money market funds and investment grade commercial paper.

Marketable Securities. Investments in marketable debt securities are classified as held to maturity and are stated at amortized cost, which approximates estimated fair value. At December 31, 2001, marketable securities consist mainly of investment grade commercial paper, with an original maturity of approximately three months. These securities are classified as held-to-maturity because of the Company's intent and ability to hold its investments to maturity.

Concentration of Credit Risk. Financial instruments that may subject the Company to significant concentrations of credit risk consist primarily of trade receivables. The Company has two major distribution partners in the medical diagnostic device industry who market and sell the Company's products globally under exclusive distribution agreements. As of December 31, 2001 and 2000, outstanding accounts receivable for one of these distributors represented 95% and 85%, respectively, of total outstanding accounts receivable, and sales to this distributor represented 90%, 82% and 63% of sales for the years ended December 31, 2001, 2000 and 1999, respectively. Customer creditworthiness is routinely monitored and collateral is not required.

Sources of Supply. The majority of the raw materials and purchased components used to manufacture the Company's products are readily available. Many of these raw materials and components are purchased from single sources due to technology, price, quality or other considerations. Some of these single-sourced components are manufactured to the Company's design and specifications. Most of these items, however, may be sourced from other suppliers, often after a requalification process. Sourcing from alternative suppliers in some cases may require product design or software changes to accommodate variations from the original components. In the event that the Company's supply of critical raw materials or components was interrupted due to the time required to requalify materials or components or modify product designs, the Company's ability to manufacture the related

product in desired quantities and in a timely manner could be adversely affected. The Company attempts to mitigate these risks by working closely with key suppliers to coordinate product plans and the transition to replacement components for obsolete parts.

Inventories. Inventories are stated at the lower of cost or market using the first in, first out method.

Property and Equipment. Property and equipment and purchased software are recorded at cost. Depreciation and amortization are computed using the straight-line method over estimated useful lives of 2 to 7 years for equipment and furniture and the term of the underlying lease for leasehold improvements. Costs of computer software to be sold are accounted for in accordance with Statement of Financial Accounting Standards ("SFAS") No. 86 "Accounting for the Costs of Computer Software to Be Sold, Leased or Otherwise Marketed," and are amortized over a three-year estimated product life pro-ratably with projected sales over that period. Maintenance and repairs are expensed as incurred.

Other Assets. Other assets consist principally of intangible assets representing purchased completed technology and other intangible assets resulting from the excess of the cost of a purchased business over the fair value of the net assets acquired. The intangible assets are amortized using the straight-line method over five years. The recoverability of the purchased completed technology and other intangible assets is assessed quarterly based upon an analysis of undiscounted cash flows projected to be generated by the acquired business. As of December 31, 2001, the purchased completed technology and other intangible assets were fully amortized.

Revenue Recognition. The Company recognizes revenue upon its shipment of product to its distributors or end-user customers or, in the case of trial instruments and monitors placed directly with end-user customers, upon the customer's acceptance of the product. The Company's sales terms to its distributors and end-user customers provide no right of return outside of the Company's standard warranty policy discussed below under "Product Warranty," and payment terms consistent with industry standards apply. Sales terms and pricing extended to the Company's distributors are governed by the respective distribution agreements, together with binding purchase orders for each transaction. Most of the Company's sales since 1999 (after the inception of the Company's distribution partnerships with Philips and Codman) have been to its distribution partners, totaling 94% of total sales in 2001, and 90% and 70% in 2000 and 1999, respectively. The Company's distribution partners purchase the Company's products to meet sales demand of their end-user customers as well as to fulfill their internal requirements associated with the sales process and contractual purchase commitments under the respective distribution agreements. Internal and other requirements include purchases of products by Philips (and to a lesser extent, Codman) for training, demonstration and evaluation purposes, clinical evaluations, product support, establishing inventories and for meeting minimum purchase requirements. As a result, the level of the Company's revenue during any period is not indicative of its distributors' sales to end-user customers during that period, which are estimated to be substantially less than the Company's sales to those distributors in each of the last three years.

Research and Development. Research and development costs relate to hardware and software development and enhancements to existing products. All such costs are expensed as incurred, with the exception of software costs incurred after the technological feasibility of a software product to be sold has been established. Such software costs are capitalized and amortized in accordance with SFAS 86, discussed under "Property and Equipment" above. Research and development funds earned by the Company under the Philips distribution agreement are recorded as a reduction of the development costs incurred.

Net Loss Per Common Share. Basic earnings per share ("EPS") is calculated by dividing net loss by the weighted average common shares outstanding during the period. Diluted EPS reflects the potential dilution to basic EPS that could occur upon conversion or exercise of securities, options, or other such items, to common shares using the treasury stock method based upon the weighted average fair value of the Company's common shares during the period. For each period presented, basic and diluted loss per share amounts are identical, as the effect of potential common shares is antidilutive.

The following is a summary of outstanding securities which have been excluded from the calculation of diluted EPS because the effect on net loss per common share would have been antidilutive:

	December 31,		
	2001	2000	1999
Common stock options	2,556,518	2,422,141	2,496,241
Common stock warrants	1,406,667	1,414,667	2,121,217
Convertible senior secured fixed rate notes	869,047	869,047	869,047

Product Warranty. The Company, in general, warrants its new hardware and operating system software products to be free from defects in material and workmanship under normal use and service for a period of eighteen months after date of shipment in the case of distributors, and one year after date of sale in the case of end-user customers. The Company warrants its disposable products to be free from defects in material and workmanship under normal use until its stated expiration date. Provisions are made for the estimated cost of maintaining product warranties for the hardware, software and disposable products at the time the products are sold.

Income Taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Due to historical net losses of the Company, a valuation allowance is established to offset the deferred tax asset.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the 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. The Company's significant estimates primarily relate to the assessment of required accounts receivable and inventory valuation allowances, the fair value of long-lived assets, and accounting for foreign currency translation and transactions. Actual results could differ from those estimates.

Stock Based Compensation. The Company applies the intrinsic-value method prescribed in Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," to account for the issuance of stock incentives to employees and directors and, accordingly, no compensation expense related to employees' and directors' stock incentives has been recognized in the financial statements.

Impairment of Long-lived Assets. The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

Reclassifications. Certain 1999 amounts have been reclassified from prior reported balances to conform to the 2001 presentation.

New Accounting Pronouncements. In July 2001, The Financial Accounting Standards Board ("FASB") issued SFAS No. 141 "Business Combinations," and SFAS No. 142 "Goodwill and Other Intangible Assets," which change the accounting for business combinations and goodwill. SFAS No. 141 requires that the purchase method of accounting be used for business combinations initiated after June 30, 2001. Use of the pooling-of-

interests method is prohibited. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including goodwill recorded in past business combinations, will therefore cease upon adoption of the Statement, which for the Company will be January 1, 2002. The Company has evaluated SFAS No. 141 and SFAS No. 142, and has concluded that they do not have a material effect on its financial statements.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." This Statement supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of," and addresses significant issues related to the implementation of SFAS No. 121. SFAS No. 144 establishes a single accounting method under which long-lived assets to be disposed of by sale are measured, which is the lower of book value or fair value less costs to sell. Additionally, SFAS No. 144 expands the scope of discontinued operations to include all components of an entity with operations and cash flows that (1) can be distinguished from the rest of the entity and (2) will be eliminated from the ongoing operations of the entity in a disposal transaction. SFAS No. 144 is effective January 1, 2002 and its provisions are to be applied prospectively. The Company has evaluated SFAS No. 144 and has concluded that it does not have a material effect on its financial statements.

(2) LIQUIDITY

The Company incurred a net loss of \$3,875,899 for the year ended December 31, 2001 and has incurred net losses since inception. The full principal balance of the Company's \$7.3 million Convertible Senior Fixed Rate Notes becomes due August 4, 2003, unless the note holders elect prior to that date to convert the notes into shares of the Company's Common Stock at a conversion price of \$8.40 per share. If the note holders do not exercise the conversion option or do not elect to extend the due date, the Company plans to refinance the notes with debt or equity to the extent cash flows from operations or partnering activities are not sufficient to retire the notes. There is no assurance that the Company will be able to refinance the notes or be able to refinance under favorable terms. The Company believes, however, that excluding the impact of retiring or refinancing the notes, currently available funds and cash generated from projected operating revenues, supplemented by proceeds from employee stock plans, warrant exercises, asset based credit and partnering activities, will meet the Company's currently anticipated working capital needs and capital expenditure requirements. If the amount or timing of funding from these sources or cash requirements vary materially from those currently planned, the Company could require additional capital. While there can be no assurance that adequate funds will be available when needed or on acceptable terms, management believes that the Company will be able to raise adequate funding if needed.

(3) INVENTORIES

	<u>2001</u>	<u>2000</u>
Raw materials	\$1,739,134	\$1,735,460
Work-in-process	1,130,307	1,320,521
Finished goods	1,197,523	1,224,253
	<u>\$4,066,964</u>	<u>\$4,280,234</u>

(4) PROPERTY AND EQUIPMENT

	December 31,	
	2001	2000
Manufacturing equipment	\$ 7,725,234	\$ 7,417,492
Laboratory fixtures and equipment	1,897,190	1,870,254
Data equipment and furniture	3,680,745	3,678,089
Leasehold improvements	3,338,138	3,352,540
Purchased software	1,212,593	1,022,330
Tooling	2,586,469	2,601,734
Demonstration instruments	1,612,885	1,765,246
Equipment-in-progress	847,196	766,562
	<u>22,900,450</u>	<u>22,474,247</u>
Less accumulated depreciation and amortization	<u>(16,721,645)</u>	<u>(15,137,964)</u>
	<u>\$ 6,178,805</u>	<u>\$ 7,336,283</u>

(5) OTHER ASSETS

	December 31,	
	2001	2000
Purchased completed technology, net	\$ —	\$ 328,381
Acquired customer base and other intangible assets, net	—	67,259
Other	6,700	5,600
	<u>\$ 6,700</u>	<u>\$ 401,240</u>

Amortization charged to expense for intangible assets was \$395,640 in 2001 and \$474,772 in both 2000 and 1999.

(6) ACCRUED EXPENSES

	December 31,	
	2001	2000
Employee compensation	\$ 1,338,895	\$ 1,195,974
Product upgrades	—	171,577
Other	457,495	546,858
	<u>\$ 1,796,390</u>	<u>\$ 1,914,409</u>

(7) DEFERRED CREDITS AND REVENUE

	December 31,	
	2001	2000
Deferred research and development funding	\$ 1,666,667	\$ 833,334
Other deferred	83,333	167,031
	<u>\$ 1,750,000</u>	<u>\$ 1,000,365</u>

The Company's distribution agreement with Philips provides for prepaid funding of research and development costs over the initial term of the agreement. These prepayments are being recognized ratably over the periods earned.

(8) BORROWINGS

	December 31,	
	2001	2000
Long-term debt:		
Convertible senior secured fixed rate notes	\$7,300,000	\$7,300,000
Notes payable and bank loan	171,688	597,990
	<u>7,471,688</u>	<u>7,897,990</u>
Less current portion of long-term debt	(161,771)	(425,775)
	<u>\$7,309,917</u>	<u>\$7,472,215</u>

The aggregate maturities of outstanding long-term debt are:

Year ending December 31:	
2002	\$ 161,771
2003	<u>7,309,917</u>
	<u>\$7,471,688</u>

On August 4, 1998, the Company issued Convertible Senior Secured Fixed Rate Notes with proceeds aggregating \$7,300,000. Interest on the Convertible Senior Secured Fixed Rate Notes is payable quarterly in arrears, at 7% per annum. The full principal balance is due August 4, 2003. The notes are secured by the issued and outstanding shares of DML, 100% of which are owned by the Company.

The Convertible Senior Secured Fixed Rate Note agreements contain provisions, which in the event of a change in control of the Company, allow the note holders to require the Company to repurchase all or a portion of the holders' notes at a purchase price of 100% of the principal amount plus accrued and unpaid interest. In addition, the note agreements contain provisions under which the note holders may convert the notes into shares of Common Stock of the Company at a conversion price of \$8.40 per share, subject to adjustment for the impact of certain transactions initiated by the Company that result in dilution of the note holders' investment in the Company.

Amounts outstanding under notes payable are financed with DVI, Inc. and total \$125,396 and \$513,796 at December 31, 2001 and 2000, respectively, and require principal and interest payments in monthly installments at varying amounts through September 2002. The annual interest rates for the notes range from 10.1% to 10.95%. The amount outstanding under the bank loan totals \$46,292 and \$84,194 at December 31, 2001 and 2000, respectively, and bears interest at a fluctuating rate equal to the bank's base rate plus 2.25%. Maturity dates of the notes and loan range from May 25, 2002 to September 25, 2003, and all related borrowings are secured by equipment. See also note 14.

The Company has a \$1,000,000 receivable backed credit line with DVI, Inc. The loan agreement requires the Company's accounts receivable collections be applied to reduce the loan balance, including advances, interest and fees. All advances under the line of credit bear interest on the unpaid principal amount at a fluctuating rate equal to the Prime Rate plus three percent. Interest is payable monthly in arrears. The loan agreement requires the monthly payment of an annualized unutilized loan fee equal to one half of one percent (.5%) of the difference between the committed available loan amount and the average outstanding loan balance. The full \$1,000,000 available under the line of credit was unused at December 31, 2001. The line of credit agreement will not be renewed upon its expiration on June 29, 2002; however, the Company plans to re-establish a line of credit agreement with another source in 2002. See also note 14.

(9) LEASES

The Company is obligated under equipment capital leases that expire at various dates during the next four years. The lease agreements are secured by the related equipment and require principal and interest payments in monthly installments through January 2005, at annual rates ranging from 9.67% to 12%. The capital lease for the manufacturing equipment is with DVI, Inc. See also note 14. The gross amount included in property and equipment and related accumulated amortization relating to capital leases is as follows:

	December 31,	
	2001	2000
Manufacturing equipment	\$481,542	\$ —
Laboratory fixtures and equipment	20,520	—
	<u>502,062</u>	<u>—</u>
Less accumulated amortization	(40,715)	—
	<u>\$461,347</u>	<u>\$ —</u>

The present value of future minimum capital lease payments is as follows:

Year ending December 31:	
2002	\$ 159,511
2003	159,511
2004	154,554
2005	<u>12,121</u>
Total minimum lease payments	485,697
Less amount representing interest	<u>(94,947)</u>
Present value of minimum capital lease payments	390,750
Less current portion of capital lease obligations	<u>(127,915)</u>
Capital lease obligations, excluding current portion	<u>\$ 262,835</u>

(10) STOCK OPTIONS AND WARRANTS

Under the terms of the 1990 Stock Option Plan, incentive stock options and non-qualified stock options to purchase up to 4,450,000 shares of common stock may be granted to Company employees and consultants.

Additionally, the 1993 Directors' Stock Option Plan provides grants to non-employee directors of the Company of non-qualified stock options to purchase up to an aggregate of 467,500 shares of common stock.

Under the plans, the option price is equal to the fair value on the date of grant. Under the 1990 Stock Option Plan, options become exercisable over varying periods and terminate up to ten years from the date of grant. Under the 1993 Directors' Stock Option Plan, initial grants of options to new directors become exercisable over a three-year period and terminate ten years from the date of grant. Subsequent annual grants to directors vest six months after the date of grant. At December 31, 2001, 924,479 and 100,338 additional shares were available for grant under the 1990 Stock Option Plan and 1993 Directors' Stock Option Plan, respectively.

The following tables reflect the per share weighted-average fair value of stock options granted during 2001, 2000 and 1999 under each of the plans on the date of grant using the Black Scholes option-pricing model with the following assumptions: annualized volatility of 85.20%, 77.94% and 76.93% for 2001, 2000 and 1999, respectively; risk-free interest rate of 4.56% in 2001, 5.9% in 2000 and 5.6% in 1999; and for each year, an expected life of five and three years for the 1990 Stock Option Plan and 1993 Directors' Stock Option Plan, respectively.

Summarized below is the status of the Company's stock option plans as of December 31, 2001, 2000 and 1999 and changes during those years:

	2001		2000		1999	
	Shares	Weighted average exercise price	Shares	Weighted average exercise price	Shares	Weighted average exercise price
1990 Stock Option Plan						
Outstanding at beginning of year	2,212,568	\$6.45	2,292,079	\$ 5.50	2,392,714	\$5.43
Granted	324,000	4.22	284,000	11.80	447,668	6.02
Exercised	(53,550)	2.35	(280,236)	4.14	(223,723)	4.38
Expired	(226,793)	6.85	(83,275)	6.23	(324,580)	6.46
Outstanding at end of year	<u>2,256,225</u>	6.19	<u>2,212,568</u>	6.45	<u>2,292,079</u>	5.50
Options exercisable at year-end	1,576,100	5.92	1,572,067	5.57	1,422,129	5.22
Weighted-average fair value of options granted during the year	\$ 2.94		\$ 7.03		\$ 4.00	
1993 Directors' Stock Option Plan						
Outstanding at beginning of year	209,573	\$6.88	204,162	\$ 6.17	160,131	\$6.12
Granted	124,000	4.92	57,334	8.80	44,031	6.38
Exercised	—	—	(33,119)	5.34	—	—
Expired	(33,280)	7.36	(18,804)	7.78	—	—
Outstanding at end of year	<u>300,293</u>	6.02	<u>209,573</u>	6.88	<u>204,162</u>	6.17
Options exercisable at year-end	191,293	6.26	191,573	6.77	195,162	6.13
Weighted-average fair value of options granted during the year	\$ 2.81		\$ 4.79		\$ 3.42	

The following table summarizes information concerning stock options outstanding and exercisable options at December 31, 2001 for the above plans:

OPTIONS OUTSTANDING				OPTIONS EXERCISABLE	
Range of exercise prices	Number outstanding	Weighted average remaining life	Weighted average exercise price	Number exercisable	Weighted average exercise price
\$ 1.72 - 3.88	70,725	5.7	\$ 3.36	68,225	\$ 3.38
4.22 - 4.94	837,512	6.4	4.49	514,262	4.65
5.00 - 5.94	573,744	7.0	5.55	336,044	5.48
6.00 - 6.88	554,404	4.4	6.15	550,279	6.15
7.00 - 7.94	76,354	6.2	7.43	58,929	7.41
8.00 - 9.75	199,115	6.4	8.46	177,240	8.49
11.25 - 12.63	244,664	8.2	12.00	62,414	11.99
	<u>2,556,518</u>	6.3	6.17	<u>1,767,393</u>	5.96

The Company applies APB Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for its plans. Accordingly, no compensation expense has been recognized for its stock-based compensation plans as they relate to employees and directors. Had the Company determined

compensation cost based upon the fair value at the grant date for its stock options under SFAS No. 123, the Company's net loss and net loss per share would have increased to the pro forma amounts indicated below:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Net loss as reported	\$(3,875,899)	\$(2,647,617)	\$(10,243,547)
Net loss pro forma	\$(5,470,925)	\$(4,699,675)	\$(12,045,839)
Net loss per share as reported	\$ (0.14)	\$ (0.10)	\$ (0.41)
Net loss per share pro forma	\$ (0.20)	\$ (0.18)	\$ (0.49)

In connection with certain financing and marketing arrangements entered into since the Company's inception, the Company has granted stock purchase warrants for the purchase of common stock. The stock purchase warrants become exercisable over varying periods and expire up to ten years from the date of grant. Warrant holders exercised warrants for the purchase of 686,550 shares during 2000, which exceeded the number of related shares of common stock issued by the Company by 84,283 shares. This occurred due to cashless exercise provisions in certain of the warrant agreements that allowed the warrant holders to purchase shares of the Company's common stock by surrendering warrants valued at the then current market value of the common stock. At December 31, 2001, stock purchase warrants representing 1,406,667 shares were exercisable. Stock warrants outstanding under these arrangements are summarized as follows:

	<u>2001</u>		<u>2000</u>		<u>1999</u>	
	<u>Shares</u>	<u>Exercise price per share</u>	<u>Shares</u>	<u>Exercise price per share</u>	<u>Shares</u>	<u>Exercise price per share</u>
Outstanding at beginning						
of year	1,414,667	\$4.53 - 8.40	2,121,217	\$1.72 - 8.40	1,713,086	\$1.72 - 8.40
Granted	—	—	—	—	452,381	8.40
Exercised	—	—	(686,550)	1.72 - 6.75	—	—
Expired	(8,000)	5.00	(20,000)	5.25	(44,250)	6.00
Outstanding at end of year . . .	<u>1,406,667</u>	4.53 - 8.40	<u>1,414,667</u>	4.53 - 8.40	<u>2,121,217</u>	1.72 - 8.40
Warrants exercisable at						
year-end	1,406,667	4.53 - 8.40	1,414,667	4.53 - 8.40	2,112,880	1.72 - 8.40

(11) EMPLOYEE STOCK PURCHASE PLAN

The Company adopted an employee stock purchase plan (the "Plan") effective July 3, 1995, under which 400,000 shares of common stock are available for sale to employees. The Plan enables all employees, after an initial 90-day waiting period, to contribute up to 10 percent of their wages toward the purchase of the Company's common stock at 85 percent of the lower of fair market value for such shares on the first or last business day of each quarter.

Participant elections resulted in the issuance of 35,971 shares at an average price per share of \$2.97 in 2001, 19,044 shares at an average price per share of \$5.67 in 2000 and 32,852 shares at an average price per share of \$4.46 in 1999.

(12) EMPLOYEE BENEFIT PLANS

The Company has a 401(k) savings plan for its U.S. employees. U.S. employees of the Company who meet certain age and service requirements may contribute up to 20 percent of their salaries to the plan on a pre-tax basis. The Company has the discretion to match employee contributions \$.50 for each \$1.00 contributed by an employee up to a maximum company contribution of \$1,000 per year. The matching contributions in 2001, 2000 and 1999 totaled \$55,714, \$51,390 and \$0, respectively.

As part of its acquisition of DML in November 1996, the Company assumed sponsorship of the subsidiary's contributory defined benefit retirement plan (the "Retirement Plan"), covering the majority of the subsidiary's employees. The Retirement Plan provides benefits based upon final pensionable salary and years of credited service. The Company's funding policy for the Retirement Plan is to contribute into a trust fund at a rate that is intended to remain at a level percentage of total pensionable payroll. The assets of the Retirement Plan are held separately from those of the Company and invested in the London and Manchester Secure Growth Fund, Balanced Fund and a small holding in the Performance Fund. A portion of the Retirement Plan assets are also invested in the Scottish Equitable Funds.

Contributions to the Retirement Plan are charged to expense so as to provide for the cost of the pensions over the employees' working lives with the Company. The contributions are determined by a qualified actuary on the basis of a valuation using the "attained age" valuation method.

The following provides a reconciliation of the projected benefit obligation, plan assets and funded status of the Retirement Plan at December 31, along with the components of net periodic pension cost for each year presented:

	<u>2001</u>	<u>2000</u>
Change in Projected Benefit Obligation		
Projected benefit obligation at beginning of year	\$ 5,873,855	\$5,442,408
Service cost	426,240	404,320
Interest cost	319,680	290,320
Plan participants' contributions	99,500	143,201
Actuarial (gain) loss	(506,694)	35,266
Benefits paid	(96,805)	(26,466)
Foreign currency exchange rate changes	(154,641)	(415,194)
Projected benefit obligation at end of year	<u>\$ 5,961,135</u>	<u>\$5,873,855</u>
Change in Plan Assets		
Fair value of plan assets at beginning of year	\$ 4,912,570	\$5,011,470
Actual loss on plan assets	(573,777)	(150,062)
Employer contribution	391,082	308,448
Plan participants' contributions	99,500	143,201
Benefits paid	(96,805)	(26,466)
Foreign currency exchange rate changes	(133,315)	(374,021)
Fair value of plan assets at end of year	<u>\$ 4,599,255</u>	<u>\$4,912,570</u>
Funded status	\$ (1,361,880)	\$ (961,285)
Unrecognized actuarial loss	1,567,035	1,091,350
Net amount recognized	<u>\$ 205,155</u>	<u>\$ 130,065</u>
Amounts recognized in the balance sheet consist of:		
Accrued benefit liability	\$ (960,300)	\$ (414,115)
Minimum pension liability	1,165,455	544,180
Net amount recognized	<u>\$ 205,155</u>	<u>\$ 130,065</u>
Rate assumptions:		
Discount rate	5.75%	5.75%
Rate of salary progression	3.50%	3.75%
Long-term rate of return on assets	8.00%	8.00%

	Years ended December 31,		
	2001	2000	1999
Components of Net Periodic Benefit Cost			
Service cost	\$ 426,240	\$ 404,320	\$ 373,689
Interest cost	319,680	290,320	279,862
Expected return on plan assets	(371,520)	(389,120)	(310,598)
Recognized net actuarial loss	57,600	—	21,030
	<u>\$ 432,000</u>	<u>\$ 305,520</u>	<u>\$ 363,983</u>

(13) INCOME TAXES

The Company has incurred net operating losses since inception. The Company has not reflected any benefit of such net operating loss carryforwards in the accompanying financial statements.

As of December 31, 2001 the Company had U.S. tax net operating loss and research and development tax credit carryforwards of approximately \$120,838,000 and \$1,386,000, respectively. Should a cumulative "change in ownership" occur within a three-year period, use of the Company's net operating loss carryforwards may be limited. If not used, net operating loss carryforwards begin to expire in 2005 at the following amounts each year:

Year ending December 31:	
2005	\$ 500,000
2010	1,900,000
2011	4,300,000
2012	13,600,000
2013	11,800,000
Thereafter through 2021	<u>88,700,000</u>
Total net operating loss carryforwards	<u>\$120,800,000</u>

The Company's foreign subsidiary also has a net operating loss carryforward of approximately \$47,044,000 which can be carried forward indefinitely, subject to review by the governmental taxing authority.

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities are as follows at December 31:

	2001	2000
Tax credits	\$ 1,386,000	\$ 1,307,000
Federal net operating loss carryforward	44,710,000	43,477,000
Foreign net operating loss carryforward	15,525,000	15,275,000
Deferred revenue	401,000	313,000
Fixed asset depreciation	321,000	524,000
Amortization of goodwill	576,000	488,000
Accrued expenses	173,000	163,000
Other differences	97,000	124,000
Valuation allowance	<u>(63,189,000)</u>	<u>(61,671,000)</u>
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

The provision for income taxes differs from the expected tax expense, computed by applying the federal corporate rate of 34% to earnings before income taxes as follows:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Expected federal benefit	\$(1,318,000)	\$ (900,000)	\$(3,483,000)
State tax, net of federal benefit	(93,000)	(104,000)	(293,000)
Compensation expense for tax purposes in excess of amounts recognized for financial reporting purposes	(4,000)	(238,000)	—
Other, net	(103,000)	(241,000)	(259,000)
Increase in valuation allowance	1,518,000	1,483,000	4,035,000
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

(14) RELATED PARTY TRANSACTIONS

In August 1998, the Company completed the sale in a private placement of 2,142,858 shares of Common Stock at a price of \$7.00 per share as part of a Common Stock Purchase Agreement, resulting in aggregate proceeds to the Company of \$15,000,006. The purchasers also received five-year warrants to purchase 714,286 shares of Common Stock at \$8.40 per share. In addition, the Company issued Convertible Senior Secured Fixed Rate Notes, with proceeds aggregating \$7,300,000, which were used to retire other debt of the Company. The investor group in both transactions was lead by BCC Acquisition II LLC.

Two of the directors of the Company are affiliated with BCC Acquisition II LLC, and one of these directors participated in the Common Stock Purchase Agreement and the related sale of Convertible Senior Secured Fixed Rate Notes. This director is also a director of DVI, Inc., a health care finance company with which the Company has an available receivable backed credit line (that expires on June 29, 2002), outstanding notes payable and a capital lease. See notes 8 and 9 for further detail on the credit line, notes payable, capital lease and Convertible Senior Secured Fixed Rate Notes.

The Company's exclusive distributors, Philips and Codman, are shareholders of the Company. Additionally, the agreements with both distribution partners provide for minimum annual purchase amounts and market development commitments, and the Philips agreement provides for research and development funding. Sales to these parties were approximately \$23.1 million, \$22.7 million and \$13.1 million for the years ended December 31, 2001, 2000 and 1999, respectively. Outstanding accounts receivable for these distributors represented 98% and 89% of total outstanding accounts receivable as of December 31, 2001 and 2000, respectively.

(15) BUSINESS SEGMENT INFORMATION

The Company develops, manufactures and markets blood and tissue analysis systems that provide immediate or continuous diagnostic results at the point-of-patient care. The Company's blood and tissue analysis systems consist of two technology platforms. The first platform includes intermittent blood testing products based on electrochemical biosensor technology, and the second platform includes continuous monitoring products based on fiberoptic biosensor technology. Effective November 1, 1999, the Company's products are sold primarily to acute care hospitals via third party distribution channels including corporate partners strategically positioned to access worldwide markets. Prior to this, sales in the U.S., United Kingdom and Germany were made through the Company's direct sales force. The Company's disposable cartridges and sensors for the intermittent and continuous monitoring technology platforms, respectively, are manufactured at the Company's facilities. Hardware components of both technology platforms are sub-contracted to outside vendors with portions of the hardware assembly performed internally at the Company's facilities. Both technology platforms are subject to similar regulatory monitoring by the United States Food and Drug Administration and comparable agencies in other countries. The Company's long term outlook for the two technology platforms is that with increased sales volumes, they will exhibit similar financial performance in terms of sales trends and gross margins. Based upon the above, the Company has identified one reportable operating segment consisting of medical diagnostic products which provide blood and tissue analysis at the point-of-patient care.

Information regarding the Company's operations in different geographies for the years ended December 31 is as follows:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Sales to unaffiliated customers			
Germany	\$18,517,416	\$17,338,465	\$ 6,250,366
United States	5,212,462	6,219,310	10,281,646
Japan	262,895	883,299	968,118
All other foreign countries	496,155	817,333	1,187,054
	<u>\$24,488,928</u>	<u>\$25,258,407</u>	<u>\$18,687,184</u>
Long-lived assets			
United States	\$ 3,963,314	\$ 4,770,092	\$ 3,301,162
United Kingdom	2,215,491	2,566,191	2,473,335
	<u>\$ 6,178,805</u>	<u>\$ 7,336,283</u>	<u>\$ 5,774,497</u>

Sales attributed to geographic areas are based upon customer location. Long-lived assets consist of property and equipment located at the Company's facilities in the United States and the United Kingdom.

Sales to one major customer represented 90%, 82% and 63% of total net sales for the years ended December 31, 2001, 2000 and 1999, respectively. The customer for which the above sales were generated is a distributor of the Company operating in the medical diagnostic device industry.

(16) COMMITMENTS

The Company leases its facilities and some of its equipment under non-cancelable operating lease arrangements. The rental payments under these leases are charged to expense as incurred. Rent expense included in the accompanying consolidated statements of operations was \$863,828, \$896,526 and \$873,687 for the years ended December 31, 2001, 2000 and 1999, respectively.

The following is a schedule of future minimum rental payments, excluding property taxes and other operating expenses, required under all non-cancelable operating leases:

Year ending December 31:	
2002	\$ 760,762
2003	695,249
2004	350,465
2005	160,080
2006	37,631
Thereafter	<u>9,484</u>
Total minimum lease payments	<u>\$ 2,013,671</u>

(17) LEGAL PROCEEDINGS

There are no legal proceedings pending, threatened against or involving the Company, which, in the opinion of management, will have a material adverse effect upon consolidated results of operations or financial condition.

(18) QUARTERLY RESULTS OF OPERATIONS (unaudited)

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
2001				
Net sales	\$ 5,715,894	\$6,127,674	\$6,262,823	\$6,382,537
Gross profit	1,314,741	1,674,814	1,705,822	1,809,210
Operating loss	(1,091,893)	(945,337)	(841,612)	(699,144)
Net loss	(1,127,900)	(1,026,951)	(924,591)	(796,457)
Net loss per common share	(0.04)	(0.04)	(0.03)	(0.03)
2000				
Net sales	\$ 5,670,894	\$6,090,343	\$6,580,956	\$6,916,214
Gross profit	1,400,937	1,648,834	1,987,875	2,482,658
Operating loss	(1,179,930)	(949,379)	(534,240)	(79,413)
Net loss	(1,143,409)	(892,620)	(487,271)	(124,317)
Net loss per common share	(0.04)	(0.03)	(0.02)	0.00

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

PART III

Item 10. Directors and Executive Officers of the Registrant

Directors of the Registrant

The information contained under the heading "Election of Directors" in the Company's definitive Proxy Statement for its 2002 Annual Meeting of Shareholders to be held on May 22, 2002, which definitive Proxy Statement will be filed within 120 days after the close of the fiscal year ended December 31, 2001 (the "Proxy Statement"), is incorporated herein by reference.

Executive Officers of the Registrant

See Part I, Item 1 of this Report for information on Executive Officers of the Company.

The information contained under the heading "Compliance with Section 16(a) of the Securities Exchange Act of 1934" in the Proxy Statement is incorporated herein by reference.

Item 11. Executive Compensation

The information contained under the heading "Executive Compensation" in the Proxy Statement is incorporated herein by reference, except that, pursuant to Item 402(a)(8) of Regulation S-K, the subsections under "Executive Compensation" entitled "Report of Compensation Committee on Executive Compensation" and "Comparative Stock Performance" provided in response to paragraphs (k) and (l) of Item 402 are not incorporated by reference herein.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information contained under the heading "Security Ownership of Certain Beneficial Owners and Management" in the Proxy Statement is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions

The information contained under the heading "Certain Transactions" in the Proxy Statement is incorporated by reference.

PART IV

Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a) 1. Financial Statements

The following consolidated financial statements of Diametrics Medical, Inc. and Independent Auditors' Report are filed as part of this Report on pages 23 through 41.

Independent Auditors' Report

Consolidated Statements of Operations for each of the years in the three-year period ended December 31, 2001

Consolidated Balance Sheets at December 31, 2001 and 2000

Consolidated Statements of Shareholders' Equity and Comprehensive Loss for each of the years in the three-year period ended December 31, 2001

Consolidated Statements of Cash Flows for each of the years in the three-year period ended December 31, 2001

Notes to Consolidated Financial Statements

2. Financial Statement Schedules

The following consolidated financial statement schedule of Diametrics Medical, Inc. is filed as part of this Report and should be read in conjunction with the consolidated financial statements of Diametrics Medical, Inc.

Schedule II—Valuation and Qualifying Accounts

All other schedules have been omitted because they are not applicable or not required, or because the required information is included in the consolidated financial statements or the notes thereto.

3. Exhibits

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
3.1	Articles of Incorporation of the Company (as amended)	(12)
3.2	Bylaws of the Company (as amended)	(11)
4.1	Form of Certificate for Common Stock	(1)
4.2	Form of Registration Rights Agreement between the Company and certain of its shareholders and warrant holders	(1)
4.3	Form of Registration Rights Agreement dated as of February 3, 1995 between the Company and certain of its shareholders	(2)
4.4	Registration Rights Agreement, dated as of January 30, 1997, by and between the Company and purchasers of Series I Junior Participating Preferred Stock	(4)
4.5	Registration Rights Agreement, dated as of June 10, 1997, by and between the Company and the Purchasers	(5)
4.6	Form of Certificate for Series I Junior Participating Preferred Stock	(4)
4.7	Form of Stock Purchase Warrant, dated as of January 30, 1997	(4)
4.8	Form of Stock Purchase Warrant, dated as of June 10, 1997	(5)
10.1	Real Property Lease Agreements dated July 31, 1996, between Commers-Klodt, a Minnesota General Partnership, and the Company	(9)
10.2	Amendments, dated June 15, 1999, to Real Property Lease Agreements dated July 31, 1996, between Commers-Klodt, a Minnesota General Partnership, and the Company	(11)

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
10.3	Master Equipment Lease Agreement dated as of June 15, 1993, between the Company and Phoenix Growth Capitol Corp., as amended by Amendment No. 1 dated June 8, 1994 (including form of warrant issued in connection therewith)	(1)
10.4*	1990 Stock Option Plan (as amended and restated), including form of option agreement	(12)
10.5*	1993 Directors' Stock Option Plan (as amended and restated)	(12)
10.6*	1995 Equalizing Director Stock Option Plan	(3)
10.7	1995 Employee Stock Purchase Plan (as revised and restated)	(12)
10.8	Stock Purchase Agreement, dated as of January 30, 1997, between the Company and the Purchasers named therein	(4)
10.9	Stock Purchase Agreement dated as of June 10, 1997, between the Company and the Purchasers named therein	(5)
10.10	Loan and Security Agreement, dated March 31, 1998, between DVI Business Credit and the Company	(6)
10.11	Common Stock Purchase Agreement, dated June 30, 1998, between the Company and the Purchasers named therein	(7)
10.12	Form of Stock Purchase Warrant, dated August 4, 1998	(7)
10.13	Note Purchase Agreement, dated August 4, 1998, between the Company and the Purchasers named therein	(7)
10.14	Form of Convertible Senior Secured Fixed Rate Note due August 4, 2003	(7)
10.15	Distribution Agreement, dated October 1, 1998, between the Company and Johnson & Johnson Professional, Inc.	(8)
10.16	Put Option and Stock Purchase Agreement, dated October 1, 1998, between the Company and Johnson & Johnson Development Corporation	(8)
10.17	Severance Pay Agreement (in the event of Change of Control) dated July 31, 1998, between the Company and David T. Giddings	(8)
10.18	Form of Severance Pay Agreement (in the event of Change of Control) dated July 31, 1998, between the Company and its executive officers	(8)
10.19	Form of Severance Pay Agreement (in the event of Termination Without Cause) dated July 31, 1998, between the Company and its executive officers	(8)
10.20	Distribution Agreement, dated June 6, 1999, between the Company and Hewlett-Packard Company	(10)
10.21	Common Stock Purchase Agreement, dated June 6, 1999, between the Company and Hewlett-Packard Company	(10)
10.22	Stock Purchase Warrant, dated effective as of June 28, 1999	(10)
21	List of Subsidiaries	Filed herewith
23	Consent of KPMG LLP	Filed herewith
24	Powers of Attorney (included in signature page of Report)	Filed herewith
99	Cautionary Statements Under the Private Securities Litigation Reform Act	Filed herewith

* Management compensatory plan filed pursuant to Item 601(b)(10)(iii)(A) of Regulation S-K.

(1) Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration Number 33-78518) (the "Registration Statement").

- (2) Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration Number 33-94442).
- (3) Incorporated by reference to the Company's 1995 Annual Report on Form 10-K.
- (4) Incorporated by reference to the Company's Current Report on Form 8-K filed March 25, 1997.
- (5) Incorporated by reference to the Company's Current Report on Form 8-K filed June 26, 1997.
- (6) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the Quarter ended March 31, 1998.
- (7) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the Quarter ended June 30, 1998.
- (8) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the Quarter ended September 30, 1998.
- (9) Incorporated by reference to the Company's 1998 Annual Report on Form 10-K.
- (10) Incorporated by reference to the Company's Current Report on Form 8-K filed July 23, 1999.
- (11) Incorporated by reference to the Company's 1999 Annual Report on Form 10-K.
- (12) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2001.

(b) Reports on Form 8-K

No Current Reports on Form 8-K were filed by the Company during the fourth quarter of the year ended December 31, 2001.

(c) See Item 14(a)(3) above.

(d) See Item 14(a)(2) above.

Independent Auditors' Report on Financial Statement Schedule

The Board of Directors and Shareholders
Diametrics Medical, Inc.

Under date of January 29, 2002, we reported on the consolidated balance sheets of Diametrics Medical, Inc. and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity and comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2001, which are included in the Annual Report on Form 10-K. In connection with our audits of the aforementioned consolidated financial statements, we also audited the related financial statement schedule as listed in the accompanying index. The financial statement schedule is the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statement schedule based on our audits.

In our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP

Minneapolis, Minnesota
January 29, 2002

Schedule II—Valuation and Qualifying Accounts

	<u>Balance at Beginning of Period</u>	<u>Charged to Costs and Expenses</u>	<u>Charged to Other Accounts</u>	<u>Deductions</u>	<u>Balance at End of Period</u>
Allowance for doubtful accounts:					
2001	\$153,750	\$ —	\$ —	\$ (59,930)*	\$ 93,820
2000	200,000	15,000	—	(61,250)*	153,750
1999	280,000	301,836	—	(381,836)*	200,000
Inventory reserve:					
2001	\$134,818	\$ 55,729	\$ —	\$ (61,475)**	\$129,072
2000	70,125	64,693	—	—	134,818
1999	45,135	24,990	—	—	70,125

* Trade accounts receivable written off against the allowance for doubtful accounts.
** Excess, slow moving or obsolete inventory written off against the inventory reserve.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Roseville, State of Minnesota, on March 27, 2002.

DIAMETRICS MEDICAL, INC.

By /s/ DAVID T. GIDDINGS
 David T. Giddings
 President and Chief Executive Officer

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 March 27, 2002.

KNOW ALL MEN BY THESE PRESENTS, that the undersigned do hereby constitute and appoint David T. Giddings and Laurence L. Betterley, and each of them, each with full power to act without the other, his true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to the Annual Report on Form 10-K for the year ended December 31, 2001 of Diametrics Medical, Inc. , and to file the same, with any and all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all of each of said attorneys-in-fact and agents or any of them may lawfully do or cause to be done by virtue thereof.

<u>Name</u>	<u>Title</u>
<u> /s/ DAVID T. GIDDINGS </u> David T. Giddings	President, Chief Executive Officer and Director (Principal Executive Officer)
<u> /s/ LAURENCE L. BETTERLEY </u> Laurence L. Betterley	Senior Vice President and Chief Financial Officer (Principal Financial Officer)
<u> /s/ JILL M. NUSSBAUM </u> Jill M. Nussbaum	Corporate Controller (Principal Accounting Officer)
<u> /s/ ANDRÉ DE BRUIN </u> André de Bruin	Director and Chairman of the Board
<u> /s/ GERALD L. COHN </u> Gerald L. Cohn	Director
<u> /s/ CARL S. GOLDFISCHER </u> Carl S. Goldfischer, M.D.	Director
<u> /s/ ROY S. JOHNSON </u> Roy S. Johnson	Director
<u> /s/ MARK B. KNUDSON </u> Mark B. Knudson, Ph.D.	Director

EXHIBIT INDEX

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