VENTANA MEDICAL SYSTEMS INC
Form 10-K
March 15, 2005
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2004

OR

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

For the transition period from_____ to _____

Commission file number: 000-20931

VENTANA MEDICAL SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-2976937**

(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
1910 Innovation Park Drive	
Tucson, AZ	**85737**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (520) 887-2155

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

None

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

Common Stock with a par value of $0.001

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 x No ¨

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

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

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant (based on the closing price for the common stock on the Nasdaq National Market on June 30, 2004, which is the last business day of the Registrant s most recently completed second fiscal quarter) was approximately $487,065,339. Shares of common stock held by each officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 1, 2005 there were 35,468,416 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Form 10-K incorporates information by reference from the Registrant s definitive proxy statement to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2004.

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I

This document contains forward-looking statements that are based upon current expectations that are within the meaning of the Private Securities Reform Act of 1995. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance, or achievements, and may contain the words believe , anticipate , expect , estimate , project , will be , wil continue , will likely result , or words or phrases of similar meaning. Forward-looking statements involve risks and uncertainties that may cause actual results to differ materially from the forward-looking statements. We intend such statements be protected by the safe harbor created thereby. Forward-looking statements involve risks and uncertainties and our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. The risks and uncertainties are detailed from time to time in reports filed by us with the SEC, including Forms 8-K, 10-Q, and 10-K. Examples of such forward-looking statements include, but are not limited to statements about:

- timing, willingness, and ability of hospital, academic, and research laboratories to switch to automated slide processing;
- the size and annual growth of the potential markets for our products;
- timing of the introduction of our newly developed products;
- the utility or protection of our intellectual property; our ability to obtain regulatory clearances for our products, and to meet ongoing regulatory requirements related to manufacturing;
- our ability to obtain licenses or rights to intellectual property from third parties and ability to renew existing rights to intellectual property;
- future expectations regarding trade secrets, technological innovations, licensing agreements, and outsourcing of certain business functions;
- ongoing and potential litigation and the strength of our claims and defenses in existing litigation;
- the sufficiency of our current resources to fund our operations over the next twelve months;
- potential competitors or competitive products and our relative strengths;
- potential future dividends;
- potential impact of interest rate and foreign currency fluctuations;
- ability of users of our products to obtain adequate reimbursement;

- expected future sources of revenue and capital or increasing cash needs; and

- accounting assumptions, including assumptions about effective tax rates, recoverability of our deferred tax assets, the adequacy of reserves, valuation of options, and the impact of new accounting rules.

In addition, such statements are subject to the risks and uncertainties discussed in the Risk Factors section and elsewhere in this document. The risks included here are not exhaustive. Other sections of this report may include additional factors that could adversely affect our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for management to predict all such risk factors, nor can it assess the impact of all such risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place reliance on forward-looking statements as a prediction of actual results.

Item 1. Business

Summary of Our Business

Ventana Medical Systems, Inc., was incorporated in California in 1985 and reincorporated in Delaware in 1993. We launched our first instrument-reagent system in 1991 and have since launched numerous new products using both internally developed and acquired technologies. Unless the context requires otherwise, all references

Table of Contents

to we , our , us , Ventana , registrant , or Company refer to Ventana Medical Systems, Inc., and our four subsidiaries: Ventana Medical Syste GmbH, Ventana Medical Systems, Japan K.K., Ventana Medical Systems, Pty. Ltd. and Ventana Medical Systems, S.A.

We develop, manufacture, and market instrument-reagent systems that automate slide staining in anatomical pathology and drug discovery laboratories worldwide. Our products are designed to provide users with automated high-quality and consistent results with high throughput and significant labor savings. Our clinical systems are important tools for anatomical pathology labs in analyzing human tissue to assist in the diagnosis and treatment of cancer and infectious diseases. Our drug discovery systems are used by pharmaceutical and biotechnology companies to accelerate the discovery of new drug targets and to evaluate the safety of new drug compounds. In addition to instruments, we market consumable products, including reagents and other accessories, required to operate our instruments. Our customers include the majority of the top fifty U.S. cancer centers, including recognized leaders in cancer research and treatment, such as Johns Hopkins Hospital, the Mayo Clinic, Memorial Sloan-Kettering Cancer Center, and M.D. Anderson Medical Center.

For the purposes of financial reporting, we have two reportable segments: North America (primarily the United States) and International (primarily France, Germany, Japan, and Australia). Please see Note 15 in the Notes to Consolidated Financial Statements for additional information concerning our North American and International business segments.

Market Overview

There are two target markets for our instrument-reagent systems: (1) anatomical pathology laboratories, which comprise both histology and cytology laboratories, and (2) drug discovery laboratories. We currently obtain the majority of our revenues and profits from ongoing sales of consumables and instruments to anatomical pathology labs worldwide.

According to the National Cancer Institute, cancer is the leading cause of death in the United States. Mortality rates are improved by early detection and the selection of appropriate therapies. Pathologists and oncologists use histology and cytology tests to assist in the diagnosis of cancer and infectious diseases and to select an appropriate therapy. Based upon our modeling of the market, we estimate anatomical pathology labs worldwide currently purchase approximately $1.4 billion in instruments and consumables annually. Most anatomical pathology labs are hospital-based, although some independent reference labs offer these services.

Histology

Histology is the study of the microscopic structure of tissues. In a histology lab, an anatomical pathologist attempts to identify the causes and consequences of disease in a specific part of the body by examining tissue samples obtained during surgery. Structural and other changes in cells, tissues, and organs are determined by using tools ranging from powerful microscopes to molecular analysis of cell proteins and genes. Anatomical pathology examinations are among the most reliable ways to establish a diagnosis of the type of disease suffered by the patient, a prognosis on the likely progression of the disease, and a determination as to which therapies are most likely to be effective in treating the patient.

All patient tissue samples entering the histology lab move through seven sample preparation and work cells:

- *Accessioning* Tissue is entered into the hospital information system for medical records and billing purposes.

- *Grossing* Following accessioning, the entire tissue specimen, termed gross specimen, is examined by a pathologist. Several tissue samples are then cut from the gross specimen for further examination and placed in small plastic cassettes.

- *Tissue Processing* Cassettes from gross specimens are placed in an instrument called a tissue processor. Tissue processors preserve the tissue through the use of a fixative and infuse the tissue with paraffin so it can be cut more readily, or sectioned.

Table of Contents

- *Embedding* Processed tissue is removed from each cassette and embedded in a paraffin block to produce a tissue block of uniform size.

- *Sectioning* Each tissue block is next transferred to the sectioning area of the lab where very thin sections are cut on a microtome and then mounted on a microscope slide.

- *Hematoxylin and Eosin, or H&E, Staining* Each microscope slide is then stained with two basic stains, Hematoxylin and Eosin, that help the pathologist identify each cell s nucleus, cytoplasm, and membrane.

- *Microscopic Examination* Finally, each H&E stained slide is examined by a pathologist using a microscope to determine if the tissue or cells are healthy or diseased. To identify an infectious disease, the pathologist is looking for the presence of microorganisms. To identify cancer, the pathologist looks for deformed cells that could indicate the presence of cancer. In cases where an H&E stained slide appears to have abnormalities, the pathologist performing the initial examination of a patient specimen may request the slide undergo additional testing.

Additional tests, which may be requested by the pathologist, include immunohistochemistry, *in situ* hybridization, or Special Stains tests. These tests are significantly more complex than the H&E stains and require special reagents.

- Immunohistochemistry, or IHC, stains are used primarily by pathologists and oncologists to assist in the diagnosis of cancer and the determination of different treatment options. IHC staining is used to test for the presence or over expression of the proteins involved in cancer.

- *In situ* hybridization, or ISH, stains can be used to assist in the diagnosis of infectious diseases or genetic mutations that are usually associated with the presence of cancer.

- Special Stains are used primarily to assist in the diagnosis of infectious diseases, although they can also be used to assist in cancer diagnosis. Special Stains are chemical dye stains that localize to microorganisms found in tissue and to specific tissue types.

We currently offer products that are used in IHC staining, ISH staining, and Special Stains staining.

IHC Staining. The majority of IHC slides are stained in hospital-based histology labs. However, in North America, Japan, and Australia some hospitals send their IHC slides to regional reference labs for staining, rather than perform the work themselves. We estimate the number of IHC slides processed across all labs in the U.S. is growing about 6% to 8% annually. The first factor increasing the number of IHC slides is the increasing incidence of cancer as the general population ages, thereby increasing histology-producing surgical cases. The second factor is the emergence of new stains that may influence therapeutic choices.

ISH Staining. The clinical market for ISH staining is small currently, due to the difficulty of performing ISH stains manually and the small number of ISH tests, or assays, accepted for clinical use. Currently, ISH is used principally to detect cancer and infectious diseases, primarily viruses, in tissue. We expect automation to grow the clinical ISH staining market significantly, and ISH tests for genetic mutations will become important clinical tools.

Special Stains Staining. We estimate the Special Stains slide market is growing, but is smaller than the worldwide IHC market. There is an opportunity to place instruments with virtually every hospital-based histology lab, as Special Stains slides are rarely sent to reference labs. Currently, nearly all Special Stains slides are processed manually; we believe a major segment of the market will switch to automated slide processing over the next five to ten years.

Cytology

Cytology involves the collection and microscopic analysis of cell samples from various parts of the body for identifying significant abnormal cell changes. The information obtained by cytological analysis allows the physician to detect, diagnose, and monitor cancerous and pre-cancerous disease. Cytology is utilized in the detection and management of cervical cancer, bladder cancer, and lung cancer, among others.

Table of Contents

Cell samples are gathered by the clinician using scraping, brushing, lavaging, or aspiration. The cells are examined, fresh or fixed, and stained by a cytotechnologist who searches for the morphologic abnormalities that characterize disease. The cytopathologist takes this information, along with the patient s medical history and clinical condition, and classifies the findings according to accepted categories. The cytological diagnosis enables the clinician to identify patients who may be at risk for the subsequent development of cancer, detect those who already have cancer, and to monitor the response of cancer to treatment.

In those cases where abnormalities are found to exist, tests, including IHC, ISH, or Special Stains, can be done to assist the cytopathologist in assessing patient samples.

Worldwide, the greatest application of cytology is in cervical cancer screening. Cervical cancer is the second most common cancer in women and is the principal cancer of women in developing countries, which account for 80% of the reported cases. Globally, more than 400,000 cases of cervical cancer are diagnosed annually. In the United States, according to historical incidence data from the National Cancer Institute, there are approximately 15,000 new cases of cervical cancer diagnosed each year. Because cervical cancer can be a highly treatable disease, there is an emphasis on screening and early detection through the use of cervical cytology. According to Women s Health in Primary Care, of the 50 to 60 million American women who undergo cervical cytology, or Pap, testing each year, approximately 3.5 million will have a cytologic abnormality that requires further evaluation.

Drug Discovery

The research market for new drugs comprises over 500,000 researchers worldwide located in labs operated by traditional pharmaceutical and biopharmaceutical companies, governments, and medical research centers. Research is conducted in these labs to determine the causes of disease and to identify specific drugs to treat disease. Both genomics, the study of genes and their function, and proteomics, the study of proteins and their function, seek to accelerate the drug discovery process by understanding the molecular mechanisms of disease.

Genomics has created opportunities to impact the field of human medicine through the discovery of new biological targets for drugs and an improved ability to diagnose and manage disease. Interest in understanding the relationships between genes and disease has generated a worldwide effort to identify and sequence the genes of many organisms, including the approximately three billion nucleotide pairs and the estimated 30,000 genes within the human genome. Researchers then use gene expression and ISH experiments to identify targets and to study localized gene expression. Large pharmaceutical and biotechnology companies use our DISCOVERY® family of systems to hybridize gene expression arrays and to run ISH experiments.

Proteomics is the analysis of proteins that are encoded by active genes, the direct cause of disease in the body. Common belief is there are many more proteins in the human body than genes, which will make mapping the human proteome significantly more challenging than mapping the genome. In drug discovery laboratories, measuring protein expression is a critical step in target validation and determining the mechanism of action for drug candidates. Our DISCOVERY systems are used by large pharmaceutical and biotechnology companies to run IHC and ISH experiments in their target validation, biomarker discovery, and toxicology laboratories.

Strategy

Our objective is to build shareholder value by expanding our competitive position in histology lab automation and by leveraging the core technologies we have developed for histology labs into drug discovery labs. Key elements of our strategy include the following:

- *Provide high-quality, innovative, and flexible automation systems for tissue and cellular analysis.* Our position in histology lab automation has been built on innovative automated instrument-reagent systems. These systems have been designed as broad enabling platforms that permit customers to expand their test menu easily and to provide superior patient care with high-quality, consistent, and timely tissue staining. Labs also benefit by increasing output and reducing labor costs through automation and walk-away convenience.

Table of Contents

- *Provide high-throughput, value-added testing systems for drug discovery applications.* We will expand our position in the research market by continuing to leverage the core competencies developed in our clinical business.

- *Maximize domestic and worldwide placement of automated systems in anatomical pathology and drug discovery laboratories.* The size and quality of our direct sales force is important to our objective of maximizing instrument placements and revenue stream per placement. We believe establishing a large base of our instruments will give us a competitive advantage.

- *Increase consumables revenue generated from our instruments.* Each IHC/ISH or Special Stains instrument placed provides a recurring revenue stream from reagents and other consumable supplies. Our strategy is to increase this revenue stream by expanding our menu of high-value tests, thereby increasing the consumable revenue from each instrument.

- *Continue on-going technological development and improvement of our instrumentation and reagents.* We design our instrumentation products internally. Our engineering, reagent research and development, and marketing organizations work closely with their manufacturing counterparts on all new products to ensure cost-effective production. We seek to protect these designs with an aggressive intellectual property strategy.

Our Products

Our product offerings are summarized as follows.

Staining Systems and Associated Reagents

The principal benefits of automated cellular and tissue analyses using our integrated systems, compared with manual methods, are as follows:

- improved reliability;

- enhanced quality through reproducibility and consistency;

- faster turnaround time;

- increased test throughput;

- reduced dependence on skilled technicians;

- ability to obtain maximum clinical information from minimally sized biopsies;

- ability to document processing protocols; and

- standardization of slide preparation among institutions.

In addition to the critical clinical and operational advantages, our automated approach has shown significant cost savings over manual methods.

Primary Staining. We devoted a great deal of our research and development investment in 2004 to SYMPHONY, our first H&E system. We expect to conduct an initial launch of the system in the middle of 2005 and ramp up the distribution of the product late in 2005 and early 2006. When SYMPHONY is introduced to the histology market, it will be our first entrance into the H&E staining market.

Advanced Staining. Our first product, the ES®, launched in 1991, was an instrument-reagent system to automate IHC staining. Prior to the introduction of this system, all IHC staining was performed manually or with low levels of automation. In early 1996, we acquired BioTek Solutions, Inc., and the TECHMATE® automated stainer. The TECHMATE 500 batch processing instrument had a 120-slide capacity and was designed for large-volume, single-application testing, applicable to large and moderate-sized hospital clinical and reference labs. Though no longer available for sale, there are TECHMATE instruments still in operation.

Table of Contents

Today, we market IHC instrument systems with a full line of complementary reagents and accessories. Our NexES® IHC staining system, launched in 1997, was the first real advance in automating IHC slide staining and introduced a new level of staining quality, while combining system modularity and ease of operation for improved laboratory productivity. The NexES IHC continues to be used by many small to mid-sized laboratories.

Our groundbreaking BENCHMARK® and DISCOVERY® IHC/ISH systems were launched in late 2000 and 1999, respectively, and subsequently replaced by the BENCHMARK XT, BENCHMARK LT, and DISCOVERY XT systems. The BENCHMARK series instruments are the only slide preparation systems to offer fully automated Baking Through Staining (BTS) technology and the flexibility of multiple technologies (IHC and ISH), providing superior, standardized stain quality, increased testing efficiency, and maximum laboratory productivity. BTS technology describes the automation process, which saves work by performing the baking, deparaffinization, cell conditioning or antigen unmasking, and staining all on-line, thereby providing full walk-away convenience. The BENCHMARK and DISCOVERY systems use a bar code that is affixed to each slide to identify the sample and the testing procedures to be performed. Dispensing, incubation (i.e., temperature and time control), and washing are performed using proprietary chemical and mechanical methods critical to obtaining precise, sensitive, and rapid test results. All aspects of the testing procedure are controlled by our proprietary software, which makes the systems reliable and easy to use.

Our current-generation BENCHMARK XT and BENCHMARK LT systems, introduced in late 2003 and early 2004, respectively, represent the latest and most advanced instrumentation developed to date by us. The XT and LT provide additional flexibility by providing more protocol options, including the ability to optimize temperature, incubation, and pretreatment steps, in addition to allowing simultaneous processing of IHC and ISH samples. The XT also adds more capacity by increasing throughput by up to 50%. The next-generation DISCOVERY XT, introduced in early 2004, combines all of the improvements of the BENCHMARK XT, with the added advantage of microarray capability and research-level flexibility for protocol development.

We manufacture and market an extensive line of primary antibodies, probes, and detection chemistries for use on our systems. In combination, these reagents detect antigens of interest in tissue samples by generating a visual signal in an IHC/ISH reaction at the site where a primary antibody or probe is bound to a specific antigen or molecule in the cell or tissue.

Customers performing tests with our instruments must use our detection chemistries on all tests but have the option of purchasing primary antibodies from other sources. Our detection chemistries, primary antibodies, probes, and other reagents have been developed using proprietary formulations that, when combined with our instruments, optimize the results of the tests performed.

Special Stains. In late 1998, we offered anatomical pathology labs the first automated system for Special Stains testing with the launch of our second instrument-reagent system. The Special Stains module can be operated with the same control computer that operates our NexES IHC and BENCHMARK series of systems, with up to eight complete systems operating from one computer. This flexibility enables customers to design a combination Special Stains/IHC/ISH system that meets their specific needs and provides flexibility for future lab growth. Presently, our 14 Special Stains kits, all developed using proprietary protocols, potentially serve 90% of all Special Stains testing performed in anatomical pathology labs.

Image Analysis. In the second half of 2004, we signed an agreement with TriPath Imaging Inc. of Burlington, North Carolina. Under the agreement, we obtained exclusive rights to sell and distribute worldwide a Ventana-branded version of TriPath Imaging s interactive histology imaging system that will be optimized for both Ventana and TriPath Imaging assays. The interactive histology imaging system is being developed to offer anatomic pathology laboratories a cost-effective solution utilizing on-demand digital imaging, direct visualization of IHC stained slides, and real-time quantitative analysis of tissue samples. In 2005, we expect to launch the image analysis system, bringing us into a new segment of the pathology laboratory.

Contracts

Instruments are placed through direct sales, instrument rentals, and our Performance Evaluation Period (PEP) program. The PEP program is a formal agreement whereby a staining system is installed on the premises

Table of Contents

of a pre-qualified customer for the purpose of allowing the customer to evaluate the system s functionality over an extended trial period. The customer agrees to purchase a reagent starter kit at the time of installation and to purchase a minimum volume of reagents over the life of the trial period. Minimum purchase requirements vary by customer. Upon completion of the trial period, the customer purchases the staining system or returns it to us.

Research and Development

Our research and development organization is divided into two distinct but complementary teams. One team is focused on core research/discovery in the area of technology development and the second team is focused on new product development. As new technologies are proven to be feasible by the Discovery team, they are transferred to the Development team for incorporation into new products. Our efforts are focused on innovative combined instrument-reagent systems, as well as enhancements to existing instruments. In addition, we are developing new reagents for current and future customer applications.

Our 142 research and development employees perform the majority of our research and development activities. Their efforts are supplemented by consulting services and assistance from scientific advisors. We incurred research and development expenses of $21.2 million, $19.6 million, and $16.4 million in 2004, 2003, and 2002, respectively.

Instrumentation Development Projects

Our instrumentation development is focused on product improvement and new product development. The modular platform used by our NexES IHC system enabled us to develop new products rapidly, such as the NexES Special Stains system, the DISCOVERY system, the BENCHMARK system, and most recently the BENCHMARK XT/LT and DISCOVERY XT systems. This modular development strategy will continue as we explore new opportunities in instrument systems and in automating manual lab processes.

In 2004, our Research and Development teams devoted significant time to developing SYMPHONY, our first H&E staining system. When SYMPHONY is introduced to the histology market in 2005, it will be our first entry into the primary staining market.

Reagent Development Projects

Our reagent development is divided into five principal areas:

- primary antibodies;
- detection chemistries;

- molecular probes;

- biological stains;

- ISH and IHC applications for the BENCHMARK XT/LT and DISCOVERY XT.

We continue to monitor third-party development of new primary antibodies used to identify abnormal levels of protein expression in patients and to assist pathologists in recommending treatment. We will license or purchase these antibodies as appropriate. New detection chemistries with improved sensitivity continue to be developed through our research efforts. Reagent development for our systems is on going.

Customers

Our customers consist of hospital-based anatomical pathology labs, independent reference labs, the drug discovery labs of pharmaceutical companies, biotechnology companies, government labs, medical research centers, and resellers serving these entities. None of our customers accounted for more than 5% of our consolidated revenues in 2004, 2003, or 2002.

Table of Contents

Patents and Proprietary Rights

We seek to establish and maintain our proprietary rights in our technology and products through the use of patents, copyrights, trademarks, and trade secret laws. We file applications for and obtain patents, copyrights, and trademarks in the United States and in selected foreign countries where we believe filing for such protection is appropriate. We also seek to protect our trade secrets and confidential information by non-disclosure policies and through the use of appropriate confidentiality agreements. We have obtained a substantial number of patents and trademarks in the United States and in other countries. There can be no assurance, however, that these patents are valid or can be enforced against competitive products in every jurisdiction.

Many of our products include intellectual property licensed from third parties. While it may be necessary in the future to seek or renew licenses relating to various aspects of our products, based upon experience and standard industry practice, we believe such licenses could generally be obtained on commercially reasonable terms. Nonetheless, there can be no assurance that the necessary licenses would be available on acceptable terms, if at all. Our inability to obtain certain licenses or other rights or to obtain such licenses or rights on favorable terms or the need to engage in litigation regarding these matters, could have material adverse effects on our business, operating results, and financial condition.

The industry in which we compete is characterized by rapidly changing technology, a large number of patents, and frequent claims and related litigation regarding patent and other intellectual property rights. For example, in the CytoLogix litigation, described in further detail under *Item 3, Legal Proceedings*, we have received an adverse judgment and were determined to infringe CytoLogix s patents for Moving Platform Slide Stainer With Heating Elements (U.S. 6,180,061), and Random Access Slide Stainer with Independent Slide Heating Regulation (U.S. 6,183,693). Currently, we are enjoined from the manufacture and sale of our first-generation DISCOVERY and BENCHMARK instruments and may have to pay damages, including royalties, if our appeal is unsuccessful. Our second-generation BENCHMARK XT/LT instruments are also the subject of a separate patent litigation by CytoLogix (see *Item 3, Legal Proceedings*).

There can be no assurance that our patents and other proprietary rights will not be challenged, invalidated, or circumvented, that others will not assert intellectual property rights to technologies that are relevant to us, or that our rights will give us a competitive advantage. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as the laws of the United States. The risks associated with patents and intellectual property is more fully discussed in the section of this report titled *Risk Factors* .

Sales and Marketing

Our sales and marketing strategy is to provide superior levels of service to our customers. In our major markets, including North America, Europe, Japan, and Australia, we seek to achieve this goal by selling our products directly to our customers. We believe we have the largest direct sales force calling on histology labs today. Our sales teams are organized by region in North America, except for national and certain key accounts, and by country internationally. In smaller markets, we rely on strategic distributors to sell and service our products.

To augment our clinical anatomical pathology tactical marketing and sales organizations, we have established similar operations to cover our drug discovery line of business. These sales forces in North America, Europe, and Japan primarily promote our DISCOVERY XT systems and related consumables.

A complementary worldwide marketing team is responsible for identifying new product opportunities, for working with our research and development group on product development, and for driving worldwide revenues through marketing support.

Competition

We face an array of competitors in the anatomical pathology lab and drug discovery lab markets. Competition is intense and is based on product performance, product price, product line breadth, and after-sales service.

Table of Contents

Histology

While we are a leader in automated IHC and ISH staining, we face strong competition from the manual method of performing IHC and ISH tests and from competitors marketing instrument-reagent IHC and ISH staining systems. A number of anatomical pathology labs in the U.S. and the majority outside the U.S. continue to perform IHC and ISH slide staining manually. Significant barriers exist to automation in countries where insurance or government healthcare reimbursement for IHC testing is low. Additionally, labs in which pathologists prefer manually stained slides remain reluctant to automate their processes.

Currently, direct competition comes from five competitors selling instrument-reagent IHC staining systems. These competitors are DakoCytomation A/S (Dako), a Danish company that holds a significant share of the market for manual IHC reagents; BioGenex Laboratories, Inc., a company marketing instruments with a reagent annuity; Lab Vision Corporation, a subsidiary of Apogent Technologies, Inc., a company that supplies Dako with instruments and markets its instruments through distributors and a direct sales force; Diagnostics Products Corp., a company that markets high-volume IHC staining systems in Europe, and Vision Bio Systems Ltd. (Vision), an Australian biomedical company. Dako launched an automated IHC system in 2004. Vision launched an automated IHC/ISH staining system in Europe and Asia Pacific during 2004 but postponed the U.S. launch of this system due to a Court ruling that the system infringes on two of our patents (see *Item 3, Legal Proceedings*). Two automated Special Stains systems compete with our Special Stains module: one system offered by Dako, which is the subject of a patent infringement lawsuit filed by us, and another offered by BioGenex. We believe our success in the Special Stains market will attract additional competitors.

Cytology

The current Human Papillomavirus (HPV) testing market is dominated by Digene Corporation with its U.S. Food and Drug Administration (FDA) approved HYBRID CAPTURE II® liquid-based prep assay holding more than 95% of the HPV testing market.

Drug Discovery

Our focus is on the study of the hybridization of nucleic acid microarrays and messenger RNA expression. Our competitors in nucleic acid micro array hybridization include Tecan Group Ltd., Affymetrix, Inc., and Amersham Biosciences UK Limited. Currently, we do not face competition providing automated systems for messenger RNA expression studies. In drug discovery IHC staining, competition includes clinical IHC competitors, Dako and BioGenex.

Manufacturing

All of our instrument and reagent manufacturing operations are housed in a single facility located in Tucson, Arizona. Medical device manufacturing operations are conducted under the FDA Quality System Regulations. These regulations subject our facilities to inspections to verify compliance and require us to maintain documentation and controls for our manufacturing and quality activities. ISO 13485 is the international quality standard for medical device manufacturers, based upon the ISO 9001 quality standard, with additional specific industry requirements consistent with the FDA Quality System Regulation. We received ISO 13485 certification in February 2003.

Employees

As of December 31, 2004, we had 732 full-time employees, including our 5 officers.

Available Information

We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission (SEC), including

Table of Contents

reports on the following forms: annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934.

The public may read and copy any materials we file with the SEC at the SEC s Public Reference Room at 450 Fifth Street NW, Washington, DC 20549. Members of the public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains at http://www.sec.gov an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

You may also find electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 on our website at http://www.ventanamed.com. Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC.

FACTORS THAT COULD AFFECT FUTURE RESULTS

Because of the following factors, as well as other variables affecting our operating results, past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods.

Our products could infringe the intellectual property rights of others, which might cause us to engage in costly litigation, and if we are not successful, could cause us to pay substantial damages and prohibit us from selling our products.

Third parties may assert patent, trademark, or copyright infringement or other intellectual property claims against us, based on their patents or other intellectual property. We may be required to pay substantial damages (including treble damages) for past infringement, if it is ultimately determined our products infringe a third-party s intellectual property rights. Even if infringement claims against us are without merit, defending a lawsuit takes significant time, is expensive, and may divert management s attention from other business concerns. If we are not successful in a lawsuit, we may be unable to sell our products or to continue to sell our products until we obtain a license from the owner of the relevant technology or other intellectual property rights, which may not be available to us. Even if a license is available, it may require us to pay substantial royalties. (For further discussion of litigation matters, please refer to *Item 3, Legal Proceedings*).

If we are unsuccessful in appealing the adverse judgment we received in connection with the CytoLogix litigation, we may be forced to pay damages to CytoLogix.

As discussed in more detail under *Item 3. Legal Proceedings*, we have been involved in litigation with CytoLogix, Inc., pursuant to which a jury determined that we infringed certain CytoLogix patents. The patents in question relate to prior versions of our BENCHMARK and DISCOVERY instruments and do not apply to the current versions of the BENCHMARK XT / LT and DISCOVERY XT instruments.

We have appealed the decision. However, our success cannot be guaranteed, and, if we are ultimately unsuccessful in the litigation, we may be forced to pay damages including royalties to CytoLogix for our first-generation BENCHMARK and DISCOVERY products. In addition, our

BENCHMARK XT/LT and DISCOVERY XT instruments are the subject of separate litigation.

If we fail to comply with the FDA s Quality System regulations, our manufacturing operations could be delayed, and our product sales and profitability could suffer.

When manufacturing our medical devices, including Analyte Specific Reagents, we are required to adhere to Quality System regulations, which require us to manufacture our products and maintain records in a prescribed manner. We are subject to future FDA Quality System inspections, and we cannot assure you that we will pass these inspections or maintain compliance.

Table of Contents

Complying with international regulatory requirements is an expensive, time-consuming process, and approval is never certain.

Sales of our products in the European Union (EU) are subject to strict regulatory requirements, and approval is never certain. All of our products must be in compliance with the *In Vitro* Diagnostics Directive and bear the CE mark before being imported for sale in the EU. The CE mark is a symbol indicating the device conforms to the essential requirements of the applicable directive and can be commercially distributed throughout the EU. The *In Vitro* Diagnostic Directive also subjects our manufacturing facilities to compliance inspections and requires design, manufacturing, and quality process documentation and controls. Some of our products do not bear the CE mark. We cannot assure you that the CE mark will be granted for all our products or that regulatory review will not involve delays that would harm our ability to market and sell our products in the EU.

If our customers do not receive adequate third-party reimbursement, our products may not be accepted in the market.

In the United States, our products are primarily purchased by medical institutions and laboratories that bill third-party payers, such as government health administration authorities, private health coverage insurers, managed care organizations, and other similar organizations. Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available to our customers from third-party payers. Third-party payers are increasingly attempting to limit both the coverage and the level of reimbursement of products to contain costs, and if successful, our ability to sustain revenue growth and profitably will be adversely affected.

Clinical Laboratory Improvement Act (CLIA) regulations could harm our business by limiting the potential market for our products.

Any of the customers using our products for clinical use in the United States may be regulated under the CLIA. CLIA is intended to ensure the quality and reliability of clinical laboratories in the U.S. by mandating specific standards in the areas of personnel qualification, administration, proficiency testing, patient test management, quality control, quality assurance, and inspections. The regulations promulgated under CLIA establish three levels of clinical tests, and the standards applicable to a clinical laboratory depend on the level of the tests it performs. CLIA requirements may prevent some clinical laboratories from using our products. Therefore, CLIA regulations and future administrative interpretations of CLIA could harm our business by limiting the potential market for our products.

Unanticipated changes in our tax rates or exposure to additional tax liabilities could affect our profitability.

We are subject to income taxes in both the U.S. and various foreign jurisdictions, and our domestic and international tax liabilities are subject to the allocation of expenses in different jurisdictions. Our effective tax rates could be adversely affected by changes in the mix of earnings in countries with differing statutory tax rates, in the valuation of deferred tax assets and liabilities or in tax laws, or by material audit assessments, which could affect our profitability. In particular, the carrying value of deferred tax assets, which are predominantly in the U.S., is dependent on our ability to generate future taxable income in the U.S. In addition, the amount of tax we pay is subject to ongoing audits in various jurisdictions, and a material assessment by a governing tax authority could affect our profitability. Further, if we elect to repatriate cash held outside the U.S. pursuant to The American Jobs Creation Act of 2004, our tax rate may increase even if by a lesser amount than without such legislation.

If we have problems with key suppliers, our product development and commercialization efforts could be delayed or stopped.

Our reagent products are formulated from chemical and biological materials using proprietary technology and standard processing techniques. We purchase components and raw materials used to make our reagent

Table of Contents

products from single-source vendors. We cannot assure the materials or reagents will be available in commercial quantities or at acceptable prices. Any supply interruption or yield problems encountered in the use of materials from these vendors could have a significant effect on our ability to manufacture our products. Developing alternative or additional suppliers could be time consuming and expensive.

A number of components used to manufacture instruments is made on a custom basis to our specifications and is available from a limited number of sources. If the supply of materials or components from any of these vendors were delayed or interrupted for any reason, or if the quality or reliability of the materials or components proves inadequate for use in our instruments, our ability to make instruments in a timely fashion could be impaired, and our results of operations would suffer.

We could bring litigation to enforce our intellectual property rights, which might result in substantial expense.

We rely on patents to protect our intellectual property rights. The strength of this protection, however, is uncertain. In particular, it is not certain that:

- our patents and pending patent applications use technology that we invented first;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate our technologies;
- any of our pending patent applications will result in issued patents; or
- any patents issued to us will provide a basis for commercially viable products, will provide us with any competitive advantages, or will not face third-party challenges or be the subject of further proceedings limiting their scope.

We may become involved in interference proceedings in the U.S. Patent and Trademark Office to determine the priority of our inventions. We also could become involved in opposition proceedings in foreign countries challenging the validity of our patents. In addition, costly litigation could be necessary to protect our patent position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving, and consequently, patent positions in our industry are generally uncertain. We may not prevail in any lawsuit, or if we do prevail, we may not receive commercially valuable remedies. Failure or inability to protect our patent rights or intellectual property could have serious adverse effects on our business and could affect our profitability.

We also rely on trade secrets, unpatented proprietary know-how, and continuing technological innovation that we seek to protect with confidentiality agreements with employees, consultants, and others with whom we discuss our business. These individuals may breach our confidentiality agreements, and our remedies may not be adequate to enforce these agreements. Disputes may arise concerning the ownership of intellectual property or the applicability or enforceability of these agreements, and we may not be able to resolve these disputes in our favor. Furthermore, competitors may independently develop trade secrets and proprietary technology similar to ours. We may not be able to maintain the confidentiality of information relating to products.

We deal with hazardous materials and generate hazardous wastes and must comply with environmental laws and regulations, which can be expensive and restrict how we do business. We could also be liable for damages or penalties, if we are involved in a hazardous material or waste spill or other accident.

Our manufacturing processes, primarily those involved in producing some of our reagent products, require the use of potentially hazardous and carcinogenic chemicals. We are subject to federal, state, and local laws and regulations governing the use, manufacture, storage, handling, and disposal of these materials and waste. In the event of a hazardous material or waste spill or other accident, we could also be liable for damages or penalties. In addition, we may be liable or potentially liable for injury or contamination as a result of our own, or a third party s, use of these materials, and such liability, if significant, could seriously impair our financial position.

Table of Contents

We cannot assure you that we will be able to fund our future capital requirements through internal sources or from other sources.

We anticipate our existing capital resources and borrowing capacity will be adequate to satisfy our capital requirements for the next 12 months. Our future capital requirements will depend on many factors including:

- the extent that our products gain market acceptance;
- the mix of instruments placed through direct sales, rental, or through our PEP program;
- the progression of our product development programs;
- competing technological and market developments;
- expansion of our sales and marketing activities;
- the cost of manufacturing scale-up activities;
- possible acquisitions of complementary businesses, products, or technologies; and
- our ability to sustain profitability with the uncertain timing of regulatory approvals.

We may require additional capital resources and cannot assure you that capital will be available to the extent required, on terms acceptable to us, or at all. Any such future capital requirements could result in the issuance of equity securities, which may affect the market price of our common stock and would dilute the interests of our existing stockholders.

Recent legislation requires us to undertake an annual evaluation of our internal control over financial reporting (ICFR) that may identify internal control weaknesses requiring remediation that could harm our reputation or subject us to investigation and sanctions by regulatory authorities.

We have recently completed our evaluation of the design, remediation, and testing of effectiveness of our ICFR required to comply with the management certification and attestation by our independent registered public accounting firm, as required by Section 404 of the Sarbanes-Oxley Act of 2002. While our assessment, testing, and evaluation of the design and operating effectiveness of our ICFR resulted in our conclusion that our ICFR was effective as of December 31, 2004, we cannot predict the outcome of our testing in future periods. If we conclude in future periods our ICFR is not effective, we may be required to change our ICFR to remediate deficiencies, which could result in lost investor confidence in the reliability of our financial statements, and we may be subject to investigation and/or sanctions by regulatory authorities. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented, or amended from time to time, we may not be able to ensure we can conclude on an ongoing basis that we have effective controls over financial reporting in accordance with Section 404, and our independent auditors may not be able to render the required attestation concerning our assessment and the

effectiveness of the internal controls over financial reporting. If we fail to maintain an effective internal control environment or our independent auditors are unable to render the required attestation, it could have a material adverse effect on investor confidence in our reported financial information. Any such events could adversely affect our financial results and/or the market price of our common stock, and our reputation may be harmed.

Item 2. Properties

Our U.S. operation, including research laboratories, instrument, and reagent manufacturing facilities and administrative offices, is located in approximately 182,400-square-feet of owned space in Tucson, Arizona.

Our European operation is located in approximately 39,000-square-feet of owned space in Strasbourg, France.

Our Japanese operation is located in 1,400-square-feet of leased office space in Yokohama. The lease for the Yokohama facility expires in January 2007.

Table of Contents

Our Asia Pacific operation is located in approximately 700-square-feet of leased office space in Melbourne, Australia. The lease for the Melbourne facility expires in February 2006.

We believe our properties described above are adequate for our current operations.

Item 3. Legal Proceedings

VENTANA v. DAKOCYTOMATION, Civil Action No. 04-1522, was filed in December 2004, in the U.S. District Court, District of Delaware, alleging infringement of U.S. Patent No. 6,827,901 (Automated Biological Reaction Apparatus) by the making, using, and selling of the ARTISAN staining system. The suit seeks injunctive relief including a Preliminary Injunction against the continued making, using, and selling of the instrument and unspecified damages. DakoCytomation filed an Answer to the Complaint in January 2005.

CYTOLOGIX v. VENTANA, Civil Action No. 04-04-232, was served in April 2004, in the U.S. District Court, District of Delaware alleging infringement of U.S. Patent No. 6,541,261 B1. CytoLogix alleges the manufacture, use, and sale of our BENCHMARK XT slide staining system infringes the 261 patent. We dispute all of these contentions and we will defend ourselves vigorously. CytoLogix has asked for an injunction, unspecified damages, and enhanced damages for willful infringement. We filed our Answer and Counterclaim to the Complaint in May 2004, along with a Motion to Transfer the case to the U.S. District Court, Eastern District of Massachusetts. In July 2004, the Delaware District Court granted the motion and the case has been transferred to the Federal District Court in Boston, Civil Action No. 04-11783 (RWZ). The parties have commenced discovery and are currently awaiting entry of a Scheduling Order.

CYTOLOGIX v. VENTANA, Civil Action No. 00-12231 REK, was filed in October 2000 in the U.S. District Court, Eastern District of Massachusetts. The complaint alleges, under state-law based unfair competition law, Ventana misappropriated CytoLogix s trade secrets related to individual slide heating and incorporated such secrets into our DISCOVERY and BENCHMARK instruments. CytoLogix seeks assignment of our patent applications relating to individual slide heating claiming the idea, treble damages (unspecified amount), and an injunction against our further sales of DISCOVERY and BENCHMARK instruments (see, related case no. 01-10178 REK and discussion below). In February 2002, CytoLogix filed a motion to amend their complaint to add the related claims of attempted monopolization and monopolization under the Sherman Act, and various Lanham Act violations, which was allowed by the Court.

CYTOLOGIX v. VENTANA, Civil Action No. 01-10178 REK, was filed in January 2001 in the U.S. District Court, Eastern District of Massachusetts. This complaint alleges we infringed on CytoLogix s patent No. 6,180,061, titled Moving Platform Slide Stainer with Heating Elements , and the Complaint was later amended to add U.S. Patent No. 6,183,693, issued in February 2001, titled Random Access Slide Stainer with Independent Slide Heating Regulation , both assigned to CytoLogix. CytoLogix seeks assignment of our patent applications claiming the independent slide heater idea, treble damages for willful infringement (unspecified amount), and an injunction against our further manufacture and sale of DISCOVERY and BENCHMARK instruments.

At the December 2003, conclusion of the trial on the issues of patent infringement and trade secret misappropriation, the jury found Ventana liable for infringement on the two patent cases (no willful infringement), and on the trade secret issue, the jury determined we had not misappropriated any trade secrets. We filed post-trial motions for judgment as a matter of law and for a new trial. A hearing for a permanent injunction occurred in February 2004. At the hearing, the Judge ruled on several issues, including denying the parties post-trial motions and framing the scope of the injunction. A permanent injunction was entered by the Court in April 2004, which prohibits us from making and selling the DISCOVERY/BENCHMARK systems but does not prohibit their continued use by customers and will not prohibit us from servicing the instruments or supplying reagents to customers. In May 2004, we filed Notices of Appeal to the Court of Appeals for the Federal Circuit, on the

patent infringement claims and CytoLogix, on the willfulness and misappropriation claims. In the ensuing months, both parties filed their respective appellate briefs. In February 2005, the Appeals

Table of Contents

Court dismissed CytoLogix s appeal as not presently before the Court and ordered corrected briefing. The appeal is likely to be decided in mid-year 2005. Hearings on the issues of patent damages and the antitrust-related claims will not be scheduled until the conclusion of the Ventana appeal.

CYTOLOGIX v. VENTANA, Case No. 4 Ni 54/00 (EU) (Nullity suit), was filed in November 2000 in the German Federal Patent Court, Munich, Germany. In a decision at an oral hearing in March 2002, the German Federal Patent Court ruled our German Patent No. DE 69117052.5, which covers various aspects of our previous generation GENII® automated slide staining system, is invalid. The technology addressed by the German patent is unrelated to the technologies involved in any of the other patent litigations, including the individual slide heating technology that is the subject of the Boston-based patent litigation. The decision affects our ability to enforce this patent in Germany subject to an appeal and final decision on validity. In May 2002, we filed an appeal to the German Federal Court of Justice seeking the previous judgment be set aside and the complaint be dismissed by substituting an amended claim into the patent. We have been advised by German Patent Counsel that the case is behind schedule, and a hearing may occur in the 2005-2006 time frame.

VISION BIOSYSTEMS, LTD v. VENTANA, Civil Action No. 03 CV 10391-GAO was filed in March 2003, in the U.S. District Court, Eastern District of Massachusetts. We were served with a Summons and Complaint by Vision BioSystems (Vision) for a Declaratory Judgment seeking a declaration of no infringement and invalidity of U.S. Patent Nos. 5,355,439 and 6,352,861, both owned by us. The Complaint alleges we have asserted that Vision s BOND system infringes both of the aforementioned patents and Vision has a reasonable apprehension of being sued. In May 2003, we filed our Answer to the Vision Complaint in the Massachusetts action. In November 2003, Vision filed a motion for Summary Judgment of non-infringement of the 861 patent. In November 2003, we filed a motion to amend our Answer to add a counterclaim for infringement of the 439 and 861 patents by the BOND system. In January 2004, we filed our opposition to Vision s Summary Judgment motion and filed our own cross-motion for Summary Judgment of infringement. The hearing on both Summary Judgment motions was conducted in May 2004. In September 2004, the Judge denied Vision s motion for Summary Judgment and ruled in favor of our cross-motion for Summary Judgment that Vision s BOND system infringes claims 1 and 5 of the 861 patent. The Court also dismissed the 439 patent from the case. Trial on the remaining issues of patent invalidity and damages is scheduled for July 2005.

DIGENE CORPORATION v. VENTANA, Civil Action No. 01-752, was filed in November 2001, in the U.S. District Court, District of Delaware. This Complaint alleges we infringe two U.S. patents held by Digene, U.S. 4,849,331 and 4,849,332, by activities relating to our INFORM® HPV Family 16 and Family 6 probe products. We filed an Answer denying the allegations in February 2002. The parties have filed cross-motions for Summary Judgment. In addition, in November 2002, Digene filed a motion to amend its Complaint to add numerous causes of action related to our September 2002 acquisition of Beckman Coulter s (Beckman) HPV business and to add Beckman as a party. Digene seeks, among other remedies, an injunction against the sale of our INFORM HPV products, unspecified monetary damages, cancellation of the Beckman HPV acquisition, and related claims. Several motions were filed by the parties, one of them being a motion to compel arbitration by Beckman and us. In May 2003, the Judge ordered further discovery be taken on the issues of arbitrability. In January 2004, the Court held a hearing on arbitrability. In March 2004, the Judge dismissed without prejudice all of the pending motions in the case, and without comment. In May 2004, the Court ordered arbitration proceed as against Beckman, only, and stayed the proceedings pending in the District Court until the conclusion of the arbitration. Digene filed a Motion for Reconsideration of the Court s Order, which was denied by the Court in July 2004. In December 2004, Digene initiated the arbitration against Beckman before the American Arbitration Association in New York. In January 2005, the matter was removed to the International Centre for Dispute Resolution (ICDR), a division of AAA. In February 2005, we filed a Motion for Leave to Petition the Arbitral Panel to Participate in the Arbitration with the District Court and notified the ICDR of this request. The Court has not rendered a decision on our Motion. Beckman and Digene are presently in the process of selecting arbitrators.

In June 2003, Ventana and Beckman filed a request for arbitration with the International Chamber of Commerce in Paris, France, to contest the purported termination by Institut Pasteur of the Sublicense Agreement acquired by us from Beckman in September 2002. Institut Pasteur has responded, and the parties selected a panel

Table of Contents

of arbitrators. In December 2003, the panel framed the Terms of Reference, the issues to be heard in the case. In February 2004, we submitted our Statement of Claim. In March 2004, Institut Pasteur filed a Statement of Defenses. Institut Pasteur also filed a Motion to Stay the Arbitration pending the outcome of the Delaware patent litigation, and an oral hearing was conducted in May 2004. The Motion for Stay was denied, and in June 2004, we filed our Statement of Reply and rebuttal to Institut Pasteur s defenses. In July 2004, Institut Pasteur submitted its Statement of Response and rebuttal. The ICC hearing was conducted in September, 2004. Post-hearing submissions were filed in November 2004, and a Submission of Costs was filed in February 2005. The parties are awaiting the decision of the ICC, likely in early 2005.

VENTANA v. BIOGENEX LABORATORIES INC., No. CIV-03-92-TUC-RCC, was filed in February 2003, in U.S. District Court, District of Arizona alleging infringement of U.S. Patent No.6,352,861 (Automated Biological Reaction Apparatus). In September 2003, BioGenex served its Answer to the Complaint denying infringement. In September 2003, BioGenex amended its Answer to our Complaint adding the defense of invalidity. In November 2004, we filed a Motion for Summary Judgment of infringement of claim 5, along with our Claim Construction brief. In November 2004, BioGenex filed its Claim Construction brief, and in December 2004, BioGenex, filed its opposition to our motion Summary Judgment and its own cross-motion for Summary Judgment of non-infringement. No hearing date has been set for these motions. The parties are currently completing expert discovery.

BIOGENEX LABORATORIES, INC. v. VENTANA, Case No. C03 03916 JF, was filed in August 2003, in the U.S. District Court, Northern District of California, San Jose Division. This Complaint alleges we infringe three U.S. patents held by BioGenex, U.S. Patent Nos. 5,578,452, 5,244,787, and 6,451,551. BioGenex seeks, among other remedies, an injunction against our alleged infringement and unspecified monetary damages. We filed our Answer in October 2003. In June 2004, BioGenex moved to amend its Complaint adding allegations that we also infringe U.S. Patent No. 6,632,598 and has also filed an action for Contempt against us arising out of previous litigation associated with BioTek Solutions Inc., which we acquired in 1996. A show cause hearing on the contempt action was originally set for August 2004 but remains to be heard. In February 2005, the Court ruled in favor of our Motion for Summary Judgment of non-infringement of the 551 patent. The Court also found the 452 patent invalid against us for purpose of this litigation. Finally, the Court denied BioGenex s motion to add the 598 patent to the suit. A status conference is scheduled for March 2005 on the remaining matters.

BIOGENEX LABORATORIES, INC. v. VENTANA, Case No. C05 00860 WDB, was filed in March 2005, in the U.S. District Court, Northern District of California, San Jose Division. This Complaint alleges Ventana infringes U.S. Patent No. 6,632,598 held by BioGenex. BioGenex seeks, among other remedies, an injunction against our alleged infringement and unspecified monetary damages. BioGenex had moved to add the 598 patent to the other action pending before this Court (see above), however, that motion was denied.

VENTANA v. ABBOTT LABORATORIES, INC. and VYSIS, INC., Case No. 03C 4870, was filed in July 2003, in U.S. District Court, Northern District of Illinois Eastern Division alleging that various Vysis DNA probe products infringe U.S. Patent No. 6,025,126 (Methods and Compositions for the Detection of Chromosomal Aberrations) and U.S. Patent No. 6,414,133 (Multiple Fusion Probes). In particular, we alleged sales of the BCR/ABL probes, amongst others, sold by Vysis infringed one or both of the patents. The U.S. Patent and Trademark Office has declared Interferences between both patents and a University of California patent application, Gray et al., Interference No. 105,207, which are proceeding. In addition, the Court granted a joint motion to stay the litigation in April 2004. In December 2004, the parties filed an Agreed Motion to Dismiss the litigation, with prejudice, and to terminate the Interferences before the Patent and Trademark Office.

VARIAN, INC. v. VENTANA, Case No. C 03-3918 (JF), was filed in August 2003, in the U.S. District Court, Northern District of California, San Jose Division. We were served with a Complaint for a Declaratory Judgment of non-infringement of our registered U.S. trademark for its Circle-of-V s logo, Reg. No. 2087392. In February 2004, we filed our Answer and first Amended Counterclaim for trademark infringement. Pursuant to a settlement agreement, the parties filed an agreed Stipulation of Dismissal with Prejudice, terminating the action.

Table of Contents

We record contingent liabilities resulting from claims against us when it is probable (as that word is defined in Statement of Financial Accounting Standards No. 5) that a liability has been incurred and the amount of the loss is reasonably estimable. We disclose contingent liabilities when there is a reasonable possibility that the ultimate loss will exceed the recorded liability. Estimating probable losses requires analysis of multiple factors, in some cases including judgments about the potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. In all of the cases noted where we are the defendant, we believe we have meritorious defenses to the claims in these actions and resolution of these matters will not have a material adverse effect on our business, financial condition, or results of operation; however, the results of the proceedings are uncertain, and there can be no assurance to that effect.

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

No matters were submitted to a vote of security holders in the fourth quarter of 2004.

Table of Contents

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Our common stock is listed on the Nasdaq National Market under the symbol VMSI . The closing price of our common stock on March 1, 2005, adjusted for our previously announced 2-for-1 stock split effected in the form of a stock dividend that occurred on March 14, 2005, was $33.33. The following table shows the high and low sales prices in dollars per share for the last two years as reported by Nasdaq restated to reflect the 2-for-1 stock split:

	Low	High
Year Ended December 31, 2003		
First Quarter	$ 8.71	$ 11.86
Second Quarter	$ 9.15	$ 14.04
Third Quarter	$ 13.36	$ 22.40
Fourth Quarter	$ 16.68	$ 21.63
Year Ended December 31, 2004		
First Quarter	$ 19.19	$ 22.61
Second Quarter	$ 20.35	$ 26.42
Third Quarter	$ 21.64	$ 27.45
Fourth Quarter	$ 23.99	$ 32.60

As of March 1, 2005, there were approximately 4,000 record holders of our common stock.

Dividend Policy

No cash dividends were declared or paid in fiscal 2004 or fiscal 2003. We anticipate retaining all available funds to finance future internal growth and product development.

Stock Repurchase

In September 1998, our Board of Directors approved the repurchase of up to 1.5 million shares of our common stock in the open market or in privately negotiated transactions. In May 2004, our Board of Directors approved an additional repurchase up to 2.0 million shares of our common stock. During 2004, we purchased 688,248 shares of our common stock for $14.6 million.

Stock Repurchases in the Fourth Quarter

The following table sets forth the repurchases made by us in the fourth quarter of 2004.

Period	Total Number of Shares	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that may yet be Repurchased Under the Plans or Programs
October 1 October 31, 2004				2,332,800
November 1 November 30, 2004				2,332,800
December 1 December 31, 2004	21,848	$ 30.84	21,848	2,310,952

Equity Compensation Plan Information

Information regarding our equity compensation plans, including both stockholder approved plans and non-stockholder approved plans, is set forth in the section titled Executive Compensation-Equity Compensation Plan Information in our Notice of Annual Meeting of Stockholders and Proxy Statement, to be filed within 120 days after Registrant s fiscal year end of December 31, 2004, which information is incorporated herein by reference.

Table of Contents

Item 6. Selected Financial Data

The selected financial data set forth below with respect to our consolidated financial statements has been derived from our audited financial statements. The data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related notes. The selected financial data in this section is not intended to replace the consolidated financial statements. All share and per share data have been restated to reflect the 2-for-1 stock split effected in the form of a stock dividend that occurred on March 14, 2005.

Table of Contents

Selected Consolidated Financial Data

	Years Ended December 31,				
	2004	2003	2002	2001	2000
Statement of Operations Data:					
Sales:					
Reagents and other	$ 137,124	$ 103,345	$ 80,365	$ 61,586	$ 49,682
Instruments	28,978	29,035	25,072	26,227	21,467
Total net sales	166,102	132,380	105,437	87,813	71,149
Cost of goods sold	41,297	35,180	31,244	27,622	36,377
Gross profit	124,805	97,200	74,193	60,191	34,772
Operating expenses:					
Research and development	21,242	19,598	16,359	14,929	11,116
Selling, general, and administrative	74,306	64,449	51,828	42,760	43,800
Amortization of intangible assets	1,326	1,678	1,646	1,575	1,474
Special charges	1,758	5,700	1,151		4,519
Income (loss) from operations	26,173	5,775	3,209	927	(26,137)
Interest and other (expense) income	(45)	469	1,392	826	1,346
Income (loss) before taxes and cumulative effect of accounting change	26,128	6,244	4,601	1,753	(24,791)
Provision for income taxes	4,839	272	528	311	350
Income (loss) before cumulative effect of accounting change	21,289	5,972	4,073	1,442	(25,141)
Cumulative effect of accounting change, net of tax(l)					(2,154)
Net income (loss)	$ 21,289	$ 5,972	$ 4,073	$ 1,442	$ (27,295)
Amounts per common share, basic:					
Income (loss) before cumulative effect of accounting change	$ 0.63	$ 0.18	$ 0.13	$ 0.05	$ (0.85)
Cumulative effect of accounting change					(0.07)
Net income (loss) per share, basic	$ 0.63	$ 0.18	$ 0.13	$ 0.05	$ (0.92)
Amounts per common share, diluted:					
Income (loss) before cumulative effect of accounting change	$ 0.59	$ 0.17	$ 0.12	$ 0.04	$ (0.85)
Cumulative effect of accounting change					(0.07)
Net income (loss) per share, diluted	$ 0.59	$ 0.17	$ 0.12	$ 0.04	$ (0.92)
Pro forma loss assuming the accounting change is applied retroactively:					
Net loss					$ (25,141)
Net loss per common share					
basic					$ (0.85)
diluted					$ (0.85)
Balance Sheet Data:					
Cash, cash equivalents, and short-term investments	$ 53,503	$ 39,685	$ 18,708	$ 12,280	$ 38,512

Long-term debt	2,182	2,260	2,357	2,521	3,408
Other long-term liabilities	549	591	544	212	160
Working capital	70,137	56,340	39,030	33,838	49,577
Total assets	180,148	141,214	125,137	110,985	109,582
Accumulated deficit	(13,860)	(35,149)	(41,121)	(45,194)	(46,636)
Total stockholders equity	141,150	112,376	102,104	94,153	87,088

(1) During the year ended December 31, 2000, we changed our methods of revenue recognition for our products that require installation by us at the customer s site in accordance with Staff Accounting Bulletin (SAB) No. 101 *Revenue Recognition in Financial Statements.* Previously, we recognized revenue for products upon shipment to the customer, but prior to installation.

Table of Contents

The following tables contain summary unaudited quarterly consolidated statements of operations for the four quarters ended December 31, 2004 and 2003. We have prepared the quarterly consolidated statements of operations data on the same basis as the Consolidated Statements of Operations presented on page F-4. Our results of operations may continue to fluctuate significantly from quarter to quarter. Results of operations in any period should not be considered indicative of the results to be expected for any future period. All share and per share data have been restated to reflect the 2-for-1 stock split effected in the form of a stock dividend that occurred on March 14, 2005.

Summary Quarterly

Condensed Consolidated Financial Data

	Year ended December 31, 2004			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
Statement of Operations Data:				
Sales:				
Reagents and other	$ 31,036	$ 33,855	$ 34,308	$ 37,925
Instruments	5,474	8,461	4,994	10,049
Total net sales	36,510	42,316	39,302	47,974
Cost of goods sold	9,692	11,022	9,236	11,347
Gross profit	26,818	31,294	30,066	36,627
Operating expenses:				
Research and development	5,150	5,170	5,421	5,501
Selling, general, and administrative	18,253	18,297	17,638	20,118
Amortization of intangible assets	289	328	307	402
Special charges			1,758	
Income from operations	3,126	7,499	4,942	10,606
Interest and other income (expense)	50	35	126	(256)
Income before taxes	3,176	7,534	5,068	10,350
Provision for income taxes	573	1,541	1,004	1,721
Net income	$ 2,603	$ 5,993	$ 4,064	$ 8,629
Net income per common share				
Basic(1)	$ 0.08	$ 0.18	$ 0.12	$ 0.26
Diluted	$ 0.07	$ 0.17	$ 0.11	$ 0.24
Weighted average shares used in the computation:				
Basic	33,572	33,446	33,610	33,812
Diluted	35,724	35,740	35,836	36,254

(1) Per share amounts do not sum to year to date amount due to rounding.

Table of Contents

Summary Quarterly

Condensed Consolidated Financial Data

	Year ended December 31, 2003			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share data)			
Statement of Operations Data:				
Sales:				
Reagents and other	$ 23,176	$ 25,726	$ 25,436	$ 29,007
Instruments	6,084	7,725	6,524	8,702
Total net sales	29,260	33,451	31,960	37,709
Cost of goods sold	8,497	9,357	7,861	9,465
Gross profit	20,763	24,094	24,099	28,244
Operating expenses:				
Research and development	4,295	4,872	5,057	5,374
Selling, general, and administrative	14,693	15,615	15,207	18,934
Amortization of intangible assets	457	462	466	293
Special charges				5,700
Income (loss) from operations	1,318	3,145	3,369	(2,057)
Interest and other income (expense)	168	215	(33)	119
Income (loss) before taxes	1,486	3,360	3,336	(1,938)
Provision for income taxes	67	62	47	96
Net income (loss)	$ 1,419	$ 3,298	$ 3,289	$ (2,034)
Net income (loss) per common share				
Basic	$ 0.04	$ 0.10	$ 0.10	$ (0.06)
Diluted	$ 0.04	$ 0.10	$ 0.09	$ (0.06)
Weighted average shares used in the computation:				
Basic	32,724	32,708	32,984	33,298
Diluted	33,310	33,756	35,460	33,298

Table of Contents

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

Critical Accounting Policies and Estimates

Our discussion and analysis of financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and related disclosure of contingent liabilities. On an ongoing basis, we evaluate our estimates, including those related to bad debts, inventories, deferred taxes, legal contingencies, and patent capitalization. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances; the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other resources. Actual results may differ from these estimates under different assumptions or conditions.

We have adopted the following critical accounting policies used in the preparation of our consolidated financial statements. Our significant accounting policies are disclosed in Note 1 to our consolidated financial statements.

Revenue Recognition

We recognize revenue pursuant to Staff Accounting Bulletin No. 101 and No. 104 *Revenue Recognition in Financial Statements*. Accordingly, revenue is recognized when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is both fixed and determinable, and (iv) collectibility is reasonably assured.

Revenue from instrument sales made by us directly to the end user is generally recognized upon our completion of the installation. However, if the end user already has the identical instrument installed at the same location, we recognize the revenue from that sale upon shipment. Revenue from reagents is recognized upon shipment. Service contract revenue is deferred and recognized ratably over the period service is to be provided, which is typically one to three years. Out-of-warranty work is recognized as services are rendered.

A portion of our instrument revenue is from sales made to distributors under agreements that require them to assume responsibility for product installation without recourse to us. Revenue for instruments sold under these agreements is recognized upon shipment to the distributor when we assess their ability to pay as probable for that sale. There are certain foreign distributors for which revenue is not recognized until the instrument is installed and accepted by the end user, thereby making the related payment probable.

Our shipping terms are as follows for Domestic and International sales:

Domestic (primarily U.S.)

We sell direct to end customers in North America with shipping terms of FOB Point of Distribution, therefore title passes to the customer upon shipment from Ventana.

International (primarily Europe and Japan)

We sell to both end customers and distributors depending on the market. For sales to end customers and distributors our shipping terms are FOB Point of Distribution, therefore title passes to the customer upon shipment from Ventana.

Reserve for Uncollectible Accounts Receivable

We make ongoing estimates relating to the collectibility of our accounts receivable and maintain a reserve for estimated losses resulting from the inability of our customers to make required payments. In determining the

Table of Contents

amount of the reserve, we consider our historical level of credit losses and make judgments about the creditworthiness of significant customers, based on ongoing credit evaluations. Historically, losses from uncollectible accounts have not exceeded our reserves. Since we cannot predict future changes in the financial stability of our customers, actual future losses from uncollectible accounts may differ from our estimates. If the financial condition of our customers were to deteriorate, resulting in their inability to make payments, a larger reserve might be required. In the event we determined a smaller or larger reserve was appropriate, we would record a credit or a charge to selling and administrative expense in the period in which we made such a determination.

Inventory Reserves

Inventories are valued at the lower of cost or market using the first-in, first-out (FIFO) method. We write down our inventory for estimated obsolescence or unmarketable inventory in an amount equal to the difference between the cost of inventory and the estimated market value, based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those we projected, additional inventory write-downs may be required. Inventory impairment charges establish a new cost basis for inventory and charges are not subsequently reversed to income, even if circumstances later suggest increased carrying amounts are recoverable. In estimating reserves for obsolescence, we generally evaluate estimates of demand over the next 12-month period forecast and provide reserves for inventory on hand in excess of the estimated 12-month demand.

Income Taxes

When preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. We estimate our actual current tax liability together with assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within our consolidated balance sheet. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income within the relevant jurisdiction and to the extent we believe that recovery is not likely, we must establish a valuation allowance. For certain deferred tax assets, we have not provided for a valuation allowance, because we believe it is more likely than not that our deferred tax assets will be recovered from future taxable income. Should we determine we would not be able to realize all or part of our net deferred tax asset in the future, an adjustment to the deferred tax asset would be charged to expense in the period such determination was made.

Taxing authorities in the U.S. and other countries in which we do business are increasing their scrutiny of tax structures employed by businesses. We believe we maintain adequate tax reserves to offset any potential tax liabilities that may arise upon audit. If such amounts ultimately prove to be unnecessary, the associated reserves would be reversed, resulting in our recording a tax benefit in the period the reserves were no longer deemed necessary. Conversely, if our estimates prove to be less than the ultimate assessment, a charge to expense would be recorded in the period in which the assessment is determined.

Legal Contingencies

We record contingent liabilities resulting from asserted and unasserted claims against us, when it is probable that a liability has been incurred and the amount of the loss is reasonably estimable. We disclose contingent liabilities, when there is a reasonable possibility, that the ultimate loss will exceed the recorded liability. Estimating probable losses requires analysis of multiple factors, in some cases including judgments about the potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. We currently are involved in certain legal proceedings. We do not believe these proceedings will have a material adverse effect on our consolidated financial position. It is possible, however, that future results of operations for any particular quarterly or annual period could be materially affected by

changes in our assumptions or the effectiveness of our strategies related to these proceedings.

Table of Contents

Patent Capitalization

We capitalize costs associated with the filing of patent applications and/or defending our rights under patents which we own. We have incurred material legal costs, some of which have been capitalized, thereby increasing the carrying value of associated patents. These capitalized costs are amortized on a straight-line basis over the lesser of seven years or the remaining life of the patent to which they relate and are reflected net of accumulated amortization as an intangible asset in our consolidated balance sheets. We believe the inherent value of the patents exceeds their carrying value. However, if the rights afforded us under the patents are not enforced, or if the patents do not provide the competitive advantages that we anticipated at the time of capitalization, we may have to write-down the patents, and such charges could be material.

Results of Operations

Comparison of 2004 and 2003

Net sales increased by 25%, 22%, after adjusting for foreign currency fluctuations, to $166.1 million in 2004 versus $132.4 million in 2003. Reagent and other revenues increased 33% to $137.1 million in 2004 from $103.3 million in 2003. This growth was driven primarily by an increase in our total installed base from 4,600 in 2003 to approximately 5,100 in 2004 and the fact that our BENCHMARK series of instruments have a significantly larger reagent annuity stream. This latter dynamic is evidenced by the 14% increase in the average reagent annuity stream per installed instrument to $24,800 in 2004 from $21,700 in 2003. Service revenue was $12.0 million in 2004, a 36% increase from $8.8 million in 2003, primarily due to more non-warranty-related service activities. Instrument revenue in 2004 remained consistent with 2003 levels. By segment, domestic and international revenues increased 23% and 32%, respectively, versus 2003, paced by 29% and 44% growth in reagent and other revenue, respectively.

Gross Margin

Total gross margin percentage increased to 75% in 2004 from 73% in 2003. Absent a $0.7 million special charge to write-down TECHMATE and Tissue Processor inventory to net realizable value, gross margins in 2003 were 74%. The improvement in 2004 was driven primarily by the increase in our product mix toward reagents, which carry a higher margin than instruments.

Research and Development (R&D)

R&D spending increased to $21.2 million in 2004 from $19.6 million in 2003. This increase was driven primarily by our aggressive new platform development programs and our reagent chemistry application initiatives. R&D expense as a percent of sales decreased to 13% in 2004 from 15% in 2003, consistent with our medium term goal of investing in a range of 10-12% of revenue in this area.

Selling, General, and Administrative (SG&A)

SG&A expenses increased to $74.3 million in 2004 from $64.4 million in 2003. This 15% increase, 12% after adjusting for foreign currency fluctuations, is primarily the result of investments in our sales force and associated infrastructure, increased spending in quality and regulatory compliance programs, and continued development of our marketing organization. As a percentage of net sales, SG&A decreased to 45% in 2004 from 49% in 2003.

Amortization of Intangible Assets

Amortization expense of intangible assets decreased to $1.3 million in 2004 from $1.7 million in 2003 primarily due to the special charges taken in 2003 to write-off of developed technology from our 2000 acquisition of Quantitative Diagnostic Laboratories, Inc.

Table of Contents

Special Charges

On September 16, 2004, we entered into an agreement with TriPath Imaging Inc. to sell and distribute worldwide a Ventana-branded interactive histology imaging system. As a result of this transaction, we incurred a $1.8 million non-cash charge primarily associated with impairments to certain intangible and fixed assets we acquired in our 2001 transaction with Molecular Diagnostics, Inc.

Interest and Other Income (Expense)

Interest and other income (expense) decreased to ($45,000) in 2004 from $469,000 in 2003. This decrease was primarily due to lower market interest rates on our investments and accrued interest expense arising from international obligations.

Income Taxes

Our provision for income taxes increased to $4.8 million in 2004 from $0.3 million in 2003. Our effective tax rate was 18.5% in fiscal 2004, compared to 4.4% in fiscal 2003. The increase in our effective tax rate in fiscal 2004 was due to the income tax provision computed using an effective tax rate of 40% for the year, partially offset by the reversal of a previously established valuation allowance on our deferred tax assets. In the fourth quarter 2004, we reversed $3.1 million of our valuation allowance due to sustainable U.S. taxable profits for which the valuation allowance was primarily established in prior years. We have not provided for any additional valuation allowance in 2004 because we believe our deferred tax asset will be fully recovered from sustainable future operating profits at a level that meets the recoverability criteria under SFAS 109. In fiscal 2003, we provided a valuation allowance of $7.5 million against our deferred tax assets since Management s opinion at the time was that future U.S. taxable earnings were not considered more likely than not to be realized above the recorded amount. As a result of these events, our effective tax rates for 2004 and 2003 are not meaningful.

Management believes the longer term effective tax rate on our earnings will be approximately in the mid to high 30 s. Factors that will impact this range include the mix of earnings across differing tax jurisdictions, in addition to the difference in the benefits we might receive under the *American Jobs Creation Act of 2004* versus the *Extraterritorial Income Exclusion Act of 2000.* In addition, we maintain tax reserves to offset potential tax liabilities that may arise upon audit in the U.S. and other countries in which we do business. If such amounts ultimately prove to be unnecessary, the associated reserves would be reversed, resulting in our recording a tax benefit in the period the reserves were no longer deemed necessary. Conversely, if our estimates prove to be less than the ultimate assessment, a charge to expense would be recorded in the period in which the assessment is determined.

Comparison of 2003 and 2002

Net Sales

Net sales increased by 26% to $132.4 million in 2003 versus $105.4 million in 2002. Reagent and other sales increased 29%, primarily due to an increase in our total installed base to approximately 4,600 in 2003 versus 4,000 in 2002. In addition, the BENCHMARK series of instruments

automates more processes than earlier generation instruments and therefore has a significantly larger reagent annuity stream. The average reagent annuity stream per installed instrument increased by 9% during the year to $21,700 from $20,000 in 2002. Instrument revenue increased 16%, primarily due to foreign currency favorability in 2003 versus 2002. By segment, domestic and international revenues increased 20% and 43%, respectively, versus 2002, paced by 22% and 51% growth in reagent and other revenue, respectively.

Gross Margin

Total gross margin percentage increased to 73% in 2003 from 70% in 2002. Absent a $0.7 million special charge in 2003 to write-down TECHMATE and Tissue Processor inventory to net realizable value, gross margins

Table of Contents

were 74%. This improvement was driven primarily by strong manufacturing performance, an increase in our product mix toward reagents which carry a higher margin than instruments, and general pricing in our business.

Research and Development

Research and development spending increased to $19.6 million in 2003 from $16.4 million in 2002. This increase was driven primarily by our aggressive new platform development programs for the histology market and our reagent chemistry application initiatives for the histology, cytology, and molecular discovery/research businesses. Consistent with our long-term strategy of decreasing expense as a percentage of sales, research and development expense as a percent of sales decreased to 15% in 2003 from 16% in 2002.

Selling, General and Administrative

SG&A expenses increased to $64.4 million in 2003 from $51.8 million in 2002. This 24% increase primarily reflects our investments in our sales force and associated infrastructure, continued development of our marketing organization, and new product launch activities. We also continued to invest in fortifying our intellectual property position and defending ourselves in a number of litigation matters *(see Item 3. Legal Proceedings)*. As a percentage of net sales, SG&A was unchanged from 2002 at 49%.

Amortization of Intangible Assets

Amortization expense of intangible assets increased to $1.7 million in 2003 from $1.6 million in 2002, due to the incremental amortization associated with our transaction with Beckman Coulter, Inc., in the third quarter of 2002.

Special Charges

During the fourth quarter of 2003, we decided to exit the TECHMATE and tissue processor product lines, close our Chicago reference lab business, and relocate our pharma services business to Tucson, Arizona. As a result of these decisions, a special charge of $6.4 million was recorded. The following table summarizes these charges and provides a roll forward of the related reserves through December 31, 2003 (in thousands):

	Initial Charges	Costs Incurred in 2003	Reserve Balances as of December 31, 2003
Exit of Techmate product line	$ 2,385	$ 2,385	$
Discontinuance of tissue processor product line	2,006	2,006	

Exit of reference lab business	1,315	1,284	31
Costs to relocate pharma services business, other	723	473	250
Total impairment charges and other expenses	$ 6,429	$ 6,148	$ 281

The total charges of $6.4 million are included in the Statement of Operations as cost of sales ($0.7 million) and special charges ($5.7 million).

Charges of $2.4 million were taken to exit the TECHMATE product line. This includes a $1.8 million charge that was taken to write-down the customer base and a $0.3 million charge taken to write-off developed technology assets purchased during the 1996 Biotek Solutions, Inc., acquisition. In addition, a $0.3 million charge to cost of sales was taken to write-down all associated inventory to net realizable value. At December 31, 2004, $0.3 million of costs were incurred and there are no remaining reserves.

A charge of $2.0 million was taken to discontinue the tissue processor product line. This included a $1.0 million charge to write-off the developed technology purchased during the 1998 Biotechnology Tools, Inc.,

Table of Contents

acquisition. In addition, a $0.6 million charge was taken to accelerate depreciation on fixed assets and other assets, as well as a $0.4 million charge to cost of sales to write-down all associated inventory to net realizable value.

We recognized charges of $1.3 million to exit the reference lab business. Of this charge, $0.7 million was taken to write-off the developed technology purchased during the 2000 Quantitative Diagnostic Laboratories, Inc., acquisition and $0.6 million related to accelerated depreciation on fixed assets and employee severance costs.

Charges of $0.7 million were primarily taken in association with relocating the pharma services business. This expense mainly consists of lease exit costs and accelerated depreciation on leasehold improvements.

Interest and Other Income (Expense)

Interest and other income decreased to $0.5 million in 2003 from $1.4 million in 2002. This decrease was due to a $0.9 million benefit received in 2002 in connection with our claims in the United States Bankruptcy Court of the District of Delaware titled IN RE ONCOR, INC., No. 9-437 (JJF).

Income Taxes

Income tax expense consists principally of state income taxes. U.S. and international taxes were largely offset by income tax benefits existing from previously reserved deferred tax assets. We have recorded on our balance sheet deferred tax assets, net of a valuation reserve, for the portion of our total deferred tax assets that management believes are more likely than not of being recoverable in the foreseeable future. During 2003, management s estimate of the portion of our deferred tax assets that were more likely than not of being recoverable remained unchanged. To the extent management s estimates with respect to the recoverable portion of our deferred tax assets change in the future, income tax expense/benefit could be impacted by such estimates. Tax expense decreased to $0.3 million in 2003, from $0.5 million in 2002, primarily due to the mix of domestic revenues associated with state franchise taxes.

Liquidity and Capital Resources

Cash and Cash Flow

At December 31, 2004, cash and short-term investments totaled $53.5 million, up from $39.7 million at December 31, 2003. At December 31, 2004, total short-term and long-term debt was $3.0 million and represented approximately 2% of stockholders equity. At December 31, 2003, total debt was $3.0 million and represented approximately 3% of stockholders equity.

Net cash provided by operating activities was $34.4 million, $23.6 million, and $11.7 million for fiscal years 2004, 2003 and 2002, respectively. In 2004, the increase in cash provided by operating activities was due to higher net income. Working capital sources of cash included increases in employee compensation and benefits, taxes payable, and legal contingencies. The increase in employee compensation and benefits is primarily due to higher accruals related to employee bonuses and headcount. The increase in taxes payable is primarily due to higher accruals for sales and use taxes in domestic and foreign jurisdictions resulting from the Company s increase in sales and reserves established based upon its assessment of exposure associated with permanent tax differences, tax credits, and interest expense applied to temporary difference adjustments. The increase in legal contingencies is primarily due to the Company s reserves established for asserted and unasserted claims. Accounts receivable increased primarily due to an increase in sales. Despite the increase in sales, the days sales outstanding decreased to 54 days at December 31, 2004, from 60 days at December 31, 2003. When the Company adopts SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123R), the benefits of tax deductions in excess of recognized compensation costs will be reported as a financing cash flow, rather than as an operating cash flow as required under the current literature.

Investing cash flows consist primarily of capital expenditures and the proceeds of investments sold and payment for investments acquired. Net cash used in investing activities in fiscal years 2004, 2003, and 2002 was $17.8 million, $27.0 million, and $8.5 million, respectively. The higher cash used in investing activities in 2003

Table of Contents

resulted from higher net purchases of available-for-sale securities. The Company established its investment portfolio in 2003 with an initial funding of $20.0 million. Capital expenditures were $12.9 million, $6.5 million, and $7.1 million in fiscal years 2004, 2003 and 2002, respectively. The increase in capital expenditures reflects a higher investment in diagnostic equipment and machinery and equipment.

Financing cash flows consist primarily of repurchases and proceeds from the issuance of common stock through stock option and stock purchase plans. The Company used $3.4 million in net cash for financing activities in 2004, compared to $3.7 million and $3.4 million provided by financing activities in 2003 and 2002, respectively. During 2004, the Board of Directors authorized the repurchase of an additional 2.0 million shares of common stock, and in 2004, the Company purchased 0.7 million shares of common stock for $13.8 million. At December 31, 2004, approximately 2.3 million shares remained available for repurchase under existing repurchase authorizations. Proceeds from the issuance of common stock were $10.7 million, $9.8 million, and $4.1 million in fiscal years 2004, 2003 and 2002, respectively. The increase in proceeds from the issuance of common stock is due to higher stock option exercise activity in 2004.

We believe that our cash flow from operations together with our current cash reserves will be sufficient to fund our projected capital requirements for the next 12 months.

Off-Balance Sheet Arrangements

As of December 31, 2004, we are not involved in any off-balance sheet arrangements.

Contractual Obligations

The impact that our contractual obligations as of December 31, 2004, are expected to have on our liquidity and cash flow in future periods is as follows (in thousands):

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
Long-term debt obligations	$ 2,412	$ 230	$ 484	$ 518	$ 1,180
Capital lease and other obligations	620	620			
Operating lease obligations	2,123	1,232	889	2	
Purchase obligations(1)	8,938	6,610	2,012	308	8
Total	$ 14,093	$ 8,692	$ 3,385	$ 828	$ 1,188

(1) Purchase obligations include agreements to purchase goods or services that are enforceable and legally binding and that specify all significant terms, including fixed or minimum quantities to be purchased; fixed, minimum, or variable price provisions; and the approximate timing of the transaction. Purchase obligations exclude agreements that are cancelable without penalty.

New Accounting Standards

FASB Staff Position (FSP) No. 109-2, *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004* (FSP No. 109-2), provides guidance under FASB Statement No. 109, Accounting for Income Taxes (SFAS No. 109), with respect to recording the potential impact of the repatriation provisions of the American Jobs Creation Act of 2004 (the Jobs Act) on enterprises income tax expense and deferred tax liability. The Jobs Act was enacted on October 22, 2004. FSP No. 109-2 states an enterprise is allowed time beyond the financial reporting period of enactment to evaluate the effect of the Jobs Act on its plan for reinvestment or repatriation of foreign earnings for purposes of applying FASB Statement No. 109. We have not yet completed evaluating the impact of the repatriation provisions. Accordingly, as provided for in FSP No. 109-2, we have not adjusted our tax expense or deferred tax liability to reflect the repatriation provisions of the Jobs Act.

Table of Contents

In March 2004, the FASB approved the consensus reached on the Emerging Issues Task Force (EITF) Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments* (EITF No. 03-1). EITF 03-1 s objective is to provide guidance for identifying other-than-temporarily impaired investments. EITF 03-1 also provides new disclosure requirements for investments that are deemed to be impaired temporarily. In September 2004, the FAS issued FSP EITF 03-1-1 that delays the effective date of the measurement and recognition guidance in EITF 03-1 until further notice. The disclosure requirements of EITF 03-1 are effective with this annual report for 2004. Once the FASB reaches a final decision on the measurement and recognition provisions, the Company will evaluate the impact of the accounting provisions of EITF 03-1.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs An Amendment of ARB No. 43, Chapter 4* (SFAS No. 151). SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing* (ARB No. 43), to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Among other provisions, the new rule requires items, such as idle facility expense, excessive spoilage, double freight, and re-handling costs, be recognized as current-period charges regardless of whether they meet the criterion of so abnormal as stated in ARB No. 43. Additionally, SFAS No. 151 requires the allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for fiscal years beginning after June 15, 2005, and is required to be adopted by us in the first quarter of fiscal 2006, beginning on January 1, 2006. We currently are evaluating the effect that the adoption of SFAS No. 151 will have on our consolidated results of operations and financial condition but do not expect SFAS No. 151 to have a material impact.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123R), which replaces SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123), and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first interim or annual period after June 15, 2005, with early adoption encouraged. The pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. We are required to adopt SFAS No. 123R in the third quarter of fiscal 2005, beginning July 1, 2005. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost, and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS No. 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. We are evaluating the requirements of SFAS No. 123R and expect the adoption of SFAS No. 123R will have a material impact on our consolidated results of operations and earnings per share. We have not yet determined the method of adoption or the effect of adopting SFAS No. 123R and have not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123. SFAS No. 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. We cannot estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Non-monetary Assets An Amendment of APB Opinion No. 29, Accounting for Non-monetary Transactions* (SFAS No. 153). SFAS No. 153 eliminates the exception from fair value measurement for non-monetary exchanges of similar productive assets in paragraph 21(b) of APB Opinion No. 29, *Accounting for Non-monetary Transactions*, and replaces it with an exception for exchanges that do not have commercial substance. SFAS No. 153 specifies a non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the

Table of Contents

exchange. SFAS No. 153 is effective for the fiscal periods beginning after June 15, 2005, and is required to be adopted by us in the first quarter of fiscal 2006, beginning on January 1, 2006. We currently are evaluating the effect that the adoption of SFAS No. 153 will have on our consolidated results of operations and financial condition but do not expect it to have a material impact.

The adoption of the following recent accounting pronouncements did not have a material impact on our results of operations and financial condition:

- FASB issued FSP No. 106-2, *Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement and Modernization Act of 2003;* and

- EITF Issue No. 03-5, *Applicability of AICPA Statement of Position 97-2 to Non-Software Deliverables in an Arrangement Containing More-Than-Incidental Software.*

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

At December 31, 2004, our cash equivalent investments are in money market accounts and overnight reverse repurchase agreements ($23.8 million) that are reflected as cash equivalents, because all maturities are within 90 days. Our interest rate risk with respect to existing investments is limited due to the short-term duration of these arrangements and the yields earned, which approximate current interest rates.

Our investment portfolio, consisting of fixed income securities, was $20.1 million as of December 31, 2004. These securities, like all fixed income instruments, are subject to interest rate risk and will decline in value if market interest rates increase. If market rates were to increase immediately and uniformly by 10% from the levels of December 31, 2004, the decline in the fair value of our investment portfolio would not be material given that our investments typically have interest rate reset features that regularly adjust to current market rates. Additionally, we have the ability to hold our fixed income investments until maturity, and, therefore, we would not expect to recognize any material adverse impact in income or cash flows.

We have international operations and are thus subject to foreign currency rate fluctuations. A sizable portion of our revenue and capital spending is transacted in U.S. Dollars. However, we do at times enter into these transactions in other currencies, such as the Euro, the Japanese Yen, and the Australian Dollar. To date, our exposure related to exchange rate volatility has not been significant. If foreign currency rates fluctuate by 10% from the rates at December 31, 2004, the effect on our financial position and results of operation would not be material. No hedging transactions were entered into to limit this exposure.

At present, we have $3.0 million in debt obligations at December 31, 2004. As such, our interest rate risk is limited with respect to existing debt.

During the normal course of business we are subject to a variety of market risks, examples of which include, but are not limited to, interest rate movements and foreign currency fluctuations, as we discuss in this Item 7A, and collectibility of accounts receivable. We continuously assess these risks and have established policies and procedures to protect against the adverse effects of these and other potential exposures. Although we do not anticipate any material losses in these risk areas, no assurance can be made that material losses will not be incurred in these areas in the future.

Item 8. Financial Statement and Supplementary Data

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

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

There has been no change of accountants nor any disagreements with accountants on any matter of accounting principles or practices or financial statement disclosure required to be reported under this Item.

Table of Contents

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain controls and procedures designed to ensure that we are able to collect the information we are required to disclose in the reports we file with the SEC and to process, summarize, and disclose this information within the time periods specified in the rules of the SEC. Based on an evaluation of our disclosure controls and procedures as of the end of the period covered by this report conducted by our Management, with the participation of the Chief Executive and Chief Financial Officers, the Chief Executive and Chief Financial Officers have concluded these controls and procedures are effective to ensure we are able to collect, process, and disclose the information we are required to disclose in the reports we file with the SEC within the required time periods.

Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting as defined in Rules 13a-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2004. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework.* Based on their assessment, management has concluded, as of December 31, 2004, our internal control over financial reporting was effective based on those criteria.

Management s assessment of the effectiveness of internal control over financial reporting as of December 31, 2004, has been audited by Ernst & Young, LLP, the independent registered public accounting firm, which also audited our consolidated financial statements. Ernst & Young s attestation report on management s assessment of our internal control over financial reporting appears on page F-2 hereof.

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

Table of Contents

PART III

Item 10. Directors and Executive Officers of the Registrant

The information required by Items 401 and 405 of Regulation S-K is included in the definitive Proxy Statement for our Annual Meeting of Shareholders to be held May 11, 2005, and is incorporated herein by reference.

In complying with new regulations requiring the institution of policies and procedures, it has been the goal of our Board of Directors and senior leadership to do so in a way that does not inhibit or constrain our culture and that does not unduly impose a bureaucracy of forms and checklists. Accordingly, formal written policies and procedures have been adopted in the simplest possible way, consistent with legal requirements. Our Corporate Governance Guidelines, our charters for each of our Audit, Compensation, and Nominating and Corporate Governance Committees and our Code of Ethics, covering all directors, officers, and employees, are available on our website, *www.ventanamed.com*. We post on our Web site amendments to, or waivers from, our Code of Ethics.

Item 11. Executive Compensation

The information required by Item 402 of Regulation S-K is included in the definitive Proxy Statement for our Annual Meeting of Shareholders to be held May 11, 2005, and is incorporated herein by reference. See Compensation of Executive Officers .

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by Items 201(d) and 403 of Regulation S-K is included in the definitive Proxy Statement for our Annual Meeting of Shareholders to be held May 11, 2005, and is incorporated herein by reference. See Voting Securities and Principal Shareholders .

Item 13. Certain Relationships and Related Transactions

The information required by Item 404 of Regulation S-K is included in the definitive Proxy Statement for our Annual Meeting of Shareholders to be held May 11, 2005, and is incorporated herein by reference. See Election of Directors .

Item 14. Principal Accountant Fees and Services

The information required by Item 9(e) of Schedule 14A of Regulation S-K is included in the definitive Proxy Statement for our Annual Meeting of Shareholders to be held May 11, 2005, and is incorporated herein by reference. See Relationship with Independent Registered Public

Accounting Firm .

Table of Contents

PART IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statements

The following consolidated financial statements of Ventana Medical Systems, Inc. and Reports of Ernst & Young LLP, Independent Registered Public Accounting Firm, are in this Form 10-K.

Financial Statement Schedules for the Years ended December 31, 2004, 2003, and 2002

Schedule II Valuation and Qualifying Accounts has been provided on page 36. All other schedules are omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

Exhibits

See Exhibits Index

Table of Contents

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 Tucson, State of Arizona, on this 15th day of March 2005.

VENTANA MEDICAL SYSTEMS, INC.

By: /s/ NICHOLAS MALDEN

Nicholas Malden

Senior Vice President, Chief Financial Officer and Secretary

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Christopher Gleeson and Nicholas Malden, and each of them individually, as his attorney-in-fact, with full power of substitution, for him in any and all capacities, to sign any amendments to this Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, hereby ratifying and confirming all that said attorney-in-fact, or his substitute, may do or cause to be done by virtue hereof.

Pursuant to the Securities Exchange Act of 1934, the following persons in the capacities and on the date indicated have signed this report below.

Signature	Title	Date
/s/ CHRISTOPHER GLEESON Christopher Gleeson	President, Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2005
/s/ NICHOLAS MALDEN Nicholas Malden	Senior Vice President, Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 15, 2005
/s/ THOMAS BROWN Thomas Brown	Director	March 15, 2005
/s/ ROD DAMMEYER Rod Dammeyer	Director	March 15, 2005
/s/ EDWARD GILES	Director	March 15, 2005

Edward Giles		
/s/ THOMAS GROGAN, M.D.	Director	March 15, 2005
Thomas Grogan, M.D.		
/s/ MARK MILLER	Director	March 15, 2005
Mark Miller		
/s/ JOHN PATIENCE	Director	March 15, 2005
John Patience		
/s/ JACK SCHULER	Director	March 15, 2005
Jack Schuler		
/s/ JAMES WEERSING	Director	March 15, 2005
James Weersing		

Table of Contents

SCHEDULE II

VALUATION AND QUALIFYING ACCOUNTS

VENTANA MEDICAL SYSTEMS, INC.

Description	Balance at Beginning of Period	Additions: Charged (credited) to Costs and Expenses	Additions: Charged (credited) to Other Accounts	Deductions	Balance at End of Period
			(in thousands)		
Year ended December 31, 2004					
Deducted from asset accounts					
Allowance for doubtful accounts	$ 1,276	$	$ (157)(1)	$ 100(2)	$ 1,019
Year ended December 31, 2003					
Deducted from asset accounts					
Allowance for doubtful accounts	$ 1,472	$	$ (56)(1)	$ 140(2)	$ 1,276
Year ended December 31, 2002					
Deducted from asset accounts					
Allowance for doubtful accounts	$ 1,520	$ (48)	$ 100(1)	$ 100(2)	$ 1,472

(1) Charged (credited) to revenue

(2) Uncollectible accounts written off, net of recoveries

Table of Contents

REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and

Stockholders of Ventana Medical Systems, Inc.

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

We conducted our audits in accordance with the auditing standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of Ventana Medical Systems, Inc., at December 31, 2004 and 2003, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Ventana Medical Systems, Inc. s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2005, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Phoenix, Arizona

March 15, 2005

Table of Contents

REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and

Stockholders of Ventana Medical Systems, Inc.

We have audited management s assessment, included in the accompanying Management s Report on Internal Control over Financial Reporting, that Ventana Medical Systems, Inc., maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Ventana Medical Systems Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that Ventana Medical Systems, Inc., maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Ventana Medical Systems, Inc., maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Ventana Medical Systems, Inc., as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2004, of Ventana Medical Systems, Inc., and our report dated March 15, 2005, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Phoenix, Arizona

March 15, 2005

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2004	**2003**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,354	$ 19,711
Short-term investments	20,149	19,974
Trade accounts receivable, net of allowance for doubtful accounts of $1,019 and $1,276, respectively	33,292	27,398
Inventories, net	10,877	10,483
Deferred tax assets	6,544	3,200
Prepaids and other current assets	2,188	1,561
Total current assets	106,404	82,327
Property and equipment, net	47,679	42,516
Deferred tax assets, net of current portion	11,329	5,602
Goodwill	2,804	2,804
Intangible assets, net	7,097	3,982
Capitalized software development costs, net	2,249	2,379
Other assets	2,586	1,604
Total assets	$ 180,148	$ 141,214
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 10,418	$ 10,081
Other current liabilities	25,849	15,906
Total current liabilities	36,267	25,987
Long-term debt	2,182	2,260
Other long-term liabilities	549	591
Commitments and Contingencies		
Stockholders equity		
Common stock $.001 par value; 50,000 shares authorized, 35,100 and 33,918 shares issued and outstanding at December 31, 2004 and 2003, respectively	35	33
Additional paid-in-capital	176,211	154,379
Accumulated deficit	(13,860)	(35,149)
Accumulated other comprehensive income (loss)	40	(171)
Treasury stock 1,189 and 501 shares, at cost, at December 31, 2004 and 2003, respectively	(21,276)	(6,716)
Total stockholders equity	141,150	112,376

Total liabilities and stockholders equity	$ 180,148	$ 141,214

See accompanying notes.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Years ended December 31,		
	2004	**2003**	**2002**
Sales:			
Reagents and other	$ 137,124	$ 103,345	$ 80,365
Instruments	28,978	29,035	25,072
	166,102	132,380	105,437
Cost of goods sold	41,297	35,180	31,244
Gross profit	124,805	97,200	74,193
Operating expenses:			
Research and development	21,242	19,598	16,359
Selling, general, and administrative	74,306	64,449	51,828
Amortization of intangible assets	1,326	1,678	1,646
Special charges	1,758	5,700	1,151
Income from operations	26,173	5,775	3,209
Interest and other (expense) income	(45)	469	1,392
Income before taxes	26,128	6,244	4,601
Provision for income taxes	4,839	272	528
Net income	$ 21,289	$ 5,972	$ 4,073
Net income per common share:			
Basic	$ 0.63	$ 0.18	$ 0.13
Diluted	$ 0.59	$ 0.17	$ 0.12
Shares used in computing net income per common share:			
Basic	33,610	32,928	32,550
Diluted	35,908	34,600	33,162

See accompanying notes.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock		Additional Paid-In-	Accumulated	Accumulated Other Comprehensive	Treasury	
	Shares	Amount	Capital	Deficit	Loss	Stock	Total
			(in thousands, except share data)				
Balance at January 1, 2002	32,220,932	$ 32	$ 140,571	$ (45,194)	$ (656)	$ (600)	$ 94,153
Net income				4,073			4,073
Translation adjustment					(176)		(176)
Comprehensive income							3,897
Issuance of common stock	470,244		4,054				4,054
Balance at December 31, 2002	32,691,176	32	144,625	(41,121)	(832)	(600)	102,104
Net income				5,972			5,972
Net unrealized gain (loss) on available for sale securities					20		20
Translation adjustment					641		641
Comprehensive income							6,633
Issuance of common stock	1,146,652	1	9,754				9,755
Repurchase of common stock	(420,800)					(6,116)	(6,116)
Balance at December 31, 2003	33,417,028	33	154,379	(35,149)	(171)	(6,716)	112,376
Net income				21,289			21,289
Net unrealized gain (loss) on available for sale securities					(84)		(84)
Translation adjustment					295		295
Comprehensive income							21,500
Tax benefit from exercise of stock options			10,430				10,430
Issuance of common stock	1,182,882	2	11,402				11,404
Repurchase of common stock	(688,248)					(14,560)	(14,560)
Balance at December 31, 2004	33,911,662	$ 35	$ 176,211	$ (13,860)	$ 40	$ (21,276)	$ 141,150

See accompanying notes.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		
	2004	**2003**	**2002**
Operating activities:			
Net income	$ 21,289	$ 5,972	$ 4,073
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	8,492	8,669	8,077
Non-cash intangibles and property and equipment charges	1,758	5,797	1,151
Deferred income tax benefit	(8,909)		
Tax benefit from exercise of stock options	10,430		
Writedown of inventory		1,004	395
Writedown of investment in Molecular Diagnostics, Inc.			338
Changes in operating assets and liabilities:			
Accounts receivable	(5,894)	(4,775)	(2,175)
Inventories	(394)	2,414	(2,533)
Other assets	(1,878)	(1,176)	(3,990)
Accounts payable	(413)	1,635	3,713
Other liabilities	9,903	4,074	2,633
Net cash provided by operating activities	34,384	23,614	11,682
Investing activities:			
Purchase of property and equipment	(12,896)	(6,456)	(7,121)
Purchase of intangible assets	(4,598)	(557)	(1,337)
Purchases of short-term investments	(23,647)	(27,824)	
Proceeds from sale of short-term investments	23,339	7,850	
Net cash used in investing activities	(17,802)	(26,987)	(8,458)
Financing activities:			
Issuance of common stock	10,664	9,755	4,054
Purchases of common stock for treasury	(13,820)	(6,116)	
Proceeds from debt		278	354
Repayments of debt	(207)	(182)	(1,028)
Net cash (used in) provided by financing activities	(3,363)	3,735	3,380
Effect of exchange rate changes on cash and cash equivalents	424	641	(176)
Net increase in cash and cash equivalents	13,643	1,003	6,428
Cash and cash equivalents, beginning of year	19,711	18,708	12,280
Cash and cash equivalents, end of year	$ 33,354	$ 19,711	$ 18,708
Supplemental cash flow information:			
Income taxes paid	$ 337	$ 272	$ 528

Interest paid	$ 116	$ 132	$ 209
Non-cash investing and financing activities:			
Tendered common stock for stock option exercises	$ 740	$	$
Net issuances of other non-employee stock benefits	$ 84	$ 84	$ 84
Payments related to business and intangible acquisitions	$ 750	$	$ 529

See accompanying notes.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share data)

1. Organization and Significant Accounting Policies

Basis of Presentation: Ventana Medical Systems, Inc. (the Company) develops, manufactures, and markets proprietary instruments and reagents that automate diagnostic procedures used for molecular analysis of cells. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Ventana Medical Systems, S.A., Ventana Medical Systems, GmbH, Ventana Medical Systems, Japan K.K., and Ventana Medical Systems. Pty. Ltd. All significant inter-company balances and transactions have been eliminated. We do not have any subsidiaries in which we do not own 100% of the outstanding stock.

Fair Value of Financial Instruments: The Company s cash and cash equivalents, investments, accounts receivable, accounts payable, and long-term debt represent financial instruments as defined by Statement of Financial Accounting Standards (SFAS) No. 107, *Disclosures About Fair Value of Financial Instruments.* The carrying value of these financial instruments is a reasonable approximation of fair value, due to their current maturities.

Cash and Cash Equivalents: Cash and cash equivalents represent cash and short-term, highly liquid investments in certificates of deposit, money market funds, and investment-grade commercial paper issued by major corporations and financial institutions that have remaining maturities of three months or less when acquired.

Short-Term Investments: Short-term investments consist of corporate and various government agency debt securities. Management classifies the Company s short-term investments as available-for-sale. Available-for-sale securities are carried at fair value with the unrealized gains and losses reported in stockholders equity. Realized gains and losses and declines in value judged to be other than temporary, if any, are included in operations. A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary results in a reduction in fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related available-for-sale security. Dividend and interest income are recognized when earned. The cost of securities sold is calculated using the specific identification method.

The Company s short-term investments are intended to establish a high-quality portfolio that preserves principal, meets liquidity needs, avoids inappropriate concentrations, and delivers an appropriate yield in relationship to the Company s investment guidelines and market conditions. These investments are carried at fair value. The following is a summary of available-for-sale securities as of December 31, 2004 and 2003:

	December 31, 2004			
	Adjusted Cost	Gross Unrealized	Gross Unrealized	Estimated

		Gains	Loss	Fair Value
Federal agency bond	$ 9,711	$	$ (70)	$ 9,641
State bonds	6,360		(24)	6,336
Corporate commercial paper and bonds	3,523		(5)	3,518
Money market	654			654
	$ 20,248	$	$ (99)	$ 20,149

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

1. Organization and Significant Accounting Policies (continued)

	December 31, 2003			
	Adjusted Cost	Gross Unrealized Gains	Gross Unrealized Loss	Estimated Fair Value
Federal agency bond	$ 8,483	$ 27	$	$ 8,510
State bonds	4,345	2		4,347
Corporate commercial paper and bonds	6,969	3		6,972
Money market	145			145
	$ 19,942	$ 32	$	$ 19,974

The Company s unrealized losses of $99 were due to fluctuations in interest rates. Management does not believe any of the unrealized losses represented an other-than-temporary impairment based on its evaluation of available evidence as of December 31, 2004.

During the year ended December 31, 2004, the Company did not have any gross realized gains or losses on sales of available-for-sale securities. The following table shows the amortized cost and estimated fair value of the available-for-sale securities at December 31, 2004, by maturity. Expected maturities can differ from contractual maturities, because the issuers of the securities may have the right to prepay obligations without prepayment penalties, and the Company views its available-for-sale securities as available for current operations.

	December 31, 2004	
	Cost	Estimated Fair Value
Available for sale		
Due in one year or less	$ 13,994	$ 13,912
Due after one year and through five years	4,204	4,187
Due after ten years	2,050	2,050

	$ 20,248	$ 20,149

Concentration of Credit Risk: The Company s financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents, accounts receivable, and investments. The Company s cash and cash equivalents and investments are maintained with major high-quality international banks and financial institutions. Generally, these securities are traded in a highly liquid market, may be redeemed upon demand, and bear minimal risk. Management regularly monitors the composition and maturities of these investments, and the Company has not experienced any material loss on its investments. Cash and cash equivalents at times may exceed the FDIC limits. The Company believes no significant concentration of credit risk exists with respect to these cash investments.

The Company sells its instruments and reagent products primarily to hospitals, medical clinics, reference laboratories, and universities and to resellers serving such entities. The Company routinely assesses the financial strength of its customers, requiring letters of credit from certain foreign customers, and provides an allowance for doubtful accounts as necessary. Credit losses have been minimal to date. No single customer accounted for 5% or more of the Company s 2004, 2003, or 2002 net sales.

Inventories: Inventories, principally chemical, biological, and instrument parts and reagents and finished instruments, are stated at the lower of cost (first-in first-out basis) or market. The Company writes down its

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

1. Organization and Significant Accounting Policies (continued)

inventory for estimated obsolescence or unmarketable inventory in an amount equal to the difference between the cost of inventory and the estimated market value, based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by the Company, additional inventory write-downs may be required. Inventory impairment charges establish a new cost basis for inventory and charges are not reversed subsequently to income, even if circumstances later suggest that increased carrying amounts are recoverable. In estimating reserves for obsolescence, the Company generally evaluates estimates of demand over the next 12-month period via a forecast and provides reserves for inventory on hand in excess of the estimated 12-month demand.

Allowance for Doubtful Accounts: The Company makes ongoing estimates relating to the collectibility of our accounts receivable and maintains a reserve for estimated losses resulting from the inability of our customers to make required payments. In determining the amount of the reserve, we consider our historical level of credit losses and make judgments about customer creditworthiness, based on ongoing credit evaluations. Historically, losses from uncollectible accounts have not exceeded our reserves. Since we cannot predict future changes in the financial stability of our customers, actual future losses from uncollectible accounts may differ from our estimates. If the financial condition of our customers was to deteriorate, resulting in their inability to make payments, a larger reserve might be required. In the event we determined a smaller or larger reserve was appropriate, we would record a credit or a charge to selling and administrative expense in the period in which we made such a determination.

Property and Equipment: Property and equipment are stated at cost. Depreciation expense is computed using the straight-line method over estimated useful lives of three to twenty years. Depreciation expense for capital lease transactions is calculated using a straight-line method over the lesser of the term of the lease or useful life of the asset. Property and equipment include diagnostic instruments used for sales demonstrations or placed with customers under several types of arrangements, including cancelable reagent plans (RAP s), performance evaluation period programs (PEP), and rentals. PEP instruments are placed with customers for evaluation periods of up to six months. The customer is required to purchase a minimum amount of reagents and at the end of the evaluation period must purchase, rent, or return the instrument. The manufacturing cost of demonstration, RAP, PEP, and rental instruments is amortized over a period of three to four years to cost of goods sold (RAP s and rentals) and selling, general, and administrative expenses (PEP s and demonstrations).

Goodwill: Goodwill represents the residual purchase price after allocation of the purchase price of assets acquired. Goodwill is not amortized but is subject to an annual impairment test. This test is conducted during the fourth quarter of the Company s fiscal year and will be performed more frequently under certain circumstances. Impairment tests are performed with respect to goodwill at the segment level of reporting. The Company s portfolio of products offered for sale are the same worldwide with all production and manufacturing performed in Tucson, Arizona. The Company has sales offices that are dependent upon North America operations, sell to the same type of customer, and use similar methods of distribution. As a result, the Company concluded there is one reporting segment which is engaged in the design, development, manufacture, and marketing of proprietary instruments and reagents that automate diagnostic procedures used for molecular analysis of cells. As of December 31, 2004, there were no impairment charges related to goodwill. There can be no assurance that future goodwill impairment tests will not result in a charge to earnings.

Intangible Assets: Intangible assets consist primarily of patent application fees and defense costs, licenses, and supply agreements. Intangible assets are carried at cost less accumulated amortization. Amortization is computed over the estimated useful lives of the respective assets, generally two to seven years.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

1. Organization and Significant Accounting Policies (continued)

Patent Capitalization: The Company capitalizes costs associated with the filing of patent applications and defending its rights under patents which it owns. The Company has incurred material legal costs, some of which have been capitalized, thereby increasing the carrying value of associated patents. The capitalized amounts for legal costs and patent application filings in fiscal 2004, 2003, and 2002 were $2,598, $557, and $337, respectively. These capitalized costs are amortized on a straight-line basis over the lesser of seven years, or the remaining life of the patent to which they relate, and are reflected net of accumulated amortization as an intangible asset in the Company s Consolidated Balance Sheets. The Company s policy is to evaluate these capitalized costs for impairment periodically and when events and circumstances indicate these assets might be impaired and the undiscounted cash flows to be generated by these assets are less than the carrying amounts of the assets. Management believes the inherent value of the patents exceed their carrying value. If the rights afforded to the Company under the patents are not enforced, or if the undiscounted cash flows resulting from the patents do not exceed the net capitalized value of the associated intangible asset, the Company would write-down the patents, and such charges could be material.

Impairment of Long-Lived Assets: Impairment losses are recorded on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flow estimated to be generated by those assets are less than the assets carrying amount. The Company s policy is to evaluate long-lived assets for impairment periodically and when events and circumstances indicate an asset might be impaired and the undiscounted cash flows to be generated by that asset are less than the carrying amounts of the asset.

Capitalized Software Development Costs: The Company capitalizes certain internal expenses related to developing computer software used in the instruments it sells. Costs incurred prior to the establishment of technological feasibility are charged to research and development expense. The Company considers technological feasibility to have been established for a product when all of the following conditions have been met: a) the detail program design has been completed and it has been determined that the necessary skills, hardware, and software technology are available to produce the product, b) the detail program design has been traced to product specifications, and c) all high-risk development issues have been resolved through coding and testing. Upon general release to customers of the product in which the software is included, capitalization ceases, and such costs are amortized using the straight-line method over an estimated life of five years.

Capitalized software development costs and accumulated costs are as follows at December 31:

	2004	2003
Capitalized costs	$ 5,469	$ 4,908
Less accumulated amortization	3,220	2,529
	$ 2,249	$ 2,379

Amortization expense of capitalized software development costs were $899, $875, and $698 in 2004, 2003, and 2002, respectively.

Deferred Tax Assets: Deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws expected to be in effect when the differences are expected to reverse. The Company records a valuation allowance to reduce its deferred tax assets to the amount that it believes is more likely than not to be realized.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

1. Organization and Significant Accounting Policies (continued)

The Company has considered future taxable income in assessing the need for the valuation allowance. In the event the Company determines it would not be able to realize all or part of its net deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to expense in the period such determination was made.

Legal Contingencies: In the ordinary course of business, the Company is involved in legal proceedings involving contractual and employment relationships, product liability claims, patent rights, and a variety of other matters. The Company records contingent liabilities resulting from asserted and unasserted claims against it, when it is probable that a liability has been incurred and the amount of the loss is reasonably estimable. The Company discloses contingent liabilities when there is a reasonable possibility that the ultimate loss will exceed the recorded liability. Estimating probable losses requires analysis of multiple factors, in some cases including judgments about the potential actions of third-party claimants and courts. Therefore, actual losses in any future period are inherently uncertain. Currently, the Company does not believe any of its pending legal proceedings or claims will have a material impact on its financial position or results of operations. However, if actual or estimated probable future losses exceed the Company s recorded liability for such claims, it would record additional charges as other expense during the period in which the actual loss or change in estimate occurred.

Foreign Currency Translations: The financial statements of foreign subsidiaries have been translated into U.S. Dollars in accordance with SFAS No. 52, *Foreign Currency Translation.* All balance sheet accounts have been translated using the exchange rates in effect at the balance sheet date. Income statement amounts have been translated using the average exchange rate for the year.

The gains and losses resulting from the changes in exchange rates from year to year have been reported in other comprehensive income. The effect on the consolidated statements of operations of transaction gains and losses is not material for all years presented.

Revenue Recognition: The Company recognizes revenue pursuant to Staff Accounting Bulletin No. 101, and No. 104, *Revenue Recognition in Financial Statements*. Accordingly, revenue is recognized when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists, (ii) delivery of the products and/or services has occurred, (iii) the selling price is both fixed and determinable, and (iv) collectibility is reasonably assured.

Revenue from instrument sales made directly to the end user is generally recognized upon our completion of the installation. However, if the end user already has the identical instrument installed at the same location, revenue is recognized from that sale upon shipment.

A portion of our instrument revenue is from sales made to distributors under agreements that require them to assume responsibility for product installation without recourse to the Company. Revenue for instruments sold under these agreements is recognized upon shipment to the distributor when the Company assesses their ability to pay for that sale. There are certain foreign distributors for which revenue is not recognized until the instrument is installed and accepted by the end user, thereby making the related payment assured.

Revenue from reagents is recognized upon shipment. Service contract revenue is deferred and recognized ratably over the period service is to be provided, which is typically one to three years. Out-of-warranty work is recognized as services are rendered.

Provisions for estimated sales returns are established as a reduction of product sales revenue at the time revenues are recognized. These revenue reductions are established by the Company s management using their

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

1. Organization and Significant Accounting Policies (continued)

best estimate at the time of sale, based on historical experience adjusted to reflect known changes in the factors that impact such reserves. These revenue reductions are reflected as a direct reduction to accounts receivable through an allowance. The Company has not had significant product returns and is not contractually obligated to accept returns unless such returns are related to warranty provisions. The Company does not accept reagent product returns due to FDA regulations and does not offer volume rebates or provide price protection.

Our Performance Evaluation Period (PEP) program is a formal agreement whereby a staining system is installed on the premises of a pre-qualified customer for the purpose of allowing the customer to evaluate the system s functionality over an extended trial period. The customer agrees to purchase a reagent starter kit at the time of installation and to purchase a minimum volume of reagents over the life of the trial period. Minimum purchase requirements vary by customer. Associated reagent revenue is recognized upon shipment of each reagent order. Upon completion of the trial period, the customer purchases the staining system or returns it to the Company. In those cases where the customer purchases the staining system, the Company recognizes revenue consistent with our revenue recognition policies. If the customer elects to rent the staining system, the rental income is presented in Instrument Sales, while the reagent revenue is presented in Reagents and Other Sales, and the cost of the staining system is depreciated to Cost of Goods Sold using the straight-line method over approximately three years.

Product Warranty: The Company generally sells products with a limited warranty of product quality and a limited indemnification of customers against intellectual property infringement claims related to the Company s products. The accrual and the related expense for known issues were not significant as of and for the fiscal years presented. Due to product testing, the short time between product shipment and the detection and correction of product failures, and a low historical rate of payments on indemnification claims, the accrual based on historical activity and the related expense were not significant as of and for the fiscal years presented.

Shipping Costs: All costs of shipping products to customers are included in costs of sales.

Stock-based Employee Compensation: At December 31, 2004, the Company has four active stock-based employee compensation plans. The Company accounts for those plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees,* and related Interpretations. No stock-based employee compensation cost is reflected in net income, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

1. Organization and Significant Accounting Policies (continued)

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123), to stock-based employee compensation:

	Year Ended December 31		
	2004	2003	2002
Net income, as reported	$ 21,289	$ 5,972	$ 4,073
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects in 2004, no tax benefit available in 2003 and 2002.	(8,413)	(8,961)	(8,086)
Pro forma net income (loss)	$ 12,876	$ (2,989)	$ (4,013)
Net income (loss) per share:			
Basic as reported	$ 0.63	$ 0.18	$ 0.13
Basic pro forma	$ 0.38	$ (.09)	$ (0.12)
Diluted as reported	$ 0.59	$ 0.17	$ 0.12
Diluted pro forma	$ 0.36	$ (.09)	$ (0.12)

As required, the pro forma disclosures above include options granted since January 1, 1995. Consequently, the effects of applying SFAS No. 123 for providing pro forma disclosures may not be representative of the effects on reported net income for future years until all options outstanding are included in the pro forma disclosures. For purposes of pro forma disclosures, the estimated fair value of stock-based compensation plans and other options is amortized to expense primarily over the vesting period. See Note 10 for further discussion of the Company s stock-based employee compensation, including assumptions relating to the pro-forma amounts above.

Use of estimates: The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Reclassification: Certain amounts in prior year financial statements have been reclassified to conform to the 2004 financial statement presentation.

Recently Issued Accounting Standards: FASB Staff Position (FSP) No. 109-2, *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004* (FSP No. 109-2), provides guidance under SFAS No. 109, *Accounting for Income Taxes* (SFAS No. 109), with respect to recording the potential impact of the repatriation provisions of the American Jobs Creation Act of 2004 (the Jobs Act) on enterprises income tax expense and deferred tax liability. The Jobs Act was enacted on October 22, 2004. FSP No. 109-2 states an enterprise is allowed time beyond the financial reporting period of enactment to evaluate the effect of the Jobs Act on its plan for reinvestment or repatriation of foreign earnings for purposes of applying SFAS No. 109. The Company has not yet completed evaluating the impact of the repatriation provisions. Accordingly, as provided for in FSP No. 109-2, the Company has not adjusted its tax expense or deferred tax liability to reflect the repatriation provisions of the Jobs Act.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

1. Organization and Significant Accounting Policies (continued)

In March 2004, the FASB approved the consensus reached on the Emerging Issues Task Force (EITF) Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments* (EITF No. 03-1). EITF No. 03-1 s objective is to provide guidance for identifying other-than-temporarily impaired investments. EITF No. 03-1 also provides new disclosure requirements for investments that are deemed to be impaired temporarily. In September 2004, the FAS issued FSP EITF No. 03-1-1 that delays the effective date of the measurement and recognition guidance in EITF No. 03-1 until further notice. The disclosure requirements of EITF No. 03-1 are effective with this annual report for 2004. Once the FASB reaches a final decision on the measurement and recognition provisions, the Company will evaluate the impact of the accounting provisions of EITF No. 03-1.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs An Amendment of ARB No. 43, Chapter 4* (SFAS No. 151). SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing* (ARB No. 43), to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Among other provisions, the new rule requires that items, such as idle facility expense, excessive spoilage, double freight, and re-handling costs, be recognized as current-period charges regardless of whether they meet the criterion of so abnormal as stated in ARB No. 43. Additionally, SFAS No. 151 requires the allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for fiscal years beginning after June 15, 2005, and is required to be adopted by the Company in the first quarter of fiscal 2006, beginning on January 1, 2006. The Company currently is evaluating the effect that the adoption of SFAS No. 151 will have on its consolidated results of operations and financial condition but does not expect SFAS No. 151 to have a material impact.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123R), which replaces SFAS No. 123, and supersedes APB No. 25. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first interim or annual period after June 15, 2005, with early adoption encouraged. The pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. The Company is required to adopt SFAS No. 123R in the third quarter of fiscal 2005, beginning July 1, 2005. Under SFAS No. 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost, and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS No. 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The Company is evaluating the requirements of SFAS No. 123R and expects that the adoption of SFAS No. 123R will have a material impact on its consolidated results of operations and earnings per share. The Company has not yet determined the method of adoption or the effect of adopting SFAS No. 123R, and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123. SFAS No. 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. We cannot estimate what those amounts will be in the future, because they depend on, among other things, when employees exercise stock options.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

1. Organization and Significant Accounting Policies (continued)

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Non-monetary Assets An Amendment of APB Opinion No. 29, Accounting for Non-monetary Transactions* (SFAS No. 153). SFAS No. 153 eliminates the exception from fair value measurement for non-monetary exchanges of similar productive assets in paragraph 21(b) of APB Opinion No. 29, *Accounting for Non-monetary Transactions*, and replaces it with an exception for exchanges that do not have commercial substance. SFAS No. 153 specifies a non-monetary exchange has commercial substance, if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for the fiscal periods beginning after June 15, 2005, and is required to be adopted by the Company in the first quarter of fiscal 2006, beginning on January 1, 2006. The Company currently is evaluating the effect that the adoption of SFAS No. 153 will have on its consolidated results of operations and financial condition but does not expect it to have a material impact.

The adoption of the following recent accounting pronouncements did not have a material impact on the Company s results of operations and financial condition:

- FASB issued FSP No. 106-2, *Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement and Modernization Act of 2003;* and

- EITF Issue No. 03-5, *Applicability of AICPA Statement of Position 97-2 to Non-Software Deliverables in an Arrangement Containing More-Than-Incidental Software.*

2. Inventories

Inventories consist of the following:

	December 31,	
	2004	**2003**
Raw materials and work-in-process	$ 4,067	$ 2,977
Finished goods	6,810	7,506
	$ 10,877	$ 10,483

3. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2004	**2003**
Land	$ 6,327	$ 6,327
Diagnostic instruments	25,429	17,334
Buildings	23,803	21,317
Machinery and equipment	8,633	10,243
Computers and related equipment	8,062	8,212
Furniture and fixtures	2,392	2,169
Leasehold improvements	406	147
	75,052	65,749
Less accumulated depreciation	28,694	23,693
Projects in progress	1,321	460
	$ 47,679	$ 42,516

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

4. Intangible Assets

Intangible assets as of December 31, 2004, consisted of the following:

	Gross Assets	Accumulated Amortization	Net
Patents	$ 3,829	$ (640)	$ 3,189
Licenses	3,778	(1,737)	2,041
Supply Agreement	2,000	(133)	1,867
	$ 9,607	$ (2,510)	$ 7,097

Intangible assets as of December 31, 2003 consisted of the following:

	Gross Assets	Accumulated Amortization	Net
Licenses	$ 3,029	$ (1,192)	$ 1,837
Developed Technology	1,795	(778)	1,017
Patents	1,231	(327)	904
Customer Base	252	(28)	224
	$ 6,307	$ (2,325)	$ 3,982

Amortization expense was $1,326, $1,678, and $1,646 for periods ending December 31, 2004, 2003, and 2002 respectively. Based on the carrying value of identified intangible assets recorded at December 31, 2004, and assuming no subsequent impairment of the underlying assets, the annual amortization expense is expected to be $1,691 2005; $1,673 2006; $1,429 2007; $1,145 2008; and $958 2009.

5. Other Current Liabilities

Other current liabilities consist of the following:

	December 31,	
	2004	2003
Employee compensation and benefits	$ 9,980	$ 7,444
Taxes payable	6,329	1,436
Current portion of deferred revenue	4,624	3,679
Legal contingencies	1,741	470
Accrued royalties	1,049	491
Current portion of long-term debt	850	787
Product warranty	762	901
Other accrued liabilities	514	698
	$ 25,849	$ 15,906

6. Line of Credit

The Company cancelled a $12,000 line of credit arrangement with a bank effective March 31, 2004.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

7. Long-term Debt

Long-term debt consists of the following:

	December 31,	
	2004	2003
Note payable for European Facility, Euribor +1.25%, due April 2015	$ 2,412	$ 2,469
Other obligation	620	578
	3,032	3,047
Less current portion	850	787
	$ 2,182	$ 2,260

The other obligation is a contingent payment of $750 subject to annual adjustments based on future performance of certain products. At December 31, 2004 and 2003, the carrying amount of the obligation represents the present value of the contingent payment using an effective interest rate of 7%. The contingent payment is due September 2007 or earlier if called by the holder.

Future payments under the above debt are as follows at December 31, 2004:

2005	$ 850
2006	238
2007	246
2008	254
2009	264
Thereafter	1,180
	$ 3,032

8. Stock Transactions

On February 4, 2005, the Company announced a 2-for-1 stock split in the form of a stock dividend that occurred on March 14, 2005, to stockholders of record at the close of business on March 4, 2005. All share and per share data have been restated to reflect this stock split.

In May 2004, the Company s Directors approved the repurchase of up to 2,000 shares of the Company s common stock. A total of 688 and 421 shares were repurchased under these authorizations in 2004 and 2003, respectively.

9. Stock Purchase Plan

In April 1996, the Board of Directors authorized the 1996 Employee Stock Purchase Plan (the 1996 Purchase Plan). A total of 1,400 shares of common stock have been reserved for issuance under the 1996 Purchase Plan. A total of 1,180 shares of common stock have been issued under the 1996 Purchase Plan at prices ranging from $4.09 to $19.91 per share. The 1996 Purchase Plan allowed eligible employees to purchase common stock through payroll deductions, subject to certain limitations. The price at which stock could have been purchased under the 1996 Purchase Plan was equal to 85% of the lower of the fair market value of the

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

9. Stock Purchase Plan (continued)

common stock on the participant s entry date into the offering period, or 85% of the fair market value on the semi-annual purchase date. Beginning January 2005, the price at which stock may be purchased under the 1996 Purchase Plan is equal to 85% of the fair market value of the common stock on the quarterly purchase date.

10. Stock Option Plans

As of December 31, 2004, the Company had four active Stock Option Plans (the 1988 Stock Option Plan, the 1996 Stock Option Plan, the 1998 Non-statutory Stock Option Plan, and 2001 Outside Director Stock Option Plan).

Under the Company s 1988 Stock Option Plan (the 1988 Plan), up to 2,679 shares of common stock have been reserved for grant to employees and directors. In order to be incentive stock options (ISOs), options must be granted at not less than 100% of fair market value of the Company s stock on the date of grant. Options generally vest over a four-year period and expire five to ten years after the date of grant. However, the Board of Directors, at its discretion, may decide the period over which options become exercisable and their expiration dates. There are currently no shares of common stock available for grant under the 1988 Plan, and 235 options remain outstanding at prices ranging from $0.42 to $8.25 per share.

In April 1996, the Company s Board of Directors authorized the 1996 Stock Option Plan (the 1996 Plan). A total of 4,950 shares of common stock have been reserved for issuance under the 1996 Plan. In order to be ISOs, options must be granted at not less than 100% of the fair market value of the Company s stock on the dates of grant. Options generally vest over four years (grants made prior to 1998), or five years (1998 and subsequent grants) and expire in ten years. In 2004, the Company granted fully vested options at escalating exercise prices. There are 515 shares of common stock available for grant under the 1996 Plan, and 2,620 options remain outstanding at prices ranging from $6.13 to $41.00 per share.

In June 1996, the Company adopted the 1996 Director Stock Option Plan (the Director Plan) and reserved a total of 500 shares of related common stock for issuance. Commencing with the Company s 1997 annual meeting of stockholders, each non-employee director was to be granted a non-statutory option to purchase an amount of shares of the Company s common stock equal to 10 shares multiplied by a fraction, the numerator of which was $7.50 per share and the denominator of which shall be the fair market value of one share of the Company s common stock on the dates of grant. The exercise price of options granted under the Director Plan is equal to the fair market value of one share of the Company s common stock on the dates of grant. Effective November 1998, the Director Plan was modified such that options are granted on a discretionary basis at fair value on the date of grant. The total shares issued under the prior and current version of the Director Plan are 500. Each option granted under the Director Plan vests on a cumulative monthly basis over a one-year period and has a 10-year term. The Director Plan terminated in June 2001 and was replaced by the 2001 Outside Director Stock Option Plan. 480 options remain outstanding at prices

ranging from $5.06 to $13.69 per share.

On March 9, 1998, the Company s Board of Directors approved the establishment of a rights plan. Pursuant to this plan, the Board of Directors declared a dividend distribution of one Preferred Shares Purchase Right on each outstanding share of the Company s Common Stock for shareholders of record on May 8, 1998. Each right entitles stockholders to buy 1/500th of a share of the Company s Series A Participating Preferred Stock at an exercise price of $42.50 per 1/500th of a share. The Rights become exercisable following the tenth day after a person or group announces an acquisition of 20% or more of the Company s Common Stock or announces commencement of a tender offer, the consummation of which would result in ownership by the person or group of 20% or more of the Common Stock. The Company is entitled to redeem the Rights at $0.01 per Right at any

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

10. Stock Option Plans (continued)

time on or before the tenth day following acquisition by a person or group of 20% or more of the Company s Common Stock. If, prior to redemption of the Rights, a person or group acquires 20% or more of the Company s Common Stock, each Right not owned by a holder of 20% or more of the Common Stock will entitle its holder to purchase, at the Right s then current exercise price, that number of shares of Common Stock of the Company (or, in certain circumstances as determined by the Board of Directors, cash, other property, or other securities) having a market value at that time of twice the Right s exercise price. If, after the tenth day following acquisition by a person or group of 20% or more of the Company s Common Stock, the Company sells more than 50% of its assets or earning power or is acquired in a merger or other business combination transaction, the acquiring person or group must assume the obligation under the Rights, and the Right will become exercisable to acquire Common Stock of the acquiring person or group at the discounted price.

At any time after an event triggering the opportunity to exercise the Rights at a discounted price and prior to the acquisition by the acquiring person or group of 50% or more of the outstanding Common Stock, the Board of Directors of the Company may exchange the Rights (other than those owned by the acquiring person or its group and affiliates) for Common Stock of the Company at an exchange ratio of one share of Common Stock per Right.

In January 1999, the Company s Board of Directors authorized the 1998 Non-statutory Stock Option Plan (the 1998 NSO Plan). In 2003, the Company increased the plan reserve by 1,000 shares for an aggregate total of 5,000 shares. Under this plan, options can not be granted to the Company s officers or directors. Options generally vest over five years and expire ten years after the date of grant; however, the Board of Directors, at its discretion, may decide the period over which options become exercisable and their expiration dates. In 2004, the Company granted fully vested options at escalating exercise prices. There are 930 shares of common stock available for grant under the 1998 NSO Plan, and 2,858 options remain outstanding at prices ranging from $8.09 to $41.00 per share.

In May 2001, the stockholders approved the adoption of the 2001 Outside Director Stock Option Plan (the 2001 Director Plan) and reserved a total of 1,000 shares of common stock for issuance to directors who are not also active full-time employees of the Company or another company in which Ventana has a 50% or more voting interest. The exercise price of options granted under the 2001 Director Plan is equal to the fair market value of one share of the Company s common stock on the date of grant. Each option granted under the 2001 Director Plan vests on a cumulative monthly basis over a one-year or three-year period and has a 10-year term. There are 266 shares of common stock available for grant under the 2001 Director Plan, and 733 options remain outstanding at prices ranging from $10.12 to $33.73 per share.

Pro forma information regarding net income (loss) and earnings (loss) per share, as disclosed in Note 1, has been determined as if the Company had accounted for its employee stock-based compensation plans and other stock options under the fair value method of SFAS No. 123. The fair value for these options was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions used for grants under the option plans:

	Years ended December 31,		
	2004	2003	2002
Weighted average risk-free interest rate	3.0%	3.0%	3.6%
Expected life of options (years)	4.4	6.5	5.9
Expected stock volatility	58.8%	72.3%	57.2%
Expected dividend yield	0%	0%	0%

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

10. Stock Option Plans (continued)

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because changes in the subjective input assumptions can materially affect the fair value estimate, in management s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options. The weighted average fair values of options granted for the years ended 2004, 2003, and 2002, for which the exercise price was equal to the fair market value of the stock were $10.92, $13.49, and $5.83 per share, respectively.

A summary of the Company s stock option activity and related information is as follows:

	Outstanding Stock Options		
	Shares Available for Options	Number of Options	Weighted Average Exercise Price Per Share
Balance at January 1, 2002	3,016	5,962	$ 9.54
Authorized	1,000		
Granted	(1,216)	1,216	10.35
Exercised		(284)	8.50
Canceled	298	(298)	11.29
Balance at December 31, 2002	3,098	6,596	$ 9.65
Authorized	1,000		
Granted	(1,108)	1,108	11.40
Exercised		(1,068)	7.78
Canceled	380	(380)	10.67
Balance at December 31, 2003	3,370	6,256	$ 10.22
Granted	(1,855)	1,855	28.26
Exercised		(989)	9.54
Canceled	196	(196)	12.37
Balance at December 31, 2004	1,711	6,926	$ 15.07

	Stock Options at December 31, 2004				
	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number of Options Outstanding	Weighted Average Exercise Price Outstanding	Weighted Average Remaining Contractual Life (Years)	Number Exercisable	Weighted Average Exercise Price
$ 0.42 $ 9.30	1,394	$ 7.93	4.1	1,226	$ 7.78
$10.00 $10.12	1,408	10.08	6.9	822	10.08
$10.22 $11.85	1,576	11.09	5.8	1,422	11.10
$12.12 $22.37	1,612	18.54	7.9	780	15.77
$24.29 $41.00	936	33.97	9.9	720	35.89
	6,926	$ 15.07	6.8	4,970	$ 14.44

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

11. Income Taxes

Income before taxes consisted of the following:

	Years Ended December 31,		
	2004	2003	2002
Current:			
Domestic	$ 25,350	$ 2,957	$ 3,833
Foreign	778	3,287	768
	$ 26,128	$ 6,244	$ 4,601

The provision for income taxes consisted of the following:

	Years Ended December 31,		
	2004	2003	2002
Current:			
U.S. Federal	$ 104	$ 48	$
State	87	181	448
Foreign	3,484	43	80
	3,675	272	528
Deferred:			
U.S. Federal	2,574		
State	311		
Foreign	(1,721)		
	$ 4,839	$ 272	$ 528

A reconciliation of the U.S. Federal statutory income tax rate to the effective tax rate follows:

	Years Ended December 31,		
	2004	2003	2002
U.S. Federal Statutory Rate	35.0%	35.0%	35.0%
State taxes net of federal benefit	4.2	2.9	6.3
Non-deductible expenses	0.8	22.5	6.6
Foreign taxes	0.1	0.7	1.7
Extraterritorial income exclusion	(1.6)	(1.6)	(4.2)
General business credits	(3.6)	(6.5)	(9.0)
Change in valuation allowance and other	(16.4)	(48.6)	(24.9)
Effective tax rate	18.5%	4.4%	11.5%

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

11. Income Taxes (continued)

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company s deferred tax assets (liabilities) consist of the following:

	December 31,	
	2004	2003
Current:		
Net operating loss carry forwards	$ 1,974	$ 1,909
Foreign loss carry forwards	108	540
Deferred revenue	1,390	1,112
Capitalized foreign inventory	858	491
Allowance for doubtful accounts	349	464
Other	1,865	1,378
Valuation reserve		(2,694)
	6,544	3,200
Non-current:		
Net operating loss carry forwards	3,581	1,549
Foreign loss carry forwards	879	1,134
General business credit carry forwards	4,973	4,040
Deferred revenue	106	159
Amortization of goodwill	621	621
Depreciation expense	(929)	212
In-process R&D write-off	690	814
Capitalized software development costs	(153)	(904)
AMT credit carry forward	346	242
Other	1,215	2,495
Valuation reserve		(4,760)
	11,329	5,602
Net deferred tax assets	$ 17,873	$ 8,802

A valuation allowance of $7,454 had been established against a portion of the Company s deferred tax assets at December 31, 2003. As of December 31, 2004, the Company believed it is more likely than not that it will be able to realize the majority of its deferred tax asset through

expected future taxable profits and released all amounts of the valuation allowance. As a result of the Company s decision, $4,360 of this reserve was recorded to additional-paid-in-capital, since this tax benefit was created by the exercise and/or disposition of employee stock options in periods prior to 2004, $2,994 was released to earnings recorded as an income tax benefit, and $100 reduced an intangible asset balance related to a prior business acquisition. In addition, a tax benefit of $6,070 was recorded to additional-paid-in-capital through current year exercises and/or dispositions of employee stock options. Should the Company determine it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to expense in the period such determination is made.

It is the Company s policy to establish reserves for taxes that may become probable in future years as a result of an examination by tax authorities. The Company establishes the reserves based upon its assessment of exposure associated with permanent tax differences, tax credits, and interest expense applied to temporary

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

11. Income Taxes (continued)

difference adjustments. The tax reserves are analyzed periodically and adjustments are made as events occur to warrant adjustment to the reserves.

At December 31, 2004, the Company had gross U.S. federal and state operating loss carry forwards of approximately $23,600 and $5,300, respectively. However, $2,900 will expire due to Internal Revenue Code Section 382, whereby the Company s use of its net operating loss carry forwards are limited as a result of cumulative changes in ownership of more than 50% over a three-year period. Future financings may cause additional changes in ownership and cause further limitations on the use of federal net operating loss carry forwards. Currently, U.S. federal and state operating loss carry forwards will begin to expire in 2009 and 2005, respectively, unless previously utilized. At December 31, 2004, the Company had federal alternative minimum tax credit carry forwards of approximately $300 that do not expire.

The Company also has gross general business credits for U.S. federal and state income purposes of approximately $6,400 and $3,500 respectively. These carry forwards will begin to expire in 2005 if not previously utilized. In addition, the company has foreign net operating loss carry forwards of approximately $3,000, which will begin to expire in 2007 if not previously utilized.

At December 31, 2004, the Company has approximately $400 of undistributed earnings of the Company s foreign subsidiaries. The American Jobs Creation Act of 2004 (the Jobs Act) creates a temporary incentive for U.S. corporations to repatriate accumulated income earned abroad by providing an 85% dividends-received deduction for certain dividends from controlled foreign corporations. The deduction is subject to a number of limitations, and currently the Company is uncertain as to how to interpret numerous provisions in the Jobs Act. The Company is not yet in a position to decide whether, and to what extent, foreign earnings that have not yet been remitted to the U.S. might be remitted. The Company expects to be in a position to finalize its analysis by December 2005.

12. Comprehensive Income (Loss)

The components of other comprehensive income for December 31, 2004, 2003, and 2002 were as follows:

	2004	2003	2002
Net income	$ 21,289	$ 5,972	$ 4,073

Net unrealized (losses) gains on available-for-sale securities	(84)	20	
Net change in cumulative translation adjustment	295	641	(176)
	$ 21,500	$ 6,633	$ 3,897

The components of accumulated other comprehensive income (loss), net of tax, were as follows:

	2004	2003
Net unrealized (losses) gains on available-for-sale securities	$ (64)	$ 20
Cumulative translation adjustment	104	(191)
	$ 40	$ (171)

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

13. Commitments and Contingencies

Lease Commitments:

The Company leases an office facility and equipment under certain operating leases. Future minimum lease payments under operating leases at December 31, 2004, are as follows:

2005	$ 1,232
2006	701
2007	188
2008	2
	$ 2,123

Lease expense totaled $1,498, $1,243, and $1,612 for the years ended December 31, 2004, 2003, and 2002, respectively.

Litigation:

The Company is litigating several matters with CytoLogix, Inc., a Massachusetts company. In December, 2003, a jury found the Company liable for infringement on the two patent cases (no willful infringement) and not liable for misappropriation of trade secrets. The Company filed post-trial motions for judgment as a matter of law and a new trial. A hearing for a permanent injunction occurred in February 2004. At the hearing, the Judge ruled on several issues, including denying the parties post-trial motions and framing the scope of the injunction. A permanent injunction was entered by the Court in April 2004, which prohibits the Company from making and selling the BENCHMARK/DISCOVERY systems but does not prohibit their continued use by customers, and does not prohibit the Company from servicing the instruments or supplying reagents to customers. In May 2004, CytoLogix and the Company filed Notices of Appeal to the Court of Appeals for the Federal Circuit. In February 2005, the Appeals Court dismissed CytoLogix s appeal as not presently before the Court and ordered corrected briefing. The appeal is likely to be decided in mid-year 2005. Hearings on the issues of patent damages and the antitrust-related claims will not be scheduled until the conclusion of the appeal. Management has not recorded any asset impairment subject to the imminent injunction or accrued any liability given that management, after conferring with legal counsel, believes it is probable, as defined in SFAS No. 5, that the Court s current position will be overturned.

In the ordinary course of business, we are involved in a limited number of other legal actions, both as plaintiff and defendant, and could incur uninsured liability in any one or more of them. Although the outcome of these actions is not presently determinable, it is the opinion of the Company s management, based upon the information available at this time, that the expected outcome of these matters, individually or in the aggregate, will not have a material adverse effect on the results of operations or financial condition of the Company.

International Taxes:

The Company is responsible for charging end customers certain taxes in numerous international jurisdictions. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. In the future, we may come under audit which could result in changes to our estimates. The Company believes it maintains adequate tax reserves to offset potential liabilities that may arise upon audit. Although the Company believes its tax estimates and associated reserves are reasonable, the final determination of tax audits and any related litigation could be materially different than the amounts established for tax contingencies. To the extent that such estimates ultimately prove to be inaccurate, the associated reserves would be adjusted resulting in our recording a benefit or expense in the period a final determination was made.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

14. Benefit Plan

Effective January 1, 1993, the Company adopted a 401 (k) Defined Contribution Benefit Plan (the Plan), which covers substantially all employees of the Company from their date of hire. The Plan permits participants to contribute to the Plan, subject to Internal Revenue Code restrictions, and the Plan also permits the Company to make discretionary matching contributions. Beginning July 2002, the Company elected to make discretionary matching contributions to the Plan for all non-management employees. The Company contributed $357, $229, and $81 in matching contributions during 2004, 2003, and 2002, respectively.

15. Operating Segment and Enterprise Data

The Company has two reportable segments: North America (primarily the United States) and International (primarily France, Germany, Japan, and Australia). These operating segments are the segments of the Company for which separate financial information is available and for which operating profit/loss amounts are regularly evaluated by the Company s Chief Operating Decision Maker (its Chief Executive Officer) in deciding how to allocate resources and in assessing performance.

The Company s Chief Operating Decision Maker evaluates performance and allocates resources based on profit or loss from operations. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies. Inventory transfers to foreign subsidiaries are made at standard cost. The North America operations include corporate activity (including all interest income) that benefits the Company as a whole. The following summary includes net sales only to unaffiliated customers. Net sales are attributed to segments based on the location from which the shipment to the customer was made; reagents and instruments are sold in each segment.

	Year ended December 31, 2004			
	North America	International	Eliminations	Totals
Sales to external customers	$ 116,034	$ 50,068	$	$ 166,102
Depreciation and amortization expense	5,972	2,520		8,492
Segment profit (loss)	22,274	(985)		21,289
Property and equipment, net	42,485	5,194		47,679
Segment assets	164,692	34,913	(19,457)	180,148
Expenditures for long-lived assets	16,613	881		17,494

Year ended December 31, 2003

	North America	International	Eliminations	Totals
Sales to external customers	$ 94,445	$ 37,935	$	$ 132,380
Depreciation and amortization expense	6,312	2,357		8,669
Segment profit	2,728	3,244		5,972
Property and equipment, net	37,306	5,210		42,516
Segment assets	131,507	27,639	(17,932)	141,214
Expenditures for long-lived assets	5,838	1,175		7,013

	Year ended December 31, 2002			
	North America	International	Eliminations	Totals
Sales to external customers	$ 78,279	$ 27,158	$	$ 105,437
Depreciation and amortization expense	7,042	1,035		8,077
Segment profit	3,385	688		4,073
Property and equipment, net	36,759	7,018		43,777
Segment assets	118,906	26,996	(20,765)	125,137
Expenditures for long-lived assets	6,615	1,843		8,458

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

16. Transaction with Quantum Dot Corporation

On August 26, 2004, the Company entered into supply and exclusive license agreements with Quantum Dot Corporation (QDC) whereby QDC is to supply and license Qdot® nanocrystals to be incorporated into the Company s next-generation rapid, quantitative, and multiplexed assays for cancer diagnosis and disease management. The Company paid $2,000 in cash and accounted for this transaction as an acquisition of an intangible asset classified as a supply agreement to be amortized over five years, which is the original term of the agreement.

17. Special Charges

Fiscal 2004:

On September 16, 2004, the Company entered into an agreement with TriPath Imaging Inc. to sell and distribute worldwide a Ventana-branded interactive histology imaging system. As a result of this transaction, the Company incurred a $1,758 non-cash charge primarily associated with impairments to certain intangible and fixed assets acquired in a 2001 transaction.

Fiscal 2003:

During the fourth quarter of 2003, the Company decided to exit the TECHMATE and tissue processor product lines, close its Chicago reference lab business, and re-locate its pharma services business to Tucson. As a result of these decisions, a special charge of $6,429 was recorded. The following table summarizes these charges and provides a roll forward of the related reserves through December 31, 2003 (in thousands):

	Initial Charges	Costs Incurred in 2003	Reserve Balances as of December 31, 2003
Exit of Techmate product line	$ 2,385	$ 2,385	$
Discontinuance of tissue processor product line	2,006	2,006	
Exit of reference lab business	1,315	1,284	31
Costs to relocate pharma services business, other	723	473	250

Total impairment charges and other expenses	$ 6,429	$ 6,148	$ 281

The total charge of $6,429 is included in the Statement of Operations as cost of sales ($729) and special charges ($5,700). Charges of $2,385 were taken to exit the TECHMATE product line. This includes a $1,806 charge taken to write-down the customer base and a $261 charge taken to write off developed technology assets purchased during the 1996 Biotek Solutions, Inc., acquisition. In addition, a $318 charge to cost of sales was taken to write-down all associated inventory to net realizable value. At December 31, 2004, $281 of costs were incurred and there are no remaining reserves.

A charge of $2,006 was taken to discontinue the tissue processor product line. This included a $953 charge to write-off the developed technology purchased during the 1998 Biotechnology Tools, Inc., acquisition. In addition, a $642 charge was taken to accelerate depreciation on fixed assets and other assets, as well as a $411 charge to cost of sales to write-down all associated inventory to net realizable value.

The Company recognized charges of $1,315 to exit the reference lab business. Of this charge, $696 was taken to write-off the developed technology purchased during the 2000 Quantitative Diagnostic Laboratories, Inc., acquisition, and $619 related to accelerated depreciation on fixed assets and employee severance costs.

Charges of $723 were primarily taken in association with relocating the Company s pharma services business. This expense mainly consists of lease exit costs and accelerated depreciation on leasehold improvements.

Table of Contents

VENTANA MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

(in thousands, except per share data)

17. Special Charges (continued)

Fiscal 2002:

On September 24, 2002, the Company entered into an agreement with Beckman Coulter, Inc. to acquire its Human Papillomavirus (HPV) business and related assets, which included its HPV intellectual property portfolio and related products, for the quantitative and qualitative identification of HPV. The acquisition principally included the intellectual property rights and the related technologies in HPV business applications. This acquisition includes assignment of the HPV intellectual property portfolio acquired by Beckman from Institute Pasteur through a 1991 sub-license agreement.

As a result of this transaction, the Company incurred a $1,151 non-cash charge to write off the value of an existing supply agreement ($885) and associated developed technology ($266) previously acquired through the purchase of certain oncology diagnostic technology and assets from Oncor, Inc., in 1998.

18. Net Income Per Share

The following table sets forth the components of the computation of 2004, 2003, and 2002 basic and diluted net income per share:

	2004	2003	2002
Numerator:			
Net income	$ 21,289	$ 5,972	$ 4,073
Denominator:			
Basic:			
Weighted average shares	33,610	32,928	32,550
Effect of dilutive securities:			
Employee stock options	2,298	1,672	612
	35,908	34,600	33,162
Net income per share:			

Basic	$ 0.63	$ 0.18	$ 0.13
Diluted	$ 0.59	$ 0.17	$ 0.12

Weighted average common equivalent shares exclude the effect of antidilutive options. As of December 31, 2004, 2003, and 2002, the weighted average number of options that were antidilutive was 28, 52, and 3,018, respectively.

Table of Contents

EXHIBITS

Exhibit Number	Description	Notes
3.1	Restated Certificate of Incorporation or Registrant	(1)
3.2	Bylaws of Registrant	(1)
4.1	Specimen Common Stock Certificate	(1)
10.1	Form of Indemnification Agreement for directors and officers	(1)
10.2	1988 Stock Option Plan and forms of agreements thereunder	(1)
10.3	1996 Stock Option Plan and forms of agreements thereunder	(1)
10.4	1996 Employee Stock Purchase Plan	(1)
10.5	1996 Directors Option Plan	(1)
10.6	1998 Nonstatutory Stock Option Plan and forms of agreements thereunder	(2), (3)
10.7	2001 Outside Director Stock Option Plan	(4)
21.1	Subsidiaries of Registrant	
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm	
24.1	Power of Attorney (on page 35 of Form 10-K)	
31.1	Certification of Chief Executive Officer	
31.2	Certification of Chief Financial Officer	
32	Section 1350 Certification of Chief Executive Officer and Chief Financial Officer	

(1) Filed with the Registration Statement on Form S-l (Commission File No. 333-4461), declared effective by the Commission July 26, 1996.

(2) Form of agreements filed with the Registration Statement on Form S-8 (Commission File No. 333-92883), filed with the Commission on December 16, 1999.

(3) Form of 1998 Nonstatutory Stock Option Plan, as amended, agreements filed with the Registration Statement on Form S-8 (Commission File No. 333-105976), filed with the Commission on June 10, 2003.

(4) Filed with the Registration Statement on Form S-8 (Commission File No. 333-69658), filed with the Commission on September 19, 2001.