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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

for the fiscal year ended December 31, 2002.

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 No. 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
220 East First Street Bethlehem, Pennsylvania	**18015**
(Address of Principal Executive Offices)	**(Zip Code)**

(610) 882-1820

(Registrant's Telephone Number, Including Area Code)

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

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

Common Stock, $.000001 par value per share

(Title of Class)

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the Registrant's most recently completed second fiscal quarter (June 28, 2002)**:** $200,531,507

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of March 26, 2003: 38,363,618 shares.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement for the 2003 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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Statements contained in this Report regarding future events or performance are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Our actual results could be quite different from those expressed or implied by the forward-looking statements. Factors that could affect our results are discussed more fully under the Sections entitled, "Forward-Looking Statements" and "Risk Factors," in Item 1 and elsewhere in this Report. Although forward-looking statements help to provide complete information about us, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements.

PART I

ITEM 1. Business.

Our Company was formed in May 2000 under Delaware law solely for the purposes of combining two companies, STC Technologies, Inc. ("STC" or "STC Technologies") and Epitope, Inc. ("Epitope"), and changing the state of incorporation of Epitope from Oregon to Delaware. STC Technologies and Epitope were merged into our Company on September 29, 2000 (the "Merger"). Our principal offices are located at 220 East First Street, Bethlehem, Pennsylvania 18015, and our telephone number is (610) 882-1820.

General

We develop, manufacture and market oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other *in vitro* diagnostic tests, and other medical devices. These products are sold in the United States and certain foreign countries to various distributors, government agencies, clinical laboratories, physicians' offices, hospitals, and commercial and industrial entities.

In vitro diagnostic testing is the process of analyzing oral fluid, blood, urine and other bodily fluids or tissue for the presence of specific substances or markers for drugs of abuse, infectious diseases or other conditions. *In vitro* diagnostic tests are performed outside the body, in contrast to *in vivo* tests, which are performed directly on or within the body. The substance or marker that a diagnostic test is intended to detect is generally referred to as an analyte.

Immunodiagnostic testing is the leading method of *in vitro* testing for antigens and antibodies. When an infectious disease caused by pathogens, such as bacteria, viruses and fungi, or other substances are present, the body responds by producing an antibody. Substances that stimulate production of antibodies are generally referred to as antigens. An antibody binds specifically with an antigen in a lock-and-key fashion that initiates a biochemical reaction to attempt to neutralize and, ultimately, eliminate the antigen. The ability of an antibody to bind with a specific antigen provides the basis for immunodiagnostic testing.

Additional information about the Company can be found on our website. Our website address is www.orasure.com. We make available free of charge through a link provided at such website our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, as well as any amendments to those Reports. Such reports are made available as soon as reasonably practicable after they are filed or furnished to the Securities and Exchange Commission. Our Internet website and the information contained in or connected to that website are not intended to be incorporated by reference into this Report.

Products

Our principal products currently include the following:

- The OraSure® and Intercept® oral fluid collection devices;
- The OraQuick® rapid HIV-1 antibody test;
- The Histofreezer® wart removal system;

- Certain immunoassay tests and reagents for insurance risk assessment, substance abuse and forensic toxicology applications;
- An oral fluid Western Blot confirmatory test for the Human Immunodeficiency Virus Type 1 ("HIV-1"); and
- The Q.E.D.® saliva alcohol test.

OraSure®/Intercept® Collection Devices

Our OraSure® oral fluid collection device is used in conjunction with screening and confirmatory tests for HIV-1 antibodies and other analytes. This device consists of a small, treated cotton-fiber pad on a nylon handle that is placed in a person's mouth for two to five minutes. The device collects oral mucosal transudate ("OMT"), a serum-derived fluid that contains higher concentrations of certain antibodies and analytes than saliva. As a result, OMT testing is a highly accurate method for detecting HIV-1 infection and other analytes.

We believe that oral fluid testing has several significant advantages over blood or urine-based testing systems, for both health care professionals and the individuals being tested. These advantages include eliminating the risk of needle-stick accidents, providing a noninvasive collection technique, requiring minimal training to administer, providing rapid and efficient collection in almost any setting, and reducing the cost of administration by a trained health care professional.

We have received premarket approval from the U.S. Food and Drug Administration (the "FDA") to sell the OraSure® collection device for use with a laboratory-based enzyme immunoassay ("EIA") screening test for HIV-1 antibody detection. This EIA screening test has been approved by the FDA for use with our OraSure® device and is manufactured and sold by another party.

HIV-1 antibody detection using the OraSure® collection device involves three steps:

- Collection of an oral fluid specimen using the OraSure® device;
- Screening of the specimen for HIV-1 antibodies at a laboratory with an EIA screening test approved by the FDA for use with the OraSure® device; and
- Laboratory confirmation of any positive screening test results with our oral fluid Western Blot HIV-1 confirmatory test (described below).

A trained health care professional then conveys test results and provides appropriate counseling to the individual who was tested. We have also received FDA 510(k) clearance for use of the OraSure® collection device with EIAs to test for cocaine and cotinine (a metabolite of nicotine) in oral fluid specimens.

A collection device that is substantially similar to the OraSure® device is sold under the name, Intercept®, and is used to collect OMT for oral fluid drug testing. We have received FDA 510(k) clearance to use the Intercept® collection device with laboratory-based EIAs to test for drugs of abuse commonly identified by the National Institute for Drug Abuse ("NIDA") as the NIDA-5 (i.e., cannabinoids (marijuana), cocaine, opiates, amphetamines/methamphetamines, and phencyclidine ("PCP")), and for barbiturates, methadone and benzodiazepines.

We believe that the Intercept® device has several advantages over certain competing drug testing products, including its lower total cost, its non-invasive nature, safety, mobility and accuracy, the ease of maintaining a chain-of-custody, the treatment of test subjects with greater dignity, no requirement for specially-prepared collection facilities, and difficulty of sample adulteration. The availability of an oral fluid test is intended to allow our customers to test for drug impairment on demand, eliminate scheduling costs and inconvenience, and streamline the testing process.

OraQuick® Rapid Test

OraQuick® is our rapid test platform designed to test an oral fluid, whole blood or serum/plasma sample for the presence of various antibodies or analytes. The device uses a porous flat pad to collect an oral fluid specimen. After collection, the pad is inserted into a vial containing a pre-measured amount of developer solution and allowed to develop. When whole blood is to be tested, a loop collection device is used to collect less than a drop of blood and mix it in the developer solution, after which the collection pad is inserted into the solution. The specimen and solution then flow through the testing device where test results are observable in approximately 20 minutes. The OraQuick® device is a screening test and requires a confirmation test where an initial positive result is obtained.

Our first product utilizing this technology is the OraQuick® rapid HIV-1 antibody test, a rapid test for the presence of antibodies against HIV-1. On November 7, 2002, we received premarket approval of this test from the FDA for detecting HIV-1 in finger-stick whole blood samples. This FDA approval is based on data indicating that the OraQuick® test has sensitivity of 99.6% and specificity of 100%, based on clinical studies we performed using finger-stick whole blood specimens. Sensitivity is a measure of the accuracy for detecting positive specimens, and specificity is a measure of the accuracy for identifying negative specimens.

As a result of this FDA approval, the OraQuick® test is available for use by the nearly 40,000 locations in the United States certified under the Clinical Laboratory Improvements Amendments of 1988 (“CLIA”), to perform moderately complex diagnostic tests. Additionally, in January 2003, we received a waiver under CLIA for the OraQuick® rapid HIV-1 antibody test. This waiver will also permit the use of the OraQuick® test by approximately 140,000 additional sites in the United States not certified under CLIA to perform moderately complex tests, such as outreach clinics, community-based organizations and physicians’ offices.

During 2003, we expect to submit an application to the FDA for approval of an OraQuick® test for use in detecting antibodies for HIV in oral fluid samples. We are also likely to pursue FDA approval of the use of the OraQuick® test for detecting HIV in venous whole blood and serum/plasma samples.

The Centers for Disease Control and Prevention (“CDC”) has identified several key areas for use of our OraQuick® device in the United States, including certain public hospitals in U.S. metropolitan areas with a relatively high incidence of HIV infection in pregnant women, AIDS service organizations, community-based organizations, outreach programs, and selected hospital emergency departments and outpatient clinics. Under a treatment Investigational Device Exemption granted by the FDA, the OraQuick® device is being used in the CDC’s Mother-Infant Rapid Intervention at Delivery Project (MIRIAD) to test pregnant women in five U.S. metropolitan areas. The goal of this project is to identify those individuals who would benefit from the administration of nevirapine, a drug used to reduce mother-to-child HIV-1 transmission. The OraQuick® device was also selected for use in the CDC’s LIFE Initiative, an international effort to address the AIDS epidemic in certain African countries, focusing on areas such as preventing mother-to-child transmission, secondary transmitted disease prevention, HIV prevention for youth, and blood safety systems.

Histofreezer®

In 1991, we became the exclusive United States distributor of the Histofreezer® wart removal system, a low-cost alternative to liquid nitrogen and other methods for removal of warts and other benign skin lesions by physicians. In June 1998, we acquired the Histofreezer® product from Koninklijke, Utermöhlen, N.V., The Netherlands. As part of the acquisition, we established a sales office in Reeuwijk, The Netherlands, and we are selling the Histofreezer® product through a dealer network in more than 20 countries worldwide. Most of our Histofreezer® sales occur in the United States to family doctors, pediatricians and podiatrists.

The Histofreezer® product mixes two environmentally friendly cryogenic gases in a small aerosol canister. When released, these gases are delivered to a specially designed foam bud, cooling the bud to –50°C. The frozen bud is then applied to the wart or lesion for 15 to 40 seconds (depending on the type of lesion) creating localized destruction of the target area.

Immunoassay Tests and Reagents

We develop and sell immunoassay tests in two formats, known as MICRO-PLATE and AUTO-LYTE®, to meet the specific needs of our customers.

AUTO-LYTE® tests are sold in the form of bottles of liquid reagents. These reagents are run on commercially available laboratory-based automated analytical instruments, which are manufactured by a variety of third parties. AUTO-LYTE® is typically used in high volume, automated, commercial reference insurance laboratories to detect certain drugs or chemicals in urine. Test results are produced quickly, allowing for high throughput.

In the MICRO-PLATE kit, the sample to be tested is placed into a small plastic receptacle, called a microwell, along with the reagents. The result of the test is determined by the color of the microwell upon completion of the reaction. Controlling the reaction involves the use of a variety of reagents by laboratory personnel. Test results are analyzed by any of a variety of commercially available laboratory instruments, which we may also provide to our laboratory customers. MICRO-PLATE tests can be performed on commonly used instruments and can detect drugs in urine, serum, and sweat specimens. MICRO-PLATE tests are also used as part of the Intercept® product line to detect drugs of abuse in oral fluid specimens.

Whenever possible, we enter into multi-year sales agreements with our customers. These agreements generally are entered into with a laboratory that has agreed to purchase a minimum number of tests over a two-to-five-year period. We also offer these customers the option of a reagent rental agreement under which we sell the tests at an increased price over a fixed period of time, which includes an additional equipment charge in exchange for providing the customer with the required analytical laboratory equipment. We obtain this equipment from third party vendors.

Western Blot HIV-1 Confirmatory Test

We market an oral fluid Western Blot HIV-1 confirmatory test that received premarket approval from the FDA in 1996. This test uses the original specimen collected with the OraSure® oral fluid collection device to confirm positive results of initial oral fluid HIV-1 EIA screening tests. The oral fluid Western Blot HIV-1 confirmatory test is marketed under an exclusive arrangement with bioMerieux Inc. (formerly Organon Teknika Corporation) (“BMX”).

In January 2001, we suspended the production of EPIblot®, a serum-based Western Blot HIV-1 confirmatory test. The serum Western Blot product accounted for approximately 5% of the Company’s 2000 revenues, but had been consistently unprofitable because of low production yields and the high cost of quality control. The discontinuation of this product had no effect on the manufacturing or sale of our oral fluid Western Blot HIV-1 confirmatory test.

Q.E.D.® Saliva Alcohol Test

Our Q.E.D.® saliva alcohol test is an on-site, cost-effective test device that is an alternative to breath or blood alcohol testing. The test is a quantitative, saliva-based method for the detection of ethanol, and has been cleared for sale by the FDA and the U.S. Department of Transportation (“DOT”). In 1997, the product also received a CLIA waiver.

Each Q.E.D.® test kit contains a collection stick that is used to collect a sample of saliva and a disposable detection device that displays results in a format similar to a thermometer. The Q.E.D.® device is easy to operate and instrumentation is not required to read the result. The product has a testing range of 0 to 0.145% blood alcohol, and produces results in approximately two minutes.

Products Under Development

UPT™ and UP*link*™ *Development*

During 2002 and prior years, much of our research and development efforts were focused on our Up-Converting Phosphor Technology ("UPT™") and the first UPT™ application expected to be commercialized, our UP*link*™ rapid, point-of-care system for detecting drugs of abuse in oral fluid.

Up-Converting Phosphor Technology. UPT™ is a proprietary label detection platform that uses phosphor particles to detect minute quantities of various substances. UPT™ utilizes the same particle shell that is coated onto a television screen, but the internal chemistry of the particle has been changed. These changes result in a particle that is excited by infrared light as compared to an ultraviolet light source for television screens. With assistance from our research partners, we have developed phosphorescent particles that up-convert infrared light to visible light, which we believe is a platform technology with broad applications.

Phosphor particles have been used for decades in television screens and in fluorescent light bulbs. When high energy ultraviolet light strikes the phosphor-coated area in a screen or bulb, it excites the particles and low energy visible colored light is produced. Our patented improvements on this base technology employ chemical changes inside the phosphor particles so that low energy infrared light can be used to produce a high energy visible colored signal and is the basis for UPT™. This use of infrared light to create a colored signal is called up-conversion as opposed to down-conversion, which occurs in phosphors designed to be used with ultraviolet light.

The use of infrared light to excite the phosphor particles and produce a visible light signal creates what we believe is an important competitive advantage for the technology in biological systems, especially human clinical diagnostics. Existing enzyme or fluorescent-based assays employ visible or ultraviolet light to generate the signals from the enzyme substrate or fluorescent molecules used as reporter signals in these systems. The disadvantage of using light in the visible or ultraviolet portion of the spectrum is that often molecules in the cells or samples for analysis can also produce background interference from these excitation sources. When this occurs, a non-specific signal is generated which dilutes or obscures the signal of interest for the diagnostic test being administered. Because up-conversion does not occur in nature, biological samples and specimens will not produce light and, therefore, will not cause background interference when excited by infrared light.

We believe that UPT™ overcomes some of the limitations of other diagnostic detection methods and offers features not commercially available today. The fact that UPT™ testing produces zero background interference dramatically increases the potential sensitivity of any test system. In addition, UPT™ offers the following other key competitive features:

- Ability to multiplex or detect biological markers for several substances simultaneously through the use of phosphor particles having various colors;
- Creation of a permanent test record not subject to fading;
- Applicability to a variety of instrument platforms;
- Compatibility with alternative testing matrices such as oral fluid, blood or others; and
- Ability to miniaturize the test platform.

We have reached certain important milestones in the development of UPT™, including improving the manufacturing process to produce UPT™ particles, working to optimize UPT™ particle coating techniques, producing four distinct colors of UPT™ particles to permit multiplexing, demonstrating initial feasibility for the use of UPT™ particles in infectious disease, cancer, and limited DNA detection applications, and developing a UPT™ collector, test cassette, and analyzer for use in testing oral fluid for drugs of abuse.

We believe UPT™ may have several potential applications for *in vitro* diagnostics, including human clinical testing for cancer, allergies, and thyroid and cardiac conditions, and for therapeutic drug monitoring, biological

warfare testing, food and environmental testing, pharmaceutical research, genomics and pharmacogenomics, veterinary testing, and surgical imaging. We also believe that UPT™ labels may be used for the detection of infectious diseases with DNA probes. However, we have not yet fully explored these potential UPT™ applications and have not determined which applications to pursue or the manner in which these opportunities will be pursued, if at all. We believe we will need to enter into partnering arrangements with other entities to exploit fully the potential of UPT™.

UP*link*™. UP*link*™ is our first product UPT™-based application under development. UP*link*™ is designed to be a rapid, point-of-care system utilizing a collector, lateral flow test cassette, and analyzer (including software), that can quickly provide instrument-read results on a variety of samples, including oral fluid, blood, serum, urine and stool samples.

In April 2002, we received 510(k) clearance from the FDA for the UP*link*™ system to detect opiates in oral fluid. This is the only point-of-care oral fluid drug test system to receive FDA clearance. The UP*link*™ analyzer has also been certified as meeting certain standards required for the sale of electrical and light-emitting equipment internationally. Although our opiates-only UP*link*™ detection system has no commercial potential, we are developing an UP*link*™ detection system for the full NIDA-5 panel of tests – cocaine, methamphetamines/amphetamines, PCP, opiates and marijuana – which we believe can be commercialized. We intend to apply for FDA 510(k) clearance of an UP*link*™ system for the full NIDA-5 panel of tests in mid-summer of 2003. Subject to receipt of this FDA clearance, we plan to market this system directly in the workplace and criminal justice markets in the United States.

Although we have made significant progress with respect to the development of the UP*link*™ rapid point-of-care drugs of abuse detection system, there can be no assurance that we will be successful in completing this development or in commercializing this potential new product. Assuming FDA 510(k) clearance is obtained, we do not expect to receive significant amounts of revenues from this product until at least 2004 or later.

In March 2000, we signed a research and development agreement with Dräger Safety AG & Co. KGaA (formerly Dräger Sicherheitstechnik GmbH) (“Dräger Safety”), a European manufacturer and supplier of medical and safety technology products for health care and industrial applications. This agreement provided for the development of the UP*link*™ system for rapid detection of drugs of abuse in oral fluid. After research and development activities are completed, Dräger Safety has the option to become our exclusive distributor of this product in Europe and certain other countries to law enforcement officials for rapidly assessing whether an operator or passenger in a motor vehicle is under the influence of one or more drugs of abuse (the “roadside market”) and ultimately to certain military, criminal justice, and workplace testing markets. We received a non-refundable fee from Dräger Safety under the agreement and will receive additional fees upon achievement of certain technical milestones.

In September 2000, we signed a research and development agreement with Meridian Bioscience, Inc. (formerly Meridian Diagnostics, Inc.) (“Meridian”), a medical diagnostics company. Under this agreement, we intended to develop a range of UP*link*™ point-of-care tests for the rapid detection of parasites, and gastrointestinal and upper respiratory diseases. Development of one test, for the respiratory syncytial virus (“RSV”), has been substantially completed and this product is currently undergoing field trials. However, due to development delays and certain other events, we have agreed in principle with Meridian to terminate this agreement. Despite the expected termination of our agreement, we intend to complete development and pursue FDA 510(k) clearance and commercialization of the RSV test. In addition, we intend to seek other potential parties to help fund the development of other infectious disease applications for UP*link*™ that we had previously intended to develop with Meridian.

We are participating in a $4.2 million, four-year grant for research and development of saliva/oral fluid-based diagnostic technologies, awarded by the National Institutes of Health (the “NIH”) to the University of Pennsylvania. The grant will cover basic research in the following three main areas:

- New technologies for collecting bacterial/viral protein and nucleic acid samples from the human mouth;

- The combination of the University of Pennsylvania's microfluidic processing technology with our UPT™ technology for sample preparation; and
- The detection of viral or bacterial markers.

The research plan under the grant contemplates achieving these goals through the use of our UP*link*™ rapid detection system.

Our portion of funding under the grant is expected to be made available over a four-year period, with approximately $400,000 available in the first year and each year thereafter. Payments under the grant in the second, third and fourth years, will be subject to availability of funds from the NIH and satisfactory progress of the research and development project.

OraSure®/Intercept® Applications

Oral mucosal transudate contains many constituents found in blood and serum, although in lower concentrations. We believe the OraSure® and Intercept® devices are a platform technology with a wide variety of potential applications, where laboratory testing is available. For example, the OraSure® device may be useful for the diagnosis of a variety of infectious diseases or conditions in addition to HIV-1, such as viral hepatitis.

OraQuick® Platform

We believe that OraQuick® has significant potential as a point-of-care test platform for physicians' offices, hospitals, and other markets. Like the OraSure® device, we believe that OraQuick® provides a platform technology that can be modified for detection of a variety of infectious diseases in addition to HIV, such as viral hepatitis and other diseases.

We have received FDA premarket approval for the OraQuick® test for detecting HIV-1 in finger-stick whole blood samples. We are developing additional applications and will likely seek FDA approval for OraQuick® for use in testing oral fluid, venous whole blood and serum/plasma samples.

Research and Development

In 2002, our research and development activities focused on the continued development of the UP*link*™ analyzer, test cassette and collector, the development of the UP*link*™ drugs of abuse and RSV assays, DNA feasibility studies, clinical trials for the OraQuick® rapid HIV-1 antibody test, and improvements to certain of our existing products.

We supplement our own research and development activities by funding external research. We have funded research at Leiden University and certain other entities, and intend to continue funding external research.

Research and development expenses totaled approximately $8.3 million in 2002, $9.4 million in 2001, and $10.4 million in 2000.

Sales and Marketing

Our strategy is to reach our major target markets through a combination of direct sales, strategic partnerships, and independent distributors. Our marketing strategy is to raise awareness of our products through a mix of trade shows, print advertising, and distributor promotions to support sales in each target market.

We market our products in the United States and internationally. Revenues attributable to customers in the United States amounted to $28.1 million, $27.3 million and $24.8 million in 2002, 2001 and 2000, respectively. Revenues attributable to international customers amounted to $3.9 million, $5.3 million and $4.0 million, or 12%, 16% and 14% of our total revenues, in 2002, 2001 and 2000, respectively.

Insurance Risk Assessment

We currently market the OraSure® oral fluid collection device for use in screening life insurance applicants in the United States and internationally to test for three of the most important underwriting risk factors: HIV-1, cocaine, and cotinine (a metabolite of nicotine). Devices are sold to insurance testing laboratories, including Lab*One*, Heritage Labs and Clinical Reference Laboratories. These laboratories in turn provide the devices to insurance companies, usually in combination with testing services.

We also maintain a direct sales force that promotes use of the OraSure® device directly to insurance companies. Insurance companies then make their own decision regarding which laboratory to use to supply their collection devices and testing services. Our OraSure® Western Blot confirmatory test is distributed through BMX to laboratories and is used to confirm oral fluid specimens that initially test positive for HIV-1.

Because insurance companies are in various stages of their adoption of the OraSure® device, there exists a wide range of policy limits where the product is being applied. Some insurance companies have chosen to extend their testing to lower policy limits where they did not test at all before, while others have used OraSure® to replace some of their blood and urine-based testing. In general, most of our insurance company customers use the OraSure® device in connection with life insurance policies having face amounts of up to $250,000, with some customers using the device for policies of up to $500,000 in amount.

Our sales force continues to encourage additional insurance companies to use OraSure® and to extend the use of the product by existing customers. A small number of companies have expanded use of OraSure® to the $1 million and higher dollar policy amounts. This expansion is attributable to several factors, including increasing acceptance of the reliability of oral fluid testing, the high quality of test results, the low cost of oral fluid testing relative to blood tests, and the ease of use of the OraSure® device.

We also sell our AUTO-LYTE® and MICRO-PLATE assays and reagents in the insurance testing market directly to laboratories, including Lab*One*, Heritage Labs, Clinical Reference Laboratory, and the laboratory testing division of the Metropolitan Life Insurance Company. AUTO-LYTE® assays are used principally to test urine samples for cotinine and other metabolites and to perform urine chemistries for risk assessment purposes. MICRO-PLATE assays are used principally to test oral fluid specimens collected with the OraSure® device for cocaine and cotinine.

Infectious Disease Testing

Our sales personnel market the OraSure® oral fluid collection device, separately and as a kit in combination with laboratory testing services (as described below), and the OraQuick® rapid HIV-1 antibody test directly to customers in the public health market for HIV-1 testing. This market consists of a broad range of clinics and laboratories and includes states, counties, and other governmental agencies, colleges and universities, correctional facilities and the military. There are also a number of organizations in the public health market such as AIDS service organizations and various community-based organizations set up primarily for the purpose of encouraging and enabling HIV-1 testing.

To better serve our public health customers, we have entered into agreements with Lab*One* and Heritage Labs to provide prepackaged OraSure® test kits, with prepaid laboratory testing and specimen shipping costs included. We also sell the OraSure® and OraQuick® devices in the international public health markets.

In June 2002, we entered into an agreement under which Abbott Laboratories was appointed as the co-exclusive distributor of the OraQuick® rapid HIV-1 antibody test in the United States. We expect Abbott ultimately to focus primarily on the hospital and physician office market, while we intend to primarily target our direct sales to the public health and criminal justice markets, the military, the CDC and other agencies.

Substance Abuse Testing

Our substance abuse products are marketed into the workplace testing, forensic toxicology, criminal justice, and drug rehabilitation markets, through direct sales and distributors. The forensic toxicology market consists of 250 – 300 laboratories including federal, state and county crime laboratories, medical examiner laboratories, and reference laboratories. The criminal justice market consists of a wide variety of entities in the criminal justice system that require drug screening, such as pre-trial services, parole and probation officials, police forces, drug courts, prisons, drug treatment programs and community/family service programs.

We have entered into agreements for the distribution of Intercept® collection kits and associated reagents for drugs-of-abuse testing in the workplace testing market in the United States and Canada through several laboratory distributors, including Lab*One*, Quest Diagnostics, Clinical Reference Laboratory and NWT, Inc., and internationally for workplace and forensic toxicology testing through Bio-Rad Laboratories, Altrix HealthCare, plc, and other distributors. We assist our laboratory customers in customizing their testing services by selling them equipment required to test oral fluid specimens collected with the Intercept® device.

We also distribute our Q.E.D.® saliva alcohol test primarily through various distributors. The markets for alcohol testing are relatively small and fragmented with a broad range of legal and procedural barriers to entry. Markets range from law enforcement testing to workplace testing of employees in safety sensitive occupations. The Q.E.D.® test has been successfully adopted by end users in the petroleum, heavy construction, trucking, and retail industries because it is a cost-effective, portable, easy-to-administer, quantitative testing method. Typical usage situations include pre-employment, random, post-accident, reasonable-cause, and return-to-duty testing.

Physicians' Offices

We sell the Histofreezer® product line to distributors that market to more than 150,000 primary care physicians and podiatrists in the United States. Major U.S. distributors include Cardinal Healthcare, McKesson HBOC, Physicians Sales & Service, AmerisourceBergen Corporation, and Henry Schein. Internationally, we market Histofreezer® in a number of countries through a network of distributors. We are presently exploring ways to further penetrate the physicians' office market and we are considering expanding into potential new markets for Histofreezer®.

International Markets

We sell a number of our products into international markets primarily through distributors with knowledge of their local markets. Principal markets include physicians' offices, insurance risk assessment, public health, and laboratory testing.

We assist our international distributors in registering the products and obtaining required regulatory approvals in each country, and we provide training and support materials. Our international marketing program includes direct assistance to distributors in arranging for laboratory services, cooperation from screening test manufacturers, and performance of Western Blot confirmatory tests when necessary.

Significant Products and Customers

Several different products have contributed significantly to our financial performance, accounting for 15% or more of total revenues during the past three years. The OraSure® and Intercept® oral fluid collection devices, Histofreezer® product, and immunoassay tests and reagents accounted for total revenues of approximately $14.3 million, $7.2 million and $7.6 million in 2002, $13.0 million, $6.7 million and $7.4 million in 2001, and $11.2 million, $6.8 million and $6.7 million in 2000, respectively. As new products are developed and commercialized, we expect to reduce our dependence on these products.

We currently have one customer, Lab*One*, that accounted for 26% of our total revenues during 2002.

In August 2001, Lab*One* acquired Osborne Group, Inc., our second largest laboratory customer in the insurance risk assessment market. As a result of this acquisition and other operating improvements, Lab*One* has achieved certain efficiencies and reduced its overall inventory levels, which in turn lowered their purchases of our insurance testing assays during 2002. We believe this is an indication that the market for our insurance testing assays will continue to come under pressure as Lab*One* and our other laboratory customers are expected to try to reduce their costs by improving their efficiencies or possibly using competing products. There can be no assurance that sales to Lab*One* will not decrease further or that this customer will not choose to replace our assays or other products with internally-developed products or products manufactured by our competitors. The loss of Lab*One* or a significant decrease in the volume of products purchased by it would have a material adverse effect on our results of operations.

Supply and Manufacturing

We have entered into an agreement with a contractor in the United States for the assembly and supply of our OraSure® and Intercept® oral fluid collection devices. This agreement has a current term through December 31, 2003 and automatically renews for additional annual periods, unless either party provides timely notice of termination prior to the end of an annual period. A change in the manufacturer of the OraSure® device would require FDA review and approval, which could require significant time to complete and disrupt our ability to manufacture this product. Subject to receipt of the applicable FDA approval, we intend to terminate the agreement with this contractor and transfer manufacturing of both the OraSure® and Intercept® collection devices to our Bethlehem, Pennsylvania facility beginning later in 2003.

We manufacture the OraQuick® test in our Bethlehem, Pennsylvania facilities. In addition, we have entered into a supply agreement for the assembly of the OraQuick® device in Thailand, in order to supply certain international markets. This agreement has an initial term of one year, and will automatically renew for additional annual periods unless either party provides a timely notice of termination prior to the end of an annual period. We believe that other firms would be able to manufacture the OraQuick® test on terms no less favorable than those set forth in the agreement if the Thailand contractor would be unable or unwilling to continue manufacturing this product.

We can purchase the HIV antigen and the nitrocellulose strips required for the OraQuick® test only from a limited number of sources. The antigen is currently purchased from a single contract supplier under a long-term agreement with an initial term ending in January 2010 and one-year automatic renewal terms thereafter. The nitrocellulose used in the test is also provided by a single contract supplier, and we are presently negotiating a long-term supply agreement with this party. If for any reason these suppliers are no longer able to supply our antigen or nitrocellulose needs, we believe that alternative supplies could be obtained at a competitive cost. However, a change in the antigen or nitrocellulose would require FDA approval and some additional development work, which would require significant time to complete and could disrupt our ability to manufacture and sell the OraQuick® device.

The oral fluid Western Blot HIV-1 confirmatory test is manufactured in our Beaverton, Oregon facility. Subject to receipt of FDA approval, we expect to transfer the manufacturing of this product to our Bethlehem, Pennsylvania facility. The HIV antigen needed to manufacture the Western Blot test is available from only a limited number of sources. For many years, we have purchased the antigen for this product from BMX on an exclusive basis. BMX is also the exclusive distributor of the Western Blot test kits.

In October 2002, we entered into new agreements with BMX, which replaced existing agreements between the companies. These new agreements provide for the continued supply by BMX of the HIV-1 antigen and distribution of the oral fluid Western Blot product by BMX on an exclusive worldwide basis. If for any reason BMX is no longer able to supply our antigen needs, we would be able to obtain alternate supplies at a competitive cost. However, a change in the antigen would require FDA approval and some additional development work, which would require significant time to complete and could disrupt our ability to manufacture and sell the Western Blot HIV-1 confirmatory test.

We expect to assemble analyzers, test cassettes and collectors used in our UP*link*™ drugs of abuse rapid detection system and to package this product for shipment at our Bethlehem, Pennsylvania facilities.

Histofreezer® is manufactured in The Netherlands by Koninklijke, Utermöhlen, N.V. ("Utermöhlen"), the company from which we acquired the product in 1998. We purchase the product pursuant to an exclusive production agreement. This agreement provides that Utermöhlen will be the exclusive supplier of the Histofreezer® product until at least December 31, 2006. We believe that additional manufacturers of the Histofreezer® product are available on terms no less favorable than the terms of the production agreement with Utermöhlen, in the event that Utermöhlen would be unable or unwilling to continue manufacturing the Histofreezer® product.

Our AUTO-LYTE® and MICRO-PLATE assays are manufactured in our Bethlehem, Pennsylvania facility. These tests require the production of highly specific and sensitive antibodies corresponding to the antigen of interest. Substantially all our antibody requirements are provided by contract suppliers. We believe that we have adequate reserves of antibody supplies and that we have access to sufficient raw materials for these products.

The Q.E.D.® saliva alcohol test is manufactured and packaged for shipment in our Bethlehem, Pennsylvania facility.

Employees

As of December 31, 2002, we had 187 full-time employees, including 38 in sales, marketing, and client services; 44 in research and development; 87 in operations, manufacturing, quality control, purchasing and shipping; and 18 in administration and finance. Seventeen of our employees hold Ph.D. degrees. This compares to 225 employees as of December 31, 2001. Our employees are not currently represented by a collective bargaining agreement.

During 2002, we implemented a 17% headcount reduction primarily as a result of lower than anticipated sales levels during 2001 and the elimination of certain development projects. We intend to close our Oregon facilities and move these operations to Bethlehem, Pennsylvania beginning later in 2003.

Competition

The diagnostic industry is a multi-billion dollar international industry and is intensely competitive. Many of our competitors are substantially larger and have greater financial, research, manufacturing, and marketing resources.

Important competitive factors for our products include product quality, price, ease of use, customer service, and reputation. Industry competition is based on the following:

- Scientific and technological capability;
- Proprietary know-how;
- Access to adequate capital;
- The ability to develop and market products and processes;
- The ability to attract and retain qualified personnel; and
- The availability of patent protection.

A few large corporations produce a wide variety of diagnostic tests and other medical devices and equipment. A larger number of mid-size companies generally compete only in the diagnostic industry, and a significant number of small companies produce only a few diagnostic products. As a result, the diagnostic test industry is highly fragmented and segmented.

The future market for diagnostic tests is expected to be characterized by consolidation, greater cost consciousness, and tighter reimbursement policies. The purchasers of diagnostic products are expected to place increased emphasis on lowering costs, reducing inventory levels, automation, service, and volume discounts. The increased complexity of the market is expected to force many competitors to enter into joint ventures or license certain products or technologies.

We expect competition to intensify as technological advances are made and become more widely known, and as new products reach the market. Furthermore, new testing methodologies could be developed in the future that render our products impractical, uneconomical or obsolete. There can be no assurance that our competitors will not succeed in developing or marketing technologies and products that are more effective than those we develop or that would render our technologies and products obsolete or otherwise commercially unattractive. In addition, there can be no assurance that our competitors will not succeed in obtaining regulatory approval for these products, or introduce or commercialize them before we can do so. These developments could have a material adverse effect on our business, financial condition and results of operations.

Several companies market or have announced plans to market oral specimen collection devices and tests outside the United States. We expect the number of devices competing with our Intercept® and OraSure® devices to increase as the benefits of oral specimen-based testing become more widely accepted.

Competition in the market for HIV testing is intense and is expected to increase. We believe that the principal competition will come from existing laboratory-based blood tests, point-of-care whole blood rapid tests, laboratory-based urine assays, or other oral fluid-based tests that may be developed. Our competitors include specialized biotechnology firms as well as pharmaceutical companies with biotechnology divisions and medical diagnostic companies.

Significant competitors for our OraQuick® rapid HIV-1 antibody test, such as the Ortho Diagnostics division of Johnson & Johnson and Bio-Rad Laboratories, sell laboratory-based HIV-1 EIAs, and Calypte, Inc. sells an HIV-1 screening test for urine, in the United States. In addition, Abbott Laboratories currently sells a competing rapid HIV test in the United States. We believe several other companies may seek FDA approval to sell competing rapid HIV tests in the United States.

In the insurance risk assessment market, our AUTO-LYTE® homogeneous assays for cocaine and cotinine compete with reagents from Microgenics, Inc. (a subsidiary of Apogent Technologies). Our AUTO-LYTE® homogeneous assays for beta-blockers and thiazide as well as MICRO-PLATE heterogeneous assays specifically designed for the detection of cocaine, cotinine, and IgG in oral fluid are the only assays available in the marketplace. However, we expect to face increasing competition from assays developed internally by our laboratory customers, which could be produced at a cost lower than the price typically paid for our products. In urine chemistries, our significant competitors include The Diagnostics Systems Group of Olympus America Inc. and DRI.

Our MICRO-PLATE drugs-of-abuse reagents are targeted to forensic testing laboratories where sensitivity, automation, and “system solutions” are important. In the past, these laboratories have typically had to rely on radioimmunoassay test methods to provide an adequate level of sensitivity. Radioimmunoassays require radioactive materials, which have a short shelf-life and disposal problems. Our MICRO-PLATE tests meet the laboratories’ sensitivity needs, run on automated equipment, are not radioimmunoassays, and are offered to the laboratory as a complete system solution of reagents, instrumentation and software to meet the specific needs of each customer. Options to buy or rent the instrumentation and software, which we purchase from third party vendors, are offered to these customers.

In the forensic toxicology market, we compete with both homogeneous and heterogeneous tests manufactured by many companies. Significant competitors in the market for these assays include Microgenics, Inc., Roche Diagnostics, and Immunalysis.

The Intercept® drug testing system competes with laboratory-based drug testing products and services using testing matrices such as urine, hair, sweat and oral fluid. Major competitors include Ansys Technologies, Inc., Dade Behring, Psychemedics, and Immunalysis.

Our UP*link*™ product also is expected to compete with other on-site, rapid drug assays and instrument-read tests. Major competitors in this area include American Biomedica, Roche Diagnostics, Biosite Diagnostics, Avitar, Inc., Ansys Technologies, Inc., and eScreen. Another potential competitor, LifePoint, Inc., has announced plans to sell a reader-based saliva test panel that will include alcohol testing.

Q.E.D.® has two direct competitors, Roche Diagnostics and Chematics. These companies offer semi-quantitative saliva-based alcohol tests and have received DOT approval. Indirect competitors who offer breath testing equipment include Intoximeters, Dräger Safety, and CMI. Although there are lower priced tests on the market that use oral fluid or breath as a test medium, these tests are qualitative tests that are believed to be substantially lower in quality and scope of benefits than our Q.E.D.® test.

The Histofreezer® product's delivery system and warmer operating temperature than liquid nitrogen provide us with the opportunity to target sales to primary care physicians, such as family practitioners, pediatricians, and podiatrists. We do not generally target sales to dermatologists because they have the volume of patients required to support the capital costs associated with a liquid nitrogen delivery system, which is also used to remove warts and other benign skin lesions. There is limited competition for convenient cryosurgical products for wart removal in the primary care physician market. Major competitors for the Histofreezer® product include CryoSurgery, Inc. in the United States and Wartner in Europe.

Patents and Proprietary Information

We seek patent and other intellectual property rights to protect and preserve our proprietary technology and our right to capitalize on the results of our research and development activities. We also rely on trade secrets, know-how, continuing technological innovations, and licensing opportunities to provide competitive advantages for our products in our markets and to accelerate new product introductions. We regularly search for third-party patents in fields related to our business to shape our own patent and product commercialization strategies as effectively as possible and to identify licensing opportunities. United States patents generally have a maximum term of 20 years from the date an application is filed.

We have sixteen United States patents and numerous foreign patents for the OraSure® and Intercept® collection devices and related technology relating to oral fluid collection, containers for oral fluids, methods to test oral fluid, formulations for the manufacture of synthetic oral fluid, and methods to control the volume of oral fluid collected and dispersed. We have also applied for additional patents, in both the United States and certain foreign countries, on such products and technology.

We have one patent and certain pending patent applications for the OraQuick® rapid HIV antibody test in the United States. We also intend to apply for additional patents for this product. We have obtained licenses to certain lateral flow patents and to certain HIV-1 patents held by other parties in order to market the OraQuick® test. We obtained these licenses through the payment of certain upfront fees and ongoing royalties. We believe these royalties are comparable to rates generally paid by other companies under similar arrangements.

We may also need to obtain licenses or other rights under, or enter into distribution or other business arrangements in connection with, certain patents for the Human Immunodeficiency Virus Type 2 ("HIV-2") and certain other lateral flow patents, in order to manufacture and sell the OraQuick® HIV test. See the Section entitled, "Risk Factors," for a further discussion of these issues.

In April 1995, we received exclusive worldwide rights under patents and know-how owned by SRI International to develop and market products that involve the use of UPT™. We also received non-exclusive worldwide rights under patents and know-how owned by the Sarnoff Corporation (a subsidiary of SRI

International formerly called the David Sarnoff Research Center) to develop and market products that involve the use of UPT™. We have the right to sublicense these rights, subject to consent from SRI and Sarnoff.

Under the agreement with SRI, we are required to make license, maintenance and royalty payments to SRI. We must also make royalty payments for a period equal to the longer of ten years from the date of the first commercial sale of the products or the term during which the manufacture, use, or sale of a product would infringe licensed patents, but for our license with SRI. We believe that the royalty rates payable to SRI are comparable to the rates generally payable by other companies under similar arrangements. Our agreement with SRI terminates upon the expiration of our obligation to pay royalties.

In 1999, we paid $1.5 million to TPM Europe Holding B.V., our sublicensor, for the termination of an existing license agreement between the sublicensor and the Company with respect to the sublicense of UPT™ patents owned by Leiden University, The Netherlands, and to secure a direct research, development, and license arrangement with Leiden University.

We have or have licensed rights under nine U.S. patents and numerous foreign patents for methods, compositions, and apparatuses relating to phosphor technologies. Several additional UPT™ patent applications remain pending in the United States and abroad. We expect to continue to expand our UPT™ patent portfolio in 2003. Several new patents were granted during 2002 in the U.S. for the design of the UP*link*™ rapid detection platform.

We have one U.S. patent relating to the method for detecting blood in urine specimens using our AUTO-LYTE® products.

We have five U.S. patents and numerous foreign patents issued for apparatuses and methods for the topical removal of skin lesions relating to our Histofreezer® product. We have also licensed another patent relating to apparatuses and methods for the topical removal of skin lesions relating to our Histofreezer® product.

We have four U.S. patents and numerous foreign patents and patent applications for the technology used in the Q.E.D.® test. These patents are related to the analog-to-digital technology color control systems and methods, systems and devices for the test, and detection of biochemical molecules.

We require our employees, consultants, outside collaborators, and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed by or made known to the individual during the course of the individual's relationship with us, is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual during his or her tenure with us will be our exclusive property.

We own rights to trademarks and service marks that we believe are necessary to conduct our business as currently operated. In the United States, we own the UPT™, UP*link*™, OraSure®, Intercept®, OraQuick®, Histofreezer®, Q.E.D.®, and AUTO-LYTE® trademarks. We also own many of these marks and others in several foreign countries.

Although important, the issuance of a patent or existence of trademark or trade secret protection does not in itself ensure the success of our business. Competitors may be able to produce products competing with our patented products without infringing our patent rights. Issuance of a patent in one country generally does not prevent manufacture or sale of the patented product in other countries. The issuance of a patent is not conclusive as to validity or as to the enforceable scope of the patent. The validity or enforceability of a patent can be challenged by litigation after its issuance. If the outcome of such litigation is adverse to the owner of the patent, the owner's rights could be diminished or withdrawn. Trade secret protection does not prevent independent discovery and exploitation of the secret product or technique.

We are not aware of any pending claims of infringement or other challenges to our patents or our rights to use our trademarks or trade secrets in the United States or in other countries.

Government Regulation

General

Most of our products are regulated by the FDA, certain state and local agencies, and comparable regulatory bodies in other countries. This regulation governs almost all aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and recordkeeping.

All of our FDA-regulated products require some form of action by the FDA before they can be marketed in the United States. After approval or clearance by the FDA, we must continue to comply with other FDA requirements applicable to marketed products. Both before and after approval or clearance, failure to comply with the FDA's requirements can lead to significant penalties and product recalls or could disrupt our ability to sell these products. In addition, the FDA could refuse permission to obtain certificates needed to export our products if the agency determines that we are not in compliance.

Domestic Regulation

Most of our diagnostic products are regulated as medical devices. Our Serum Western Blot HIV-1 confirmatory test, which was discontinued in February 2001, was regulated as a biologic or blood product.

There are two review procedures by which medical devices can receive FDA clearance or approval. Some products may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act. To obtain this clearance, the manufacturer must provide a premarket notification that it intends to begin marketing the product, and show that the product is substantially equivalent to another legally marketed product (i.e., that it has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness). In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding substantial equivalence. An applicant must submit a 510(k) application at least 90 days before marketing of the affected product commences. Although FDA clearance may be granted within that 90-day period, in some cases as much as a year or more may be required before clearance is obtained, if at all.

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA's regulations to have an approved application), the FDA must approve a premarket approval application ("PMA") before marketing can begin. PMAs must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA is typically a complex submission, including the results of preclinical and clinical studies. Preparing a PMA is a detailed and time-consuming process. Once a PMA has been submitted, the FDA is required to review the submission within 180 days. However, the FDA's review may, and often is, much longer, often requiring one year or more, and may include requests for additional data. The OraQuick® rapid HIV-1 antibody test received PMA approval in November 2002.

In 2002, Congress enacted the Medical Device User Fee and Modernization Act, which authorizes the FDA to assess and collect user fees for premarket notifications and premarket approval applications filed on or after October 1, 2002. Fees for fiscal year 2003 range from $2,187 for premarket notifications to $154,000 for premarket approval applications, although fee reductions are available for companies qualifying as small businesses. We do not currently qualify as a small business.

Biologic products must be the subject of an approved biologics license application before they can be marketed. The FDA approval process for a biologic product is similar to the PMA approval process, involving a demonstration of the product's safety and effectiveness based in part on both preclinical and clinical studies. We currently do not manufacture or sell any biologic products.

Many of our insurance testing products are used for non-medical purposes and many of our drugs-of-abuse products sold to state crime labs are for forensic use. The FDA does not currently regulate products used for these purposes.

Every company that manufactures medical devices distributed in the United States must comply with the FDA's Quality System Regulations ("QSRs"). These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation and purchasing. In complying with QSRs, manufacturers must continue to expend time, money, and effort in the area of production and quality control to ensure full technical compliance. Companies are also subject to other post-market and general requirements, including restrictions imposed on marketed products, promotional standards, and requirements for recordkeeping and reporting of certain adverse reactions. If there are any modifications made to our marketed devices, a premarket notification or premarket approval application may be required to be submitted to, and cleared or approved by, the FDA, before the modified device may be marketed. The FDA regularly inspects companies to determine compliance with QSRs and other post-market requirements. Failure to comply with statutory requirements and the FDA's regulations can result in warning letters, monetary penalties, suspension or withdrawal of regulatory approvals, operating restrictions, total or partial suspension of production, injunctions, product recalls, seizure of products, and criminal prosecution.

Products that include electrical or light emitting equipment must also comply with the FDA's safety and performance standards applicable to such equipment. Our UP*link*™ analyzer is a piece of electrical equipment that uses a laser to read the test results and is, therefore, subject to these requirements. In addition, there is an industry safety and performance standard for electrical equipment established by Underwriters Laboratories, Inc., known as UL3101-1. Although a voluntary standard, compliance with UL3101-1 supported our 510(k) submission for the UP*link*™ analyzer. Underwriters Laboratories Inc. was retained to examine and test the UP*link*™ analyzer and has certified that this product meets the FDA requirements and UL3101-1.

The Clinical Laboratory Improvements Amendments of 1988, or CLIA, prohibit laboratories from performing *in vitro* tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the U.S. Department of Health and Human Services applicable to the category of examination or procedure performed. We consider the applicability of the requirements of CLIA in the design and development of our products. We have obtained a waiver of the CLIA requirements for our OraQuick® rapid HIV-1 antibody test and Q.E.D.® alcohol saliva test and may seek similar waivers for certain other products. A CLIA waiver allows certain customers to use the waived products that may not have been able to use them without complying with certain quality control and other requirements.

Certain of our products may also be affected by state regulations in the United States. For example, there are several states that restrict or do not currently permit oral fluid drug testing in the workplace or other markets. In addition, several states prohibit or limit the use of rapid, point-of-care HIV testing. We are presently working with legislators or regulators in certain of these states in an effort to modify or remove any restrictions affecting our ability to sell products.

International

We are also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval from international public health agencies, such as the World Health Organization, in order to sell products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for U.S. governmental approvals. We generally pursue approval only in those countries that we believe have a significant market opportunity.

The International Organization for Standardization ("ISO") is a worldwide federation of national standards bodies from some 130 countries, established in 1947. The mission of ISO is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods

and services. ISO certification is evidenced by the CE mark and indicates that our quality system complies with standards applicable to activities ranging from initial product design and development through production and distribution. In addition, we must comply with the essential requirements of the In Vitro Diagnostic Directive in order to receive authorization to affix a CE mark to our products. A CE mark will be required for distribution of medical devices in the European common markets beginning in December 2003.

In the first quarter of 1999, we received authorization to use the CE mark for the OraSure® and Intercept® collection devices based on meeting ISO standards at our Beaverton facility. In December 2000, our Bethlehem facility received final certification for the European Medical Device Directive (93/42/EEC), ISO 9001, ISO 13485, and EN 46001. We have also received authorization to use the CE mark for our Histofreezer® product line.

Prior to international sale of a product containing electrical and light-emitting equipment, the safety and performance of such a product must be demonstrated. We retained Underwriters Laboratories, Inc. and Laird Technologies to examine and test the UP*link*™ analyzer, and they certified that this product meets the following international standards and directives: IEC 60825-1, IEC/EN 61010-1, CAN/CSA 22.2 No. 1010.1-92, IEC 1010-1, EN 61000 (in part), and EN 55022, EMC Directive 89/336/EEC.

We must also submit evidence of marketing approval or clearance by the FDA to Health Canada's Therapeutic Products Programme, and we must comply with certain registration requirements, prior to commencing sales in Canada. We have completed this process for several of our current products that require FDA review and may do so with respect to other products in the future.

Environmental Regulation

Because of the nature of our current and proposed research, development, and manufacturing processes, we are subject to stringent federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge and handling and disposal of materials and wastes. We believe that we have complied with these laws and regulations in all material respects. We have not been required to take any action to correct any environmental noncompliance.

Forward-Looking Statements

This Report contains certain "forward-looking statements," within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings, expenses or other financial performance, future product performance or development, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words "believes," "expects," "anticipates," "intends," "plans," "estimates," "may," "will," "should," "could," or similar expressions.

Forward-looking statements are not guarantees of future performance or results. Known and unknown factors could cause actual performance or results to be materially different from those expressed or implied in these statements. Some of these factors are: ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties; ability to obtain and timing of obtaining necessary regulatory approvals; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to

international marketing and manufacturing of products; ability to sell products internationally; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; ability to complete consolidation or restructuring activities; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in the Section entitled, “Risk Factors,” and elsewhere in this Report.

Although forward-looking statements help to provide complete information about future prospects, they may not be reliable. The forward-looking statements are made as of the date of this Report and we undertake no duty to update these statements.

Risk Factors

The following is a discussion of certain significant risk factors that could potentially negatively impact our financial condition, performance and prospects.

We Face Intense Competition From New and Existing Diagnostic Products.

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Our principal competitors often have considerably greater financial, technical and marketing resources. As new products enter the market, our products may become obsolete or a competitor’s products may be more effective or more effectively marketed and sold than ours. If we fail to maintain and enhance our competitive position, our customers may decide to use products developed by competitors which could result in a loss of revenues.

Our Research and Development Efforts May Not Succeed or Our Competitors May Develop More Effective or Successful Diagnostic Products.

In order to remain competitive, we must commit substantial resources each year to research and development. The research and development process generally takes a significant amount of time from inception to commercial product launch. This process is conducted in various stages. During each stage there is a substantial risk that we will not achieve our goals on a timely basis, if at all, and we may have to abandon a product in which we have invested substantial amounts.

During 2002, 2001 and 2000, we incurred $8.3 million, $9.4 million and $10.4 million, respectively, in research and development expenses. We expect to continue to incur significant costs from our research and development activities. A primary focus of our efforts has been, and is expected to continue to be, the development of our UPT™ technology and the related UP*link*™ rapid detection system. However, there can be no assurance that we will succeed in our research and development efforts with respect to UPT™, UP*link*™ or other technologies or products. If we fail to develop commercially successful products, or if competitors develop more effective products or a greater number of successful new products, customers may decide to use products developed by our competitors. This would result in a loss of revenues and adversely affect our results of operations, cash flows and business.

If Acceptance and Adoption of Our Oral Fluid Testing in the Market Does Not Continue, Our Future Results May Suffer.

We have made significant progress in gaining acceptance of oral fluid testing for HIV in the insurance and public health markets. We have also made significant progress in gaining acceptance of oral fluid testing for

drugs of abuse in the workplace and criminal justice testing markets. Other markets, particularly the physicians' office market, may resist the adoption of oral fluid testing as a replacement for other testing methods in use today. In addition, certain state laws prohibit or restrict the use of oral fluid testing for drugs of abuse in certain markets. There can be no assurance that we will be able to expand the use of our oral fluid testing products in these or other markets.

Our Failure to Maintain Existing Distribution Channels, or Develop New Distribution Channels, May Result in Lower Revenues.

We have marketed many of our products by collaborating with laboratories, diagnostic companies and distributors. For example, our OraSure® oral fluid collection device is distributed to the insurance industry through major insurance testing laboratories. Our sales depend to a substantial degree on our ability to sell products to these customers and develop new product distribution channels, and on the marketing abilities of the companies with which we collaborate.

Some of our distributors have recently consolidated, and such consolidation has had, and may continue to have, an adverse impact on the level of orders for our products. One of these laboratories, Lab*One*, acquired another large insurance laboratory customer, Osborne Group, in 2001. These customers together accounted for approximately 26%, 29% and 30% of our revenues for the years 2002, 2001, and 2000, respectively. As a result of efficiencies gained following this acquisition, Lab*One* purchased approximately $1 million less of our insurance assays in 2002 than both companies purchased in 2001.

In addition, some distributors have experienced, and may continue to experience, pressure from their customers to reduce the price of their products and testing services. For example, Lab*One* and our other insurance testing laboratories are facing this pressure and may consider using lower cost insurance testing assays that they develop internally or purchase from our competitors. This has reduced our sales of insurance assays and is expected to lower sales of these products in 2003 and beyond.

Although we will try to maintain and expand our business with our distributors, there can be no assurance that such companies will continue to purchase or distribute our products or maintain historic order volumes, or that new distribution channels will be available on satisfactory terms.

The Use of Sole Supply Sources For Critical Components of Our Products Could Adversely Affect Our Business.

We currently purchase certain critical components of our products from sole supply sources. For example, all of the HIV-1 antigen used to make our oral fluid Western Blot HIV-1 confirmatory test is purchased from BMX, and all of the HIV-1 antigen and nitrocellulose required to make our OraQuick® rapid HIV-1 antibody test are purchased from sole source suppliers. If these suppliers are unable or unwilling to supply the required component, we would need to find another source, and perform additional development work and obtain FDA approval for the use of the alternative component for our products. Completing that development and obtaining such FDA approval could require significant time to complete and may not occur at all. These events could either disrupt our ability to manufacture and sell certain of our products or completely prevent us from doing so. Either event would have a material adverse effect on our results of operations, cash flows and business.

The Unavailability of Certain Products Distributed by a Third Party Could Adversely Affect Sales of Our OraSure® Oral Fluid Collection Device.

In testing an oral fluid sample collected with an OraSure® device for HIV-1, our customers must use an HIV-1 screening test approved by the FDA for use with our OraSure® device. Where an oral fluid sample screens positive for HIV-1, our customers must then use our oral fluid Western Blot confirmatory test, which has also been approved by the FDA for use with our OraSure® device, to confirm that positive indication.

BMX (bioMerieux, Inc.) manufactures and sells the only oral fluid HIV-1 screening test that has received FDA approval for use in detecting HIV-1 in an oral fluid specimen collected with our OraSure® collection device. BMX has developed a new HIV-1 screening test, and has indicated that this new test will eventually replace its existing FDA-approved HIV-1 screening test. We are working with BMX to obtain FDA approval for use of the new screening test with our OraSure® device. BMX also supplies the HIV-1 antigen used to manufacture our oral fluid Western Blot HIV-1 confirmatory test and is the exclusive world-wide distributor of that product.

If BMX ceases to manufacture or sell an HIV-1 screening test approved by the FDA for use with our OraSure® collection device, or if our oral fluid Western Blot HIV-1 confirmatory test is not made available to our customers (because BMX either fails to supply the HIV-1 antigen required to make this product or fails to distribute this product), we would need to find alternate suppliers for these products, which would require additional development work and FDA approval. These activities would likely require significant time to complete. If our customers cannot obtain an HIV-1 screening test or Western Blot HIV-1 confirmatory test that have been approved by the FDA for use in connection with our OraSure® collection device, these customers would likely stop purchasing our OraSure® device. Sales of the OraSure® device were approximately $12.7 million and $11.5 million, or 40% and 35% of our total revenues in 2002 and 2001, respectively.

The Time Needed to Obtain Regulatory Approvals and Respond to Changes in Regulatory Requirements Could Adversely Affect Our Business.

As described more fully above under the Section entitled, “Government Regulation,” many of our proposed and existing products are subject to regulation by the FDA and other governmental or public health agencies. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products.

The process of obtaining required approvals or clearances from governmental or public health agencies varies according to the nature of, and uses for, the specific product and can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities and other costly, time-consuming procedures. For example, we will likely seek FDA approval for the use of the OraQuick® rapid HIV antibody test on oral fluid, venous whole blood and serum/plasma samples. Approval of these claims will include the submission of clinical data and could require significant time to obtain. The submission of an application to the FDA or other regulatory authority for these or other claims does not guarantee that an approval or clearance to market the product will be received. Each authority may impose its own requirements and delay or refuse to grant approval or clearance, even though a product has been approved in another country.

Moreover, the approval or clearance process for a new product can be complex and lengthy. The time taken to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. This time span increases our costs to develop new products and increases the risk that we will not succeed in introducing or selling them.

Newly promulgated or changed regulations could also require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. For example, the Substance Abuse and Mental Health Services Administration (“SAMHSA”), which is part of the U.S. Department of Health and Human Services, is in the process of drafting regulations for the use of oral fluid drug testing for federal workers. Although we believe the SAMHSA regulations, when issued in final form, will permit us to market and sell our oral fluid drug tests for use with federal workers, there is no guarantee that those regulations will do so, and our ability to sell those products in that market could be limited. Other changes in government regulations, such as the adoption of the FDA’s Quality System Regulation, may also adversely affect our results of operations by requiring that we incur the expense of changing or implementing new manufacturing and control procedures.

The regulations in some states may restrict our ability to sell products in those states. For example, certain states restrict or do not allow the testing of oral fluid for drugs of abuse or the rapid, point-of-care testing for HIV. While we intend to work with state legislators and regulators to remove or modify any applicable restrictions, there is no guarantee we will be successful in these efforts.

In addition, all *in vitro* diagnostic products that are to be sold in the European Union ("EU") must bear the CE mark indicating conformance with the essential requirements of the In Vitro Diagnostic Directive ("IVDD"). The deadline for meeting this requirement is December 7, 2003. We will not be permitted to sell our products in the EU without a CE mark after this date, which could lead to the termination of strategic alliances and agreements for sales of those products in the EU. While we intend to CE mark certain existing and future products, and are not aware of any material reason why we will be unable to do so, there can be no assurance that compliance with all provisions of the IVDD will be demonstrated and the CE mark obtained prior to the deadline.

At the present time, we have received FDA clearance or approval for the OraSure® and Intercept® oral fluid collection devices, the OraQuick® rapid HIV-1 antibody test (for use with finger-stick whole blood samples), the UP*link*™ drug testing system and opiates assay, the Histofreezer® wart removal system, the Q.E.D.® saliva alcohol test, the OraSure® oral fluid Western Blot HIV-1 confirmatory test, and various other tests. The OraSure® and Intercept® collection devices (collection pad only) and Histofreezer® product currently bear the CE mark. See the Sections entitled, "Products" and "Government Regulation," for a further discussion of regulatory approvals and clearances obtained for our products.

Failure to Comply With FDA or Other Requirements May Require Us to Suspend Production of Our Products Which Could Result in a Loss of Revenues.

We can manufacture and sell many of our products, both in the United States and in some cases abroad, only if we comply with regulations of government agencies such as the FDA. We have implemented quality assurance and other systems that are intended to comply with applicable regulations.

During 2000, the FDA issued warning letters with respect to our Serum Western Blot product, stating that we were not in compliance with the FDA's regulations. We have responded to each of these letters and voluntarily discontinued this product. Although we believe that we have satisfactorily addressed the points raised by the FDA, the FDA could force us to stop manufacturing products at our Oregon facility if the FDA concludes that we remain out of compliance with applicable regulations. The FDA could also require us to recall products if we fail to comply with applicable regulations, which could force us to stop manufacturing such products. See the Section entitled, "Government Regulation," for a further discussion of regulatory requirements.

We Have a History of Losses.

We have not achieved full-year profitability. We incurred net losses of approximately $3.3 million, $3.7 million and $12.7 million in 2002, 2001 and 2000 respectively. As of December 31, 2002, the Company had an accumulated deficit of approximately $129.4 million.

Our limited combined operating history makes it difficult to forecast our future operating results. In order to achieve sustainable profitability, our revenues will have to continue to grow at a significant rate. However, our revenues have remained essentially flat during the past three years.

Our ability to achieve revenue growth, and therefore profitability, will be dependent upon a number of factors including, without limitation, the following:

- Creating market acceptance for and selling increasing volumes of the OraSure® collection device, the Intercept® and UP*link*™ drug testing products, and the OraQuick® rapid HIV-1 antibody test;

- The degree to which certain of our new products (i.e., the OraQuick® rapid HIV-1 antibody test) may replace sales of our existing products (i.e., the OraSure® device for HIV-1 testing) and the financial impact of that change;
- Achieving growth in international markets with our OraQuick® rapid HIV-1 antibody test and other products; and
- Commercially developing, and obtaining regulatory approval and creating market acceptance for, UPT™, the UP*link*™ drugs-of-abuse rapid detection system, and other new products in a time frame consistent with our objectives.

We have not yet fully achieved these objectives and there can be no assurance that we will be able to do so. Moreover, even if we achieve our objectives and become profitable, there can be no assurance that we will be able to sustain such profitability in the future.

Our Reported Financial Results May be Adversely Affected by Changes in Accounting Principles Generally Accepted in the United States.

We prepare our financial statements in conformity with accounting principles generally accepted in the United States. These accounting principles are subject to interpretation by the Financial Accounting Standards Board, the American Institute of Certified Public Accountants, the Securities and Exchange Commission and various bodies formed to interpret and create appropriate accounting policies. A change in these policies or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change.

For example, while current accounting rules allow us to exclude the expense of stock options from our financial statements, influential legislators and business policy groups have suggested that the rules be changed to require those options to be expensed. We rely on stock options as an important component of our employee compensation packages. If we are required to expense options, we may be less likely to achieve profitability, or we may have to decrease or eliminate option grants. Decreasing or eliminating option grants may adversely impact our ability to attract and retain qualified employees.

Volatility and Other Factors May Affect Our Stock Price.

Our stock price may be volatile, and could experience substantial declines. The market price of our common stock has historically experienced and might continue to experience volatility in the future in response to a number of factors, including quarter-to-quarter variations in operating results, analysts' reports, the relatively low trading volume for our stock, market conditions in the industry, regulatory and other developments affecting our products, changes in governmental regulations, changes in general conditions in the economy or in the financial or stock markets, and terrorist attacks, civil unrest and war.

The market has also recently experienced significant decreases in value. This market decline has affected the market prices of securities issued by many companies, often for reasons unrelated to their operating performance, and may adversely affect the price of our common stock.

A Market for Our Products May Not Develop.

Our future success will depend, in part, on the market acceptance, and the timing of such acceptance, of new products such as the Intercept® drug testing service, the OraQuick® rapid HIV-1 antibody test, products currently under development such as the UP*link*™ drugs of abuse rapid detection system and other products using the UPT™ technology, and other new products or technologies that may be developed or acquired and introduced in the future. To achieve market acceptance, we must make substantial marketing efforts and spend significant funds to inform potential customers and the public of the perceived benefits of these products. We currently have limited evidence on which to evaluate the market reaction to products that may be developed, and there can be no assurance that any products will meet with market acceptance and fill the market need that is perceived to exist.

Our Success Depends on Our Ability to Protect Our Proprietary Technology.

The diagnostics industry places considerable importance on obtaining patent, trademark, and trade secret protection, as well as other intellectual property rights, for new technologies, products and processes. Our success depends, in part, on our ability to develop and maintain a strong intellectual property portfolio or obtain licenses to patents and other technology for products and technologies both in the United States and in other countries.

As appropriate, we intend to file patent applications and obtain patent protection for our proprietary technology. These patent applications and patents will cover, as applicable, compositions of matter for our products, methods of making those products, methods of using those products, and apparatus relating to the use or manufacture of those products. We will also rely on trade secrets, know-how, and continuing technological advancements to protect our proprietary technology.

We have entered, and will continue to enter, into confidentiality agreements with our employees, consultants, advisors and collaborators. However, these parties may not honor these agreements and we may not be able to successfully protect our rights to unpatented trade secrets and know-how. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know-how.

Many of our employees, including scientific and management personnel, were previously employed by competing companies. Although we encourage and expect all of our employees to abide by any confidentiality agreement with a prior employer, competing companies may allege trade secret violations and similar claims against us.

We may collaborate with universities and governmental research organizations which, as a result, may acquire part of the rights to any inventions or technical information derived from collaboration with them.

To facilitate development and commercialization of a proprietary technology base, we may need to obtain licenses to patents or other proprietary rights from other parties. Obtaining and maintaining such licenses may require the payment of substantial costs. In addition, if we are unable to obtain these types of licenses, our product development and commercialization efforts may be delayed or precluded.

We may incur substantial costs and be required to expend substantial resources in asserting or protecting our intellectual property rights, or in defending suits against us related to intellectual property rights. Disputes regarding intellectual property rights could substantially delay product development or commercialization activities. Disputes regarding intellectual property rights might include state, federal or foreign court litigation as well as patent interference, patent reexamination, patent reissue, or trademark opposition proceedings in the United States Patent and Trademark Office. Opposition or revocation proceedings could be instituted in a foreign patent office. An adverse decision in any proceeding regarding intellectual property rights could result in the loss or limitation of our rights to a patent, an invention or trademark.

The Sales Potential for OraQuick® Will be Affected by Our Ability to Obtain Certain Licenses.

There are several factors that will affect the specific countries in which we will be able to sell our OraQuick® rapid HIV antibody test and therefore the overall sales potential of the test. One factor is whether we can arrange a sublicense or distribution agreement related to patents for detection of the HIV-2 virus. HIV-2 is a type of the HIV virus estimated to represent a small fraction of the known HIV cases worldwide. Nevertheless, HIV-2 is considered to be an important component in the testing regimen for HIV in many markets. HIV-2 patents are in force in most of the countries of North America and Western Europe, as well as in Japan, Korea, South Africa, and Australia. Access to a license for one or more HIV-2 patents may be necessary to sell HIV-2 tests in countries where such patents are in force, or to manufacture in countries where such patents are in force and then sell into non-patent markets. Since HIV-2 patents are in force in the United States, we may be restricted from manufacturing an OraQuick® rapid HIV-2 antibody test in the United States and selling into other countries, even if there were no HIV-2 patents in those other countries.

The importance of HIV-2 differs by country, and can be affected by both regulatory requirements and by competitive pressures. In most countries, any product used to screen the blood supply will be required to detect HIV-2, although the OraQuick® rapid HIV antibody test has not been intended for that market purpose. In other markets, including the United States, a test that can detect only the more prevalent HIV-1 type is considered sufficient by the FDA, except in testing related to blood supply. Because the competitive situation in each country will be affected by the availability of other testing products as well as the country's regulatory environment, we may be at a competitive disadvantage in some markets without an HIV-2 product even if HIV-2 detection is not required by regulations. In particular, our ability to sell a product that does not include an HIV-2 test may be limited, or a competitor's product that includes an HIV-2 test may be preferred and have a competitive advantage over an HIV-1 only test that we sell.

We have obtained licenses to HIV-1 patents held by the manufacturer of the HIV-1 antigen used in the OraQuick® device and by the National Institutes of Health. We are not aware of any other HIV-1 patents which would need to be licensed in order to manufacture and sell the OraQuick® rapid HIV-1 antibody test.

Another factor that may affect the specific countries in which we will be able to sell an OraQuick® rapid HIV-1 or HIV-2 test, and therefore the overall sales potential, concerns whether we can arrange a sublicense or distribution agreement related to any patents which claim lateral flow assay methods and devices covering the OraQuick® rapid HIV antibody tests or their use. OraQuick® is a lateral flow assay device that tests for specific antibodies or other substances. The term "lateral flow" generally refers to a test strip through which a sample flows and which provides a test result on a portion of the strip downstream from where the sample is applied. There are numerous patents in the United States and other countries which claim lateral flow assay methods and devices. Some of these patents may broadly cover the technology used in the OraQuick® test and are in force in the United States and other countries. We may not be able to make the OraQuick® test in the United States and sell it in countries where there is no patent on the device. We have obtained licenses under several lateral flow patents, which we believe should be sufficient to permit the manufacturing and sale of the OraQuick® device as currently contemplated. However, licenses under additional patents may be required.

In the event that it is determined that a license is required and it is not possible to negotiate a license agreement under a necessary patent, we may be able to modify the OraQuick® rapid HIV antibody test such that a license would not be necessary. However, this alternative could delay or limit our ability to sell the OraQuick® rapid HIV antibody test in the United States and other markets, which would adversely affect our results of operations, cash flows and business.

If We Lose Our Key Personnel or Are Unable to Attract and Retain Qualified Personnel as Necessary, Our Business Could be Harmed.

Our success will depend to a large extent upon the contributions of our executive officers, management, and sales, marketing, and scientific staff. We may not be able to attract or retain qualified employees in the future due to the intense competition for qualified personnel among medical products businesses.

If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively sell and market our products, to meet the demands of our strategic partners in a timely fashion, or to support internal research and development programs. In particular, product development programs depend on the ability to attract and retain highly skilled scientists, including molecular biologists, biochemists and engineers, and sales and marketing efforts depend on the ability to attract and retain skilled and experienced sales and marketing representatives. Recruiting qualified personnel can be an intensely competitive and time-consuming process. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms.

All of our employees, other than a few senior officers who have employment agreements, are at-will employees, which means that either the employee or the Company may terminate their employment at any time. If we experience difficulty in recruiting and retaining qualified personnel, we may need to provide higher compensation to such personnel than currently anticipated or we may incur additional expenses for the recruitment of qualified personnel.

Our business strategies will require additional expertise in specific industries and areas applicable to the development efforts related to up-converting phosphor or other technologies. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing management personnel. The inability to acquire these services or to develop this expertise could impair the development, if any, of products related to these technologies.

Our Increasing International Presence May be Affected by Regulatory, Cultural or Other Restraints.

We intend to increase international sales of our products. Our international sales accounted for approximately $3.9 million or 12% of total revenues for 2002, approximately $5.3 million or 16% of total revenues for 2001, and approximately $4 million or 14% of total revenues for 2000.

A number of factors can slow or prevent international sales, or substantially increase the cost of international sales, including those set forth below:

- Regulatory requirements (including compliance with applicable customs regulations) may slow, limit, or prevent the offering of products in foreign jurisdictions;
- The unavailability of licenses to certain patents in force in a foreign country which cover our products may restrict our ability to sell into that country;
- Our inability to obtain the CE mark on our products in a timely manner may preclude or delay our ability to sell products to the European Union;
- Cultural and political differences may make it difficult to effectively market, sell and gain acceptance of products in foreign jurisdictions;
- Inexperience in international markets may slow or limit our ability to sell products in foreign countries;
- Exchange rates, currency fluctuations, tariffs and other barriers, extended payment terms and dependence on and difficulties in managing international distributors or representatives may affect our revenues even when product sales occur;
- The creditworthiness of foreign entities may be less certain and foreign accounts receivable collection may be more difficult;
- Economic conditions, the absence of available funding sources, terrorism, civil unrest and war may slow or limit our ability to sell our products in foreign countries;
- International markets often have long sales cycles, especially sales to foreign governments, quasi-governmental agencies and international public health agencies, thereby delaying or limiting our ability to sell our products; and
- We may be at a disadvantage if competitors in foreign countries sell competing products at prices at or below such competitors' or our cost.

In February 2000, we entered into an agreement for the distribution of our OraQuick® rapid HIV antibody test in a number of African countries. Because of the inability of our African distributor to obtain required regulatory approvals, the lack of funding sources in those countries for the purchase of our product and other factors, our distributor failed to meet its minimum purchase commitments under our agreement. As a result, we were forced to record a reserve for approximately $0.6 million of OraQuick® inventory manufactured in contemplation of sales to this distributor.

In addition, we have entered into a contract for the manufacture and supply of the OraQuick® rapid HIV antibody test in Thailand. However, we do not have significant direct experience with the use of international manufacturers. Factors such as economic and political conditions and foreign regulatory requirements may slow or prevent the manufacture of our products in countries other than the United States. Interruption of the supply of our products could reduce revenues or cause us to incur significant additional expenses in finding an alternative source of supply.

We May be Sued for Product Liabilities for Injuries Resulting From the Use of Our Diagnostic Products.

We may be held liable if any of our products, or any product which is made with the use or incorporation of any of our technologies, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. Although we have obtained product liability insurance, this insurance may not fully cover potential liabilities. As we bring new products to market, we may need to increase our product liability coverage. If we decide to obtain the required regulatory approvals and sell any of our products in the consumer or over-the-counter market, the risk of potential product liability exposure and the required level of insurance coverage could increase. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could affect our decision to commercialize new products.

*We May Not be Able to Commercialize Our UPT™, UP*link*™ or Other New Products Which Could Negatively Affect Our Future Revenues.*

Our UPT™ technology and the UP*link*™ rapid detection system are still under development. Commercial development of the UP*link*™ system or the UPT™ technology for certain other applications and other new products may not be successful. Successful products require significant development and investment, including testing, to demonstrate their cost-effectiveness or other benefits prior to commercialization. In addition, regulatory approval must be obtained before most products may be sold. Additional development efforts on these products will be required before any regulatory authority will review them. Regulatory authorities may not approve these products for commercial sale. In addition, even if a product is developed and all applicable regulatory approvals are obtained, there may be little or no market for the product. Accordingly, because of these uncertainties, the UP*link*™ rapid detection system, other applications of UPT™ or other new products may not be successfully commercialized, which could negatively affect our results of operations, cash flows and business.

We Are Dependent Upon Strategic Partners to Assist in Developing and Commercializing Some of Our Diagnostic Products.

Although we intend to pursue some product opportunities independently, opportunities that require a significant level of investment for development and commercialization or a distribution network beyond our existing sales force may necessitate involving one or more strategic partners. In particular, our strategy for development and commercialization of UPT™, including the UP*link*™ rapid detection system, and certain other products may entail entering into additional arrangements with distributors or other corporate partners, universities, research laboratories, licensees and others. We may be required to transfer material rights to such strategic partners, licensees and others. While we expect that our current and future partners, licensees and others have and will have an economic motivation to succeed in performing their contractual responsibilities, the amount and timing of resources to be devoted to these activities will be controlled by others. Consequently, there can be no assurance that any revenues or profits will be derived from such arrangements.

We are Dependent Upon Patents, Licenses and Other Proprietary Rights From Third Parties, Including Rights to Up-Converting Phosphor Compositions, Methods and Apparatuses.

We have licensed the worldwide rights to up-converting phosphor compositions, methods and apparatuses for use in diagnostic applications, which are the subject of numerous United States patents and several pending United States applications. Corresponding patents and patent applications have been granted, issued or filed in

numerous foreign countries, including, for example, European countries, Japan and Canada. We cooperate with the licensor to prosecute such patent applications and protect such patent rights. If the licensors do not meet their obligations under the license agreements or do not reasonably consent to sublicenses by us, or if the license agreement is terminated, we could lose the opportunity to develop UPT™.

We May Require Future Additional Funding to Stay in Business.

Although we have made significant progress in the past toward controlling expenses and increasing product revenue, we have historically depended, to a substantial degree, on capital raised through the sale of equity securities and bank borrowings to fund our operations.

Our future liquidity and capital requirements will depend on numerous factors, including, but not limited to, the following:

- The costs and timing of the expansion of our manufacturing capacity;
- The success of our research and product development efforts;
- The scope and results of clinical testing;
- The magnitude of capital expenditures;
- Changes in existing and potential relationships with business partners;
- The time and cost of obtaining regulatory approvals;
- The costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses;
- The costs and timing of expansion of sales and marketing activities;
- The timing of the commercial launch of new products;
- The extent to which existing and new products gain market acceptance;
- Competing technological and market developments; and
- The scope and timing of strategic acquisitions.

If additional financing is needed, we may seek to raise funds through the sale of equity or other securities or through bank borrowings. There can be no assurance that financing through the sale of securities, bank borrowings or otherwise, will be available to us on satisfactory terms, if at all.

The Recent Economic Downturn and Terrorist Attacks May Adversely Affect Our Business.

Since the September 11, 2001 terrorist attacks, the United States economy has experienced a decline. Changes in economic conditions could adversely affect our business. For example, in a difficult economic environment, customers may be unwilling or unable to invest in new diagnostic products, may elect to reduce the amount of their purchases or may perform less drug testing because of declining employment levels. A weakening business climate could also cause longer sales cycles and slower growth, and could expose us to increased business or credit risk in dealing with customers adversely affected by economic conditions.

The terrorist attacks and subsequent governmental responses to these attacks could cause further economic instability or lead to further acts of terrorism in the United States and elsewhere. These actions could adversely affect economic conditions outside the United States and reduce demand for our products internationally. Terrorist attacks could also cause regulatory agencies, such as the FDA or agencies that perform similar functions outside the United States, to focus their resources on vaccines or other products intended to address the threat of biological or chemical warfare. This diversion of resources could delay our ability to obtain regulatory approvals required to manufacture, market or sell our products in the United States and other countries.

Efforts to Consolidate or Restructure Could Adversely Affect Our Business.

We may from time to time restructure and consolidate various aspects of our operations in order to achieve cost savings and other efficiencies. For example, during 2001 we began a restructuring of our manufacturing operations which included the transfer of OraQuick® manufacturing from the Beaverton, Oregon facility to Bethlehem, Pennsylvania. In addition, we plan to close the Oregon facility and transfer all remaining manufacturing operations and research and development activities in that facility related to the Western Blot HIV-1 confirmatory test and our contract manufacturing operations for OraSure® and Intercept®, to our facilities in Pennsylvania. The transfer of operations may result in the loss of scientific or other personnel and thereby delay the transfer or disrupt the continuation of operations thereafter. We will also be required to obtain FDA approval to transfer certain operations to another location, which could delay the transfer or disrupt continued operations. Any delay or disruption of operations, and in particular manufacturing operations, could result in increased costs or could delay or prevent us from selling certain products and thereby result in a loss of revenue.

Future Acquisitions or Investments Could Disrupt Our Ongoing Business, Distract Our Management, Increase Our Expenses and Adversely Affect Our Business.

We may consider strategic acquisitions or investments as a way to expand our business in the future. These activities, and their impact on our business, are subject to the following risk factors:

- Suitable acquisitions or investments may not be found or consummated on terms that are satisfactory to us;
- We may be unable to successfully integrate an acquired company's personnel, assets, management systems and technology into our business;
- Acquisitions may require substantial expense and management time and could disrupt our business;
- An acquisition and subsequent integration activities may require greater capital resources than originally anticipated at the time of acquisition;
- An acquisition may result in the incurrence of unexpected expenses, the dilution of our earnings or our existing stockholders' percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business;
- An acquisition may result in the loss of existing key personnel or customers or the loss of the acquired company's key personnel or customers;
- The benefits to be derived from an acquisition could be affected by other factors, such as regulatory developments, general economic conditions and increased competition; and
- An acquisition of a foreign business may involve additional risks, including not being able to successfully assimilate differences in foreign business practices or overcome language barriers.

The incurrence of one or more of the above or other factors may prevent us from achieving all or a significant part of the benefits expected from an acquisition or investment. This may adversely affect our financial condition, results of operations and ability to grow our business.

The previous discussion of our business should be read in conjunction with the Financial Statements and accompanying notes included in Item 15 of this Annual Report on Form 10-K.

ITEM 2. Properties.

In October 2002, we leased an approximate 48,000 square foot facility, which is our new primary corporate office and manufacturing facility, on property in Bethlehem, Pennsylvania. The lease has a ten-year initial term ending in October 2012 and base rental rate starting at $780,000 and increasing to $858,000 per year over that initial term. The lease also has a five-year renewal option at an annual base rental rate of $975,000 and a ten-year purchase option.

In April 1999, we signed a five-year lease to rent 25,845 square feet of space at the John M. Cook Technology Center in Bethlehem, Pennsylvania, which we use for our sales and marketing and research and development offices. Annual base rent for the initial five-year term of this lease ending in March 2005 is approximately $244,000. The lease also includes a five-year renewal option at an annual base rental rate of $271,000 and a ten-year purchase option.

We own a 33,500 square foot building in Bethlehem, Pennsylvania, which is used for manufacturing, engineering and information systems activities.

We lease approximately 30,500 square feet of office, manufacturing, and laboratory space in Beaverton, Oregon, under a lease that expires in January, 2005. We have annual base lease obligations under the lease starting at $351,000 and increasing to $395,000 during the term of the lease. We expect to consolidate the research and development and manufacturing operations currently performed in Oregon with our Bethlehem operations beginning later in 2003.

We rent additional warehouse space on an as-needed basis. We also lease space for small sales offices in Chicago, Illinois and Reeuwijk, The Netherlands.

We believe that the facilities described above are adequate for our current requirements.

ITEM 3. Legal Proceedings.

From time to time we are involved in legal proceedings arising in the ordinary course of business. In our opinion, based on the advice of counsel, these proceedings are not expected to have a material adverse effect on our financial position or results of operations.

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

No matters were submitted to a vote of security holders during the fourth quarter of the year ended December 31, 2002.

PART II

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

Our Common Stock is listed for trading on the National Market tier of The Nasdaq Stock Market ("NASDAQ") under the symbol OSUR. High and low sales prices reported by NASDAQ during the periods indicated are shown below.

	Year ended December 31,			
	2002		2001	
	High	Low	High	Low
First Quarter	$ 12.280	$ 4.750	$ 10.000	$ 5.875
Second Quarter	8.350	5.500	12.640	6.688
Third Quarter	6.820	3.330	15.000	7.260
Fourth Quarter	8.150	3.700	12.880	8.890

On March 21, 2003, there were 522 holders of record and approximately 12,500 holders in street name of the Common Stock, and the closing price of the Common Stock was $7.17 per share. We have never paid any cash dividends, and the Board of Directors does not anticipate paying cash dividends in the foreseeable future. We are generally not permitted to pay dividends or make other distributions to our stockholders under the terms of our credit facilities with Comerica Bank, without first obtaining Comerica's consent. We intend to retain any future earnings to provide funds for the operation and expansion of our business.

ITEM 6. Selected Financial Data.

The following table sets forth selected financial data of the Company. On September 29, 2000, STC and Epitope were merged into the Company (the "Merger"). The Merger was accounted for as a pooling of interests and, accordingly, all prior period financial statements of Epitope have been restated to include the results of operations, financial position and cash flows of STC. The selected financial data as of September 30, 1999 and 1998 and for each of the years then ended, include Epitope's previous September 30 fiscal year amounts and STC's December 31 calendar year amounts. On September 20, 2000, the Company changed its fiscal year-end from September 30 to December 31, effective with the calendar year beginning January 1, 2000. A three-month transition period from October 1, 1999 through December 31, 1999 (the "Transition Period") precedes the start of the 2000 fiscal year. As a result of the Merger, financial statements for the Transition Period include amounts for Epitope and STC for the three months ended December 31, 1999. Accordingly, STC's results of operations for the three months ended December 31, 1999 are included in both the financial statements for the year ended September 30, 1999 and for the Transition Period.

This information should be read in conjunction with the Financial Statements and notes thereto included in Item 15 and the information set forth in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Selected Financial Data
(In thousands, except per share data)

	Year ended December 31,			Three months ended December 31,		Year ended September 30,	
	2002	2001	2000	1999	1998	1999	1998
Operating Results:					(Unaudited)		
Revenues	$ 32,010	$ 32,573	$ 28,788	$ 6,822	$ 5,138	$ 24,046	$ 20,444
Costs and expenses	35,550	36,906	42,917	7,105	5,857	28,138	22,721
Other income (expense), net	198	634	1,407	(138)	(159)	(91)	(98)
Net loss	(3,342)	(3,728)	(12,747)	(471)	(878)	(4,233)	(2,374)
Basic and diluted net loss per share	$ (0.09)	$ (0.10)	$ (0.36)	$ (0.02)	$ (0.03)	$ (0.14)	$ (0.09)
Weighted average number of shares outstanding	37,583	36,868	35,002	30,887	26,246	30,597	26,180

	December 31,					September 30,	
	2002	2001	2000	1999	1998	1999	1998
Financial position:							
Working capital	$ 18,931	$ 19,764	$ 21,440	$ 16,314	$ 8,255	$ 16,773	$ 8,725
Total assets	35,737	37,285	37,736	29,626	20,075	30,251	20,783
Long-term debt, excluding current portion	3,409	3,586	4,644	5,820	6,001	5,820	6,001
Accumulated deficit	(129,435)	(126,092)	(122,365)	(109,618)	(105,603)	(109,104)	(104,903)
Stockholders' equity	26,019	26,541	26,172	18,238	10,264	18,592	10,701

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

Statements below regarding future events or performance are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Our actual results could be quite different from those expressed or implied by the forward-looking statements. Factors that could affect results are discussed more fully under the Sections entitled, "Forward-Looking Statements" and "Risk Factors," in Item 1 and elsewhere in this Report. Although forward-looking statements help to provide complete information about us, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements.

The following discussion should be read in conjunction with the financial statements contained herein and the notes thereto, along with the Section entitled, "Critical Accounting Policies and Estimates" set forth below.

Results of Operations—2002 Compared to 2001

Total revenues decreased 2% to approximately $32.0 million in 2002 from approximately $32.6 million in 2001. The decline in 2002 revenues was primarily the result of a $1.2 million decrease in licensing and product development revenues, partially offset by higher product revenues. Product revenues were approximately $31.7 million in 2002, representing an increase of 2% over 2001 levels.

The table below shows the amount of our total revenues (in thousands, except %) generated in each of our principal markets and by licensing and product development activities.

	Dollars		Percentage Change Inc. (Dec.)	Percentage of Total Revenues (%)	
	2002	2001		2002	2001
Market revenues					
Insurance risk assessment	$12,030	$11,713	3 %	38%	36%
Infectious disease testing	6,063	5,754	5	19	18
Substance abuse testing	6,434	6,955	(7)	20	21
Physicians' office therapies	7,165	6,674	7	22	20
	31,692	31,096	2	99	95
Licensing and product development	318	1,477	(78)	1	5
Total revenues	$32,010	$32,573	(2)%	100%	100%

Sales to the insurance risk assessment market increased by 3% to approximately $12.0 million in 2002 from approximately $11.7 million in 2001, as a result of increased sales of our OraSure® laboratory-based HIV-1 test, partially offset by lower sales of assays and reagents. We expect that sales of our insurance assays and reagents will come under increased competitive pressure in the future. The laboratories that purchase these products are facing pressure from their insurance customers to reduce the cost of testing services. As a result, these laboratories are expected to reduce their purchases of our products and instead use lower cost internally developed assays or reagents or testing products purchased from our competitors. Although we will make every effort to retain this business, our revenues could be negatively impacted by as much as $1.5 million in 2003 and $2.0 million in 2004, when compared to 2002 revenues in the insurance risk assessment market.

Sales to the infectious disease testing market increased 5% to approximately $6.1 million in 2002 from approximately $5.8 million in 2001, as a result of a $0.6 million increase in sales of our OraSure® laboratory-based HIV-1 test into the public health market, offset by a $300,000 decrease in international sales of the OraQuick® rapid HIV antibody test. In June 2002, we entered into an agreement with Abbott Laboratories for the co-exclusive distribution of the OraQuick® test in the United States. We received FDA approval of the OraQuick® test for detecting HIV-1 in finger-stick whole blood samples in November 2002 and received a CLIA waiver for this product in January 2003.

We shipped an initial order for approximately $200,000 of OraQuick® devices to Abbott in the fourth quarter of 2002, representing our first domestic sale of this product following FDA approval. We expect that sales of OraQuick® will increase substantially in 2003, the first full year that this product is commercially available in the United States. We expect that Abbott will purchase at least $4.0 million of OraQuick® devices during the first 15 months of our agreement, which is the minimum purchase commitment required to retain co-exclusive distribution rights. Additionally, we expect that sales of the OraQuick® device in the public health and military markets will increase throughout the year as acceptance of this product grows. Sales of our OraSure® laboratory-based HIV-1 test are expected to be negatively affected by the successful penetration of the OraQuick® device in the public health market, as some customers will likely substitute OraQuick® for OraSure®. However, the degree of this substitution and resulting financial impact cannot be determined at this time. International sales of OraQuick® are also expected to contribute to our revenues in the infectious disease testing market in 2003.

Sales to the substance abuse testing market decreased 7% to approximately $6.4 million in 2002 from approximately $7.0 million in 2001, primarily as a result of the absence of $1.0 million in sales of laboratory equipment manufactured by third party vendors and $0.5 million in sales of UP*link*™ analyzers, which occurred in 2001. Offsetting this aggregate decrease were an approximate $400,000 increase in international sales of our Intercept® collection device and related assays and an approximate $200,000 increase in sales of domestic substance abuse products. We intend to aggressively support our Intercept® product line in 2003 through the deployment of additional sales representatives and increased marketing expenditures.

Sales to the physicians' office therapies market, which consisted solely of our Histofreezer® wart removal system, increased 7% to approximately $7.2 million in 2002 from approximately $6.7 million in 2001, as a result of increased product sales in the United States partially offset by lower international sales. The increase in domestic sales of Histofreezer® was partially attributable to distributors increasing their inventory levels in the fourth quarter of 2002 as a result of an announced price increase in the U.S. market, which became effective in December 2002. This increase in inventory levels in advance of the price increase is expected to reduce Histofreezer® product sales during the first quarter of 2003. However, we believe that Histofreezer® sales levels in the U.S. will return to a more normal pattern beginning in the second and third quarters of 2003. We are evaluating distribution channel expansion for our Histofreezer® product line in order to expand our penetration of the physicians' offices therapies market, and are considering selling Histofreezer® in certain other markets not covered by our current distribution partners.

As a percentage of total revenues, international revenues decreased to approximately 12% in 2002 from approximately 16% in 2001, with Histofreezer® accounting for approximately 48% of 2002 international revenues. This decrease is primarily attributable to lower international sales of OraQuick® and the absence of UP*link*™ analyzer sales to Dräger Safety, which occurred in 2001.

Lab*One*, our largest customer, and Osborne Group, which was acquired by Lab*One* in 2001, together accounted for approximately 26% and 29% of total revenues in 2002 and 2001, respectively. We expect this percentage to decrease further in 2003, reflecting lower anticipated sales of insurance assays and reagents to Lab*One* and increased sales of the OraQuick® rapid HIV-1 antibody test, as described above.

Licensing and product development revenues decreased 78% to approximately $300,000 in 2002 from approximately $1.5 million in 2001, reflecting a significant drop in funded research and development. During 2001, licensing and product development revenues were primarily derived from the continued development of the UP*link*™ drugs-of-abuse rapid detection system under our agreement with Dräger Safety, development of infectious disease applications for UP*link*™ under our agreement with Meridian Bioscience, and the second phase of a grant from the National Institutes of Health ("NIH") for the development of an oral fluid syphilis test. The decrease in 2002 resulted from the absence of research and development funding from both Dräger Safety and Meridian, as our projects with these companies advanced to a stage where we became responsible for funding, and the termination of work under the NIH grant for the development of the syphilis test.

We do not expect significant research and development funding from Dräger Safety in 2003 and we agreed in principle to terminate our agreement with Meridian in early 2003. However, we expect licensing and product development revenues to increase modestly in 2003 as a result of approximately $400,000 in annual research and development funding expected under our collaborative UP*link*™ and oral fluid research project with The University of Pennsylvania, which will be received under a grant awarded by the NIH.

Our gross margin decreased to approximately 60% in 2002 from 62% in 2001. This decrease was primarily the result of lower licensing and product development revenues, offset by a more favorable product mix and our ongoing cost savings efforts. Additionally, as we prepared for FDA approval and the commercial launch of OraQuick® in the United States during 2002, we incurred substantial expenses related to staffing, materials and overhead. These expenses were included in our cost of goods throughout 2002, however, we did not begin to generate revenues from OraQuick® until the initial sales of this product in the United States in December 2002. We anticipate that the benefits of these expenditures will be realized during 2003 and that the incremental revenues associated with the production and sale of OraQuick® will positively impact our gross margin in the future. We also recognized approximately $1.4 million of inventory scrap in 2002 and are implementing programs designed to reduce scrap levels in 2003. We expect that these programs will also help improve our gross margin in 2003 and beyond.

Research and development expenses declined 12% to approximately $8.3 million in 2002 from approximately $9.4 million in 2001. Decreased expenditures for staffing, consulting and travel were partially offset by increased clinical trials costs related to our efforts to obtain FDA approval of the OraQuick® rapid HIV-1 antibody test. We expect that our expenditures in support of regulatory filings for our products will increase in 2003, primarily related to clinical trials for the CLIA waiver and the oral fluid and certain other claims for OraQuick® and the transfer of manufacturing from our Beaverton, Oregon facilities to Bethlehem, Pennsylvania.

Sales and marketing expenses increased 1% to approximately $8.1 million in 2002 from approximately $8.0 million in 2001. This increase was primarily the result of additional consulting fees for the development of our strategic marketing plans and increased staffing costs, offset by lower travel expenses, sales commissions and freight costs. We expect sales and marketing expenses to increase substantially in 2003 as we support the launch of OraQuick® and invest in the promotion of our Intercept® products. We plan to increase our staffing levels in support of these, and other key products, and to incur higher related expenses for travel, sales commissions, advertising and public relations.

General and administrative expenses declined 6% to approximately $6.3 million in 2002 from approximately $6.8 million in 2001. This decrease was primarily the result of lower legal, recruiting, and staffing costs offset by an approximate $0.5 million severance charge related to the departure of our former Chief Executive Officer in the first quarter of 2002. Additionally, we had an approximate $200,000 loss on disposal of equipment in 2001, which we did not have in 2002. We expect general and administrative costs to increase during 2003, reflecting additional facility-related costs from the occupancy of our new corporate headquarters in Bethlehem, Pennsylvania, higher premium costs for directors and officers' liability insurance, and higher professional advisor fees as a result of compliance with the Sarbanes-Oxley Act of 2002.

Restructuring-related expenses were approximately $0.5 million in 2001. These costs included expenses for employee severance and travel and transport resulting from relocating and consolidating manufacturing operations. There were no such costs in 2002.

Interest expense decreased by 29% to $285,000 in 2002 from $403,000 in 2001, as a result of lower average outstanding borrowings and lower effective interest rates.

Interest income decreased by 48% to $483,000 in 2002 from $933,000 in 2001, as a result of lower cash and cash equivalents available for investment and lower interest rates.

Gain on the sale of securities was $100,000 in 2001 as a result of the sale of Lab*One* common stock we received as part of an Intercept® distribution agreement with Lab*One*, entered into in 1999. There were no such sales in 2002.

Results of Operations—2001 Compared to 2000

Total revenues increased 13% to approximately $32.6 million in 2001 from approximately $28.8 million in 2000. Excluding revenues of approximately $1.6 million in 2000 from the Serum Western Blot confirmatory test, which was discontinued in January 2001, total revenues would have increased approximately 20%.

The table below shows the amount of our total revenues (in thousands, except %) generated in each of our principal markets and by licensing and product development activities.

	Dollars		Percentage Change Inc. (Dec.)	Percentage of Total Revenues (%)	
	2001	2000		2001	2000
Market revenues					
Insurance risk assessment	$ 11,713	$ 14,693	(20)%	36%	51%
Infectious disease testing	5,754	3,453	67	18	12
Substance abuse testing	6,955	3,172	119	21	11
Physicians' office therapies	6,674	6,777	(2)	20	24
	31,096	28,095	11	95	98
Licensing and product development	1,477	693	113	5	2
Total revenues	$ 32,573	$ 28,788	13%	100%	100%

Sales to the insurance risk assessment market declined by 20% to approximately $11.7 million in 2001 from approximately $14.7 million in 2000, as a result of the discontinuation of our Serum Western Blot confirmatory test, improved efficiencies by end users in the use of OraSure® collection devices and by insurance testing laboratories in the use of immunoassay tests, inventory consolidations which resulted from the merger of our two largest insurance laboratory customers, Lab*One* and Osborne Group, and lower sales of urine assays. Partially offsetting this decline was an increase in sales of oral fluid assays resulting from increased penetration of the insurance risk assessment market.

Sales to the infectious disease testing market increased 67% to approximately $5.8 million in 2001 from approximately $3.5 million in 2000, as a result of continued penetration of the OraSure® laboratory-based HIV-1 test and shipments of the OraQuick® rapid HIV antibody test into sub-Saharan Africa.

Sales to the substance abuse testing market increased 119% to approximately $7.0 million in 2001 from approximately $3.2 million in 2000, as a result of the substantial market penetration of the Intercept® drug testing service into the workplace and criminal justice markets and increased forensic toxicology sales. Of the $7.0 million in substance abuse testing revenues, approximately $1.7 million resulted from the sale of equipment manufactured by third party vendors.

Sales to the physicians' office therapies market, which consisted solely of the Histofreezer® wart removal system, declined 2% to approximately $6.7 million in 2001 from approximately $6.8 million in 2000, as a result of inventory consolidation by distributors in the United States and lower international sales. Despite this small decline in revenues, Histofreezer® sales in the United States improved steadily throughout 2001 on a quarter-to-quarter basis.

As a percentage of total revenues, international revenues increased to approximately 16% in 2001 from approximately 14% in 2000, with Histofreezer® accounting for approximately 39% of 2001 international revenues. Lab*One*, our largest customer, and Osborne Group, which was acquired by Lab*One* in 2001, together accounted for approximately 29% and 30% of total revenues in 2001 and 2000, respectively.

Licensing and product development revenues increased 113% to approximately $1.5 million in 2001 from approximately $0.7 million in 2000, reflecting a different mix of development work performed in 2001. During 2001, licensing and product development revenues were primarily from the continued development of the UP*link*™ drugs-of-abuse rapid detection system under an agreement with Dräger Safety, development of infectious disease applications for UP*link*™ under an agreement with Meridian, and the second phase of a grant from the NIH for the development of an oral fluid syphilis test.

During 2000, licensing and product development revenues consisted primarily of income from a collaboration with Lab*One* related to the Intercept® drug testing service, development work with Dräger Safety on the UP*link*™ drugs-of-abuse rapid detection system, and the first phase of the NIH grant.

The first phase of the NIH grant was for development of a laboratory-based oral fluid syphilis test using the OraSure® collection device. During 2001, we requested and the NIH approved a change for the second phase of that grant to apply to the development of a rapid test for syphilis using the OraQuick® platform. During the first quarter of 2002, we reassessed this project and the potential marketability of the resulting product, and elected to terminate development of the syphilis test. As a result, we will not receive further funding under this NIH grant.

Our gross margin increased to approximately 62% in 2001 from 61% in 2000. This increase was primarily the result of lower material costs and productivity gains, negotiated contract savings, cost savings as a result of restructuring our manufacturing operations, and higher licensing and product development revenues, partially offset by incremental costs and manufacturing inefficiencies associated with the initial production of UP*link*™ analyzers and commencement of OraQuick® manufacturing. Additionally, during the fourth quarter of 2001, the gross margin was negatively affected by the recording of an inventory reserve of approximately $0.6 million related to OraQuick® rapid HIV antibody tests manufactured for sale to our African distributor. Because of the failure by our African distributor to meet its contractually-required minimum purchase commitments, we reevaluated our international distribution strategy for OraQuick® and terminated our agreement with this distributor in February 2002. The reserve was required because of concerns about the remaining shelf life of the inventory in relation to our ability to rapidly establish a new distribution channel to sell OraQuick® in Africa. During 2000, we wrote off approximately $0.5 million for expired OraSure® collection device inventory and $0.6 million for Serum Western Blot confirmatory test inventory that was obsolete, expired, or rendered unsaleable as a result of the discontinuation of that product.

Research and development expenses declined 10% to approximately $9.4 million in 2001 from approximately $10.4 million in 2000. Research and development efforts in 2001 were focused upon the continued development of the UP*link*™ analyzer, test cassette and collector, the development of certain UP*link*™ drugs of abuse and infectious disease assays, DNA feasibility studies, and clinical trials for the OraQuick® rapid HIV-1 antibody test. The investments in these projects were offset by reduced expenditures related to development of the OraQuick® device and lower personnel and consulting expenses at our Oregon facility.

Sales and marketing expenses increased 15% to approximately $8.0 million in 2001 from approximately $6.9 million in 2000. This increase was primarily the result of additional costs associated with increased staffing levels and related expenses, and the expansion of our customer service functions.

General and administrative expenses remained flat at approximately $6.8 million in 2001 and $6.9 million in 2000. Higher professional fees associated with certain partnering activities in 2001 were offset by cost savings from the elimination of duplicative overhead structures as a result of the Merger of STC and Epitope into the Company.

Merger-related expenses were approximately $7.6 million in 2000. These costs included fees for investment bankers, attorneys and accountants, filing fees, proxy solicitation expenses, employee severance, and integration costs. There were no such costs in 2001.

Restructuring-related expenses were $450,000 as a result of the manufacturing restructuring in the first quarter of 2001. These costs included expenses for employee severance and travel and transport resulting from relocating and consolidating manufacturing operations, and were paid by June 30, 2001. There were no such costs in 2000.

Interest expense decreased by 18% to $403,000 in 2001 from $490,000 in 2000 as a result of loan principal repayments.

Interest income decreased by 29% to approximately $0.9 million in 2001 from approximately $1.3 million in 2000 as a result of lower cash and cash equivalents available for investment and lower interest rates.

Gain on the sale of securities was $100,000 in 2001 as a result of the sale of Lab*One* common stock that we received as part of an Intercept® distribution arrangement with Lab*One*, entered into in 1999. In 2000, we recorded a gain on the sale of securities of $600,000, as a result of the sale of Andrew & Williamson Sales Company ("A&W") preferred stock we had received as part of a settlement with A&W in 1997.

During 2001 and 2000, provisions for foreign income taxes were recorded.

Liquidity and Capital Resources

	December 31, 2002	December 31, 2001
	(In thousands)	
Cash and cash equivalents	$ 4,364	$ 2,426
Short-term investments	10,544	12,765
Working capital	18,931	19,764

The Company's cash, cash equivalents and short-term investments decreased approximately $283,000 during 2002 to approximately $14.9 million at December 31, 2002, primarily as a result of the Company's net loss for 2002, an increase in inventories, a decrease in accounts payable, and capital expenditures. Offsetting these uses of cash were an increase in accounts receivable collections and proceeds from stock option exercises. At December 31, 2002, the Company's working capital was approximately $18.9 million.

Net cash used in operating activities was approximately $0.5 million in 2002, a decrease of approximately $4.7 million from the $5.3 million used in operations in 2001. The $0.5 million of cash used in operating activities resulted primarily from the Company's net loss for the year of $3.3 million and a reduction in accounts payable, offset by $2.3 million in depreciation and amortization and by a significant improvement in our collection of accounts receivable.

Net cash used in investing activities during 2002 was $231,000. We purchased approximately $1.6 million of property and equipment and expended $0.7 million on licenses, product supply and distribution agreements. These expenditures were funded through net proceeds of approximately $2.2 million generated from the sale of short-term investments.

Capital expenditures are anticipated to increase during 2003 to approximately $3.0 million as a result of additional commitments we have made for the purchase and installation of manufacturing and research and development equipment for UP*link*™ and OraQuick®. We also expect to purchase additional information systems equipment to support our new corporate and manufacturing facility in Bethlehem, Pennsylvania and to upgrade certain older equipment.

Net cash provided by financing activities was approximately $2.7 million, reflecting the proceeds received from the exercise of stock options of approximately $2.8 million, offset by $169,000 of net loan principal repayments.

In September 2002, we entered into a new $10.9 million credit facility ("New Credit Facility") with Comerica Bank, pursuant to which we refinanced substantially all of our previously outstanding mortgage and term debt and increased our equipment and working capital lines of credit. The New Credit Facility is comprised of an $887,000 mortgage loan, a $3.0 million term loan, a $3.0 million non-revolving equipment line of credit, and a $4.0 million revolving working capital line of credit.

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica's prime rate, and is repayable in fixed monthly principal and interest installments of $7,426 through September 2007, at which time the interest rate and fixed monthly repayment amount will be reset for the remaining 60 monthly installments. The outstanding balance of the loan at December 31, 2002 was $874,186.

The $3.0 million term loan matures in March 2006, bears interest at a fixed rate of 4.99% and is repayable in forty-two consecutive equal monthly principal payments of $71,429, plus interest. The outstanding balance of the loan at December 31, 2002 was $2,785,714.

Under the non-revolving equipment line of credit, we can borrow up to $3.0 million to finance eligible equipment purchases through September 9, 2003. Interest on outstanding borrowings accrues at a rate, selected at our option, equal to Comerica's prime rate, 180-day or 360-day LIBOR plus 2.625%, or the 4-year Treasury Note Rate plus 2.30%, determined at the time of each borrowing. Borrowings are repayable in 48 consecutive, equal monthly principal installments, plus interest. As of December 31, 2002, we had an outstanding balance of approximately $423,658 under this facility consisting of two individual loans of (i) $179,786 with a fixed annual interest rate of 5.07% and (ii) $243,872 with a floating annual interest rate equal to Comerica's prime rate of 4.25% at December 31, 2002. We also had $2,564,356 available for future borrowings under this facility as of December 31, 2002.

Under the revolving working capital line of credit, we can borrow up to $4.0 million to finance working capital and other needs. Interest on outstanding borrowings shall accrue at a rate, selected at our option, equal to Comerica's prime rate less 0.25%, or 30-day LIBOR plus 2.55%, determined at the time of the initial borrowing. Borrowings are repayable by September 9, 2003, with interest payable monthly. We had no outstanding borrowings under this facility at December 31, 2002.

All borrowings under the New Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our manufacturing facility in Bethlehem, Pennsylvania. Borrowings under the equipment and working capital lines of credit are limited to commercially standard percentages of equipment purchases and accounts receivable, respectively. The New Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth and that require that we achieve positive net income for the year ending December 31, 2003 and for each year thereafter. The New Credit Facility also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

In October 2002, we entered into new agreements with bioMérieux, Inc. ("BMX"), which replaced existing agreements between the parties, for the supply by BMX of HIV-1 antigen required to manufacture our oral fluid Western Blot HIV-1 confirmatory test, and for the distribution by BMX of the oral fluid Western Blot product on an exclusive worldwide basis. These agreements have an initial term ending December 31, 2005, which may be extended until December 31, 2007 under certain circumstances. As consideration for BMX entering into the new agreements, we have agreed to pay BMX $750,000 in installments through March 31, 2003.

We have entered into a ten-year facility lease with Tech III Partners, LLC ("Tech Partners"), an entity owned and controlled by two of our executive officers (See "Certain Relationships and Related Transactions," included herein). Under the terms of this operating lease, we began leasing a 48,000 square-foot facility in

October 2002 at a base rent of $780,000 per year, increasing to $852,240 per year, during the initial 10-year term. The base rental may be increased after the fifth year of the initial term in order to reflect changes in the interest rate on debt incurred by Tech Partners to finance construction of the leased facilities. We have not guaranteed any debt incurred by Tech Partners. The lease also provides us with options to renew the lease for an additional five years at a rental rate of $975,360 per year, and to purchase the facility at any time during the initial ten-year term based on a formula set forth in the lease.

The combination of our current cash position and available borrowings under our New Credit Facility is expected to be sufficient to fund our foreseeable operating and capital needs. However, our cash requirements may vary materially from those now planned due to many factors, including, but not limited to, the cost and timing of the expansion of our manufacturing capacity, the progress of our research and development programs, the scope and results of clinical testing, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the time and cost of obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, the timing of commercial launch of new products, market acceptance of new products, competing technological and market developments, the scope and timing of strategic acquisitions, and other factors.

Contractual Obligations and Commercial Commitments. The following sets forth our approximate aggregate obligations at December 31, 2002 for future payments under contracts and other contingent commitments, for the years 2003 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2003**	**2004**	**2005**	**2006**	**2007**	**Thereafter**
Long-term debt(1)	$ 4,475,328	$ 1,065,966	$ 1,073,633	$ 1,077,085	$ 425,817	$ 118,313	$ 714,514
Operating leases(2)	9,357,185	1,467,879	1,460,066	887,585	780,000	783,108	3,978,547
Employment contracts(3)	1,503,780	1,503,780	—	—	—	—	—
Purchase obligations(4)	2,097,460	2,097,460	—	—	—	—	—
Minimum commitments under contracts(5)	1,950,000	300,000	300,000	225,000	225,000	225,000	675,000
Total contractual obligations	$ 19,383,753	$ 6,435,085	$ 2,833,699	$ 2,189,670	$ 1,430,817	$ 1,126,421	$ 5,368,061

(1) Represents principal repayments required under notes payable to our lenders. See Note 8 to the financial statements included herein.
(2) Represents payments required under our operating leases. See Notes 11 and 12 to the financial statements included herein.
(3) Represents salary, retention bonus or severance payments payable under the terms of employment agreements executed by us with certain officers and employees. See Note 11 to the financial statements included herein.
(4) Represents payments required by non-cancelable purchase orders related to inventory, services and capital expenditures. See Note 11 to the financial statements included herein.
(5) Represents payments required pursuant to certain research, licensing and royalty agreements executed by the Company. See Note 11 to the financial statements included herein.

Off-Balance Sheet Arrangements. We do not have any off-balance sheet arrangements, as defined in Item 304(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934, as amended.

Critical Accounting Policies and Estimates

Management's Discussion and Analysis of Financial Condition and Results of Operations discusses our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the

reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to bad debts, inventories, investments, intangible assets, income taxes, revenue recognition, restructuring costs, contingencies, and litigation. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 2 to the financial statements included in Item 15 of this Report. We consider the following accounting estimates, which have been discussed with our Audit Committee, to be most critical in understanding the more complex judgments that are involved in preparing our financial statements and the uncertainties that could impact our results of operations, financial condition, and cash flows.

Revenue Recognition. We follow U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). This bulletin draws on existing accounting rules and provides specific guidance on revenue recognition of up-front non-refundable licensing and development fees. We license certain products or technology to outside third parties, in return for which we receive up-front licensing fees. Some of these fees can be significant. In accordance with SAB 101, we recognize this revenue ratably over the related license period.

We also enter into research and development contracts with corporate, government and/or private entities. These contracts generally provide for payments to us upon achievement of certain research or development milestones. Product development revenues from these contracts are recognized only if the specified milestone is achieved and accepted by the customer and payment from the customer is probable. Any amounts received prior to the performance of product development efforts are recorded as deferred revenues. Recognition of revenue under these contracts can be sporadic, as it is the result of achieving specific research and development milestones. Furthermore, revenue from future milestone payments will not be recognized if the underlying research and development milestone is not achieved.

We recognize product revenues when products are shipped. We do not grant price protection or product return rights to our customers, except for warranty returns. Where a product fails to comply with its limited warranty, we can either replace the product or provide the customer with a refund of the purchase price or credit against future purchases. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred. While such returns have been immaterial in the past, we cannot guarantee that we will continue to experience the same rate of warranty claims as we have in the past. Any significant increase in product warranty claims could have a material adverse impact on our operating results for the period in which the claims occur.

Allowance for Uncollectible Accounts Receivable. Accounts receivable are reduced by an estimated allowance for amounts that may become uncollectible in the future. On an ongoing basis, we perform credit evaluations of our customers and adjust credit limits based upon the customer's payment history and creditworthiness, as determined by a review of their current credit information. We also continuously monitor collections and payments from our customers.

Based upon historical experience and any specific customer collection issues that are identified, we use our judgment to establish and evaluate the adequacy of our allowance for estimated credit losses, which was $292,146 at December 31, 2002. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period ($213,188, $5,193 and $4,269 in 2002, 2001 and 2000, respectively). Furthermore, there is no assurance that we will experience credit losses at the same rates as we have in the past. Also, at December 31, 2002, approximately $1.0 million or 19% of our accounts receivable were due from one major customer. Any significant changes in the liquidity or financial position of this customer, or others, could have a material adverse impact on the collectibility of our accounts receivable and future operating results.

Inventories. Our inventories are valued at the lower of cost or market, determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate the carrying value of our inventories and when, in the opinion of management, factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off. We base these decisions on the level of inventories on hand in relation to our estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. During 2002, 2001 and 2000, we wrote-off inventory which had a cost of approximately $1.4 million, $0.6 million and $1.1 million, respectively, as a result of increased scrap levels and product expiration issues. Forecasting product demand can be a complex process, especially for a new product such as our OraQuick® rapid HIV-1 antibody test, which was launched in the United States in November 2002. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of our inventories and reported operating results.

Long-lived and Intangible Assets. Our long-lived assets are comprised of property and equipment and an investment in a nonaffiliated entity, and our intangible assets primarily consist of patents and product rights. Together, these assets have a net book value of approximately $10.6 million or 30% of our total assets at December 31, 2002. Our investment in a privately-held nonaffiliated company is recorded under the cost method of accounting, because we do not have a controlling interest in this company nor do we have the ability to exert significant influence over the operating and financial policies of this investee company. Property and equipment, patents and product rights are amortized on a straight-line basis over their useful lives, which we determine based upon our estimate of the period of time over which each asset will generate revenues. An impairment of long-lived or intangible assets could occur whenever events or changes in circumstances indicate that the net book value of these assets may not be recoverable. Events which could trigger an asset impairment include significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of our use of an asset or in our strategy for our overall business, significant negative industry or economic trends, shortening of product life-cycles or changes in technology, and negative financial performance of our nonaffiliated investee company. If we believe impairment of an asset has occurred, we measure the amount of such impairment by comparing the net book value of the affected assets to the fair value of these assets, which is generally determined based upon the present value of the expected cash flows associated with the use of these assets. If the net book value exceeds the fair value of the impaired assets, we would incur an impairment expense equal to this difference. We currently believe the future cash flows to be received from our long-lived and intangible assets will exceed their book value and, as such, we have not recognized any impairment losses through December 31, 2002. Any unanticipated significant impairment in the future, however, could have a material adverse impact to our balance sheet and future operating results.

Deferred Tax Assets. We have a history of losses, which has generated a sizeable federal tax net operating loss ("NOL") carryforward of approximately $79.6 million as of December 31, 2002. The deferred tax asset associated with these NOLs and other temporary differences is approximately $31.8 million at December 31, 2002. Under generally accepted accounting principles, we are required to record a valuation allowance against our deferred tax asset if it is more likely than not that some portion or all of the deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of taxable income in the future. Due to the size of the NOL carryforward in relation to our history of unprofitable operations, we have not recognized any of our net deferred tax asset. It is possible that we could be profitable in the future at levels which would cause us to conclude that it is more likely than not that we will realize all or a portion of the deferred tax asset. Upon reaching such a conclusion, we would immediately record the estimated net realizable value of the deferred tax asset at that time and would then begin to provide for income taxes at a rate equal to our combined federal and state effective rates, which we believe would approximate 40%. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

Contingencies. In the ordinary course of business, we have entered into various contractual relationships with strategic corporate partners, customers, distributors, research laboratories and universities, licensors,

licensees, suppliers, vendors and other parties. As such, we could be subject to litigation, claims or assessments arising from any or all of these relationships. We account for contingencies such as these in accordance with Statement of Financial Accounting Standards No. 5, "Accounting for Contingencies" ("SFAS 5"). SFAS 5 requires us to record an estimated loss contingency when information available prior to issuance of our financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and the amount of the loss can be reasonably estimated. Accounting for contingencies arising from contractual or legal proceedings requires that we use our best judgment when estimating an accrual related to such contingencies. As additional information becomes known, our accrual for a loss contingency could fluctuate, thereby creating variability in our results of operations from period to period. Likewise, an actual loss arising from a loss contingency which significantly exceeds the amount accrued for in our financial statements could have a material adverse impact on our operating results for the period in which such actual loss becomes known.

Certain Relationships and Related Transactions

We have entered into a commercial lease (the "Lease") with Tech III Partners, LLC ("Tech Partners"), which provided for the construction of a 48,000 square foot facility on land adjacent to our Bethlehem, Pennsylvania headquarters, and the lease of that facility to us. Tech Partners is owned and controlled by Michael J. Gausling, the Company's President and Chief Executive Officer, and Dr. R. Sam Niedbala, the Company's Executive Vice President and Chief Science Officer. The facility will house manufacturing, research and development, and administrative operations required to support the expected growth of our business. Construction of the facility was completed in October 2002.

The Lease, as amended, has an initial ten-year term ending in October 2012 and a base rent starting at $780,000 and increasing to $858,240 per year over that term. The base rental rate may be increased after the fifth year of the initial term in order to reflect changes in the interest rate on debt incurred by Tech Partners to finance construction of the leased facilities. We have not guaranteed any debt incurred by Tech Partners. The Lease also provides us with options to renew the Lease for an additional five years at a rental rate of $975,360 per year, and to purchase the facility at any time during the initial ten-year term based on a formula set forth in the Lease.

Prior to deciding to enter into the Lease and an amendment increasing the base rental to reflect the cost of certain tenant fit-out improvements, our Board of Directors retained Imperial Realty Appraisal LLC, an independent commercial real estate appraisal firm, to evaluate the proposed base rental rate. Imperial Realty issued opinions indicating that the annual base rent set forth in the Lease, as amended, is below the market rental rate we could otherwise expect to pay to lease a comparable commercial property in the same general geographic market. The terms of the Lease are otherwise substantially similar to a commercial lease we entered into with a third party for our existing Bethlehem, Pennsylvania headquarters.

In January 2002, we terminated the employment agreement with Robert D. Thompson, our former Chief Executive Officer, and Mr. Thompson entered into a severance agreement pursuant to which Mr. Thompson will receive approximately $480,000. We also held a $75,000 note receivable previously made to Mr. Thompson in connection with his relocation from Portland, Oregon, which was repaid during 2002.

Recent Accounting Pronouncements

SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143"), which was released in August 2001, addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and their associated asset retirement costs. SFAS 143 requires an enterprise to record the fair value of an asset retirement obligation as a liability in the period in which it incurs a legal obligation associated with the retirement of intangible long-lived assets that result from the acquisition, construction, development, or normal use of the asset. The enterprise is also required to record a corresponding increase to the carrying amount of the related long-lived asset (i.e. the associated asset retirement cost) and to depreciate that

cost over the life of the asset. The liability is changed at the end of each period to reflect the passage of time (i.e. accretion expense) and changes in the estimated future cash flows underlying the initial fair value measurement. Because of the extensive use of estimates, most enterprises will record a gain or loss when they settle the obligation. We are required to adopt SFAS 143 for our fiscal year beginning January 1, 2003. We do not expect the adoption of SFAS 143 to have a material impact on our financial position or results of operations.

In April 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections" ("SFAS 145"). SFAS 145 amends existing guidance on reporting gains and losses on the extinguishment of debt to prohibit the classification of the gain or loss as extraordinary, as the use of such extinguishments have become part of the risk management strategy of many companies. SFAS 145 also amends SFAS 13 to require sale-leaseback accounting for certain lease modifications that have economic effects similar to sale-leaseback transactions. The provisions of SFAS 145 related to the rescission of SFAS 4 are applied in fiscal years beginning after May 15, 2002. Earlier application of these provisions is encouraged. The provisions of SFAS 145 related to SFAS 13 were effective for transactions occurring after May 15, 2002. The adoption of SFAS 145 is not expected to have a material effect on our financial statements.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). SFAS 146 addresses significant issues regarding the recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities. SFAS 146 also addresses recognition of certain costs related to terminating a contract that is not a capital lease, costs to consolidate facilities or relocate employees, and termination benefits provided to employees that are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract. SFAS 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 is not expected to have any impact on our financial position or results of operations.

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others, an interpretation of FASB Statements No. 5, 57 and 107 and a rescission of FASB Interpretation No. 34." This Interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees issued. The Interpretation also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of the Interpretation are applicable to guarantees issued or modified after December 31, 2002, and are not expected to have a material effect on our financial statements.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure ("SFAS 148"), an amendment of FASB Statement No. 123." SFAS 148 amends SFAS 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of Statement 123 to require prominent disclosures in both annual and interim financial statements. The disclosure modifications are required for fiscal years ending after December 15, 2002, and are included in the notes to our financial statements.

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities, an interpretation of ARB No. 51." This Interpretation addresses the consolidation by business enterprises of variable interest entities as defined in the Interpretation. The Interpretation applies immediately to variable interests in variable interest entities created after January 31, 2003, and to variable interests in variable interest entities obtained after January 31, 2003. Because we have no involvement with any variable interest entities, the application of this Interpretation is not expected to have a material effect on our financial statements.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk.

We do not hold any amounts of derivative financial instruments or derivative commodity instruments. Therefore, we have no material market risk related to derivatives to report under this Item.

Our holdings of financial instruments are comprised of U.S. corporate debt, certificates of deposit, government securities, and commercial paper. All such instruments are classified as securities available for sale. Our debt security portfolio represents funds held temporarily pending use in our business and operations. We seek reasonable assuredness of the safety of principal and market liquidity by investing in rated fixed income securities while at the same time seeking to achieve a favorable rate of return. Market risk exposure consists principally of exposure to changes in interest rates. If changes in interest rates would affect the investments adversely, we could decide to hold the security to maturity or sell the security. Our holdings are also exposed to the risks of changes in the credit quality of issuers. We typically invest in the shorter end of the maturity spectrum.

We do not currently have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in The Netherlands which are subject to foreign currency fluctuations. As currency rates change, translation of income statements of these operations from Euros to U.S. dollars affects year-to-year comparability of operating results. Our operations in The Netherlands represented approximately $1.7 million or 5% of our revenues for the year ended December 31, 2002. We do not expect the risk of foreign currency fluctuations to be material.

ITEM 8. Financial Statements and Supplementary Data.

Information with respect to this Item is contained in our Financial Statements included in Item 15 of this Annual Report on Form 10-K.

Arthur Andersen LLP (“Andersen”) audited the Company’s financial statements as of December 31, 2001 and for each of the years in the two-year period ended December 31, 2001 included in this Report. Because our former engagement team leaders have since left Andersen, Andersen did not reissue its report on those financial statements, and a copy of a previously issued report is included herein. Andersen has not consented to the use of such report or to any reference made to their firm in this Report. Andersen was convicted on June 15, 2002 of federal obstruction of justice arising from the government’s investigation of Enron Corp. You may have no effective remedy against Andersen in connection with a material misstatement or omission in the financial statements audited by Andersen, particularly in the event that Andersen ceases to exist or becomes insolvent as a result of the conviction or other proceedings against Andersen.

Additionally, as a result of the departure of our former engagement team leaders, Andersen is no longer in a position to consent to the inclusion or incorporation by reference in any prospectus of their report on the above-referenced financial statements, and investors in any offerings for which the Company uses their audit report will not be entitled to recovery against them under Section 11 of the Securities Act of 1933, as amended, for any material misstatements or omissions in those financial statements.

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

On May 21, 2002, we dismissed Arthur Andersen LLP and retained KPMG LLP as our independent accountants. Disclosure of this action is set forth in our Current Report on Form 8-K dated May 21, 2002.

PART III

We have omitted from Part III the information that will appear in our Definitive Proxy Statement for our 2003 Annual Meeting of Stockholders (the "Proxy Statement"), which will be filed within 120 days after the end of our fiscal year pursuant to Regulation 14A.

ITEM 10. Directors and Executive Officers of the Registrant.

The information required by this item is incorporated by reference to the information under the captions, "Election of Directors," "Executive Officers," and "Section 16(a) Beneficial Ownership Reporting Compliance," in the Proxy Statement.

ITEM 11. Executive Compensation.

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

ITEM 12. Security Ownership of Certain Beneficial Owners and Management.

The information required by this item with respect to the securities ownership of certain beneficial owners and management, and equity compensation plan information, is incorporated by reference to the information under the captions, "Principal Stockholders" and "Equity Compensation Plan Information," respectively, in the Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions.

The information required by this item is incorporated by reference to the information under the captions, "Certain Relationships and Related Transactions" and "Employment Agreements," in the Proxy Statement.

ITEM 14. Controls and Procedures.

(a) *Evaluation of Disclosure Controls and Procedures*. Within the 90 days preceding the filing of this Report, an evaluation was performed under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company, which is required to be included in its periodic filings with the Securities and Exchange Commission.

(b) *Changes in Internal Controls*. There have been no significant changes in the Company's internal controls or in other factors that could significantly affect internal controls (including any corrective actions with regard to significant deficiencies or material weaknesses) subsequent to the date of the evaluation referred to in paragraph (a) of this Item.

PART IV

ITEM 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.

(a)(1) and (a)(2). For a list of the Financial Statements filed herewith, see the Index to Financial Statements following the signature page to this Report. No schedules are included with the Financial Statements because the required information is inapplicable or is presented in the Financial Statements or related notes thereto.

(a)(3) *Exhibits*. See Index to Exhibits following the Financial Statements in this Report.

(b) *Reports on Form 8-K.*

1. Current Report on Form 8-K dated November 7, 2002, attaching a press release that announced the receipt of U.S. Food and Drug Administration approval of our OraQuick® Rapid HIV-1 Antibody Test for the detection of HIV-1 in finger-stick whole blood samples.

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, on March 31, 2003.

ORASURE TECHNOLOGIES, INC.

By: /s/ MICHAEL J. GAUSLING

Michael J. Gausling
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on March 31, 2003, by the following persons on behalf of the Registrant and in the capacities indicated.

Signature	Title
/s/ MICHAEL J. GAUSLING	President, Chief Executive Officer and Director
Michael J. Gausling	(Principal Executive Officer)
/s/ RONALD H. SPAIR	Executive Vice President and Chief Financial Officer
Ronald H. Spair	(Principal Financial Officer)
/s/ MARK L. KUNA	Vice President and Controller
Mark L. Kuna	(Principal Accounting Officer)
/s/ *CARTER H. ECKERT	Director
Carter H. Eckert	
/s/ *FRANK G. HAUSMANN	Director
Frank G. Hausmann	
/s/ *RICHARD J. LANE	Director
Richard J. Lane	
/s/ *GREGORY B. LAWLESS	Director
Gregory B. Lawless	
/s/ *ROGER L. PRINGLE	Director
Roger L. Pringle	
/s/ *DOUGLAS G. WATSON	Director
Douglas G. Watson	

*By: /s/ RONALD H. SPAIR

Ronald H. Spair
(Attorney-in-Fact)

Certification

I, Michael J. Gausling, certify that:

1. I have reviewed this annual report on Form 10-K of OraSure Technologies, Inc;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
   a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
   c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/s/ MICHAEL J. GAUSLING

Michael J. Gausling
President and Chief Executive Officer
(Principal Executive Officer)

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this annual report on Form 10-K of OraSure Technologies, Inc;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
   a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
   c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses

Date: March 31, 2003

/s/ RONALD H. SPAIR

Ronald H. Spair
Executive Vice President and
Chief Financial Officer
(Principal Financial Officer)

INDEX TO FINANCIAL STATEMENTS

INDEPENDENT AUDITOR'S REPORT

The Board of Directors and Stockholders
OraSure Technologies, Inc.:

We have audited the accompanying balance sheet of OraSure Technologies, Inc. as of December 31, 2002 and the related statements of operations, stockholders' equity and comprehensive loss, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements of OraSure Technologies, Inc. as of December 31, 2001 and for each of the years in the two-year period ended December 31, 2001 were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated January 31, 2002, except for the facility lease discussed in Note 12 as to which the date was March 21, 2002.

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

In our opinion, the 2002 financial statements referred to above present fairly, in all material respects, the financial position of OraSure Technologies, Inc. as of December 31, 2002, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

Philadelphia, Pennsylvania
January 27, 2003

The following is a copy of a report issued by Arthur Andersen LLP and included in the Company's 2001 Annual Report on Form 10-K. This report has not been reissued by Arthur Andersen LLP, and Arthur Andersen LLP has not issued a consent to its use in this filing.

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To OraSure Technologies, Inc.:

We have audited the accompanying balance sheets of OraSure Technologies, Inc. (a Delaware corporation) as of December 31, 2001 and 2000, and the related statements of operations, stockholders' equity and cash flows for the years ended December 31, 2001 and 2000, the three months ended December 31, 1999, and the year ended September 30, 1999. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We did not audit the financial statements of Epitope, Inc., a company acquired during 2000 in a transaction accounted for as a pooling of interests, as discussed in Note 1. Such statements are included in the financial statements of OraSure Technologies, Inc. and reflect total revenues of 39 percent and 42 percent for the three months ended December 31, 1999 and year ended September 30, 1999, respectively, of the related totals. Those statements were audited by other auditors whose report has been furnished to us, and our opinion, insofar as it relates to amounts included for Epitope, Inc., is based solely upon the report of the other auditors.

We conducted our audits in accordance with auditing standards generally accepted in the 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 and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the financial position of OraSure Technologies, Inc. as of December 31, 2001 and 2000, and the results of its operations and its cash flows for the years ended December 31, 2001 and 2000, the three months ended December 31, 1999, and the year ended September 30, 1999, in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Philadelphia, Pennsylvania,
January 31, 2002 (except for the
facility lease discussed in Note 12,
as to which the date is March 21, 2002)

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31, 2002	December 31, 2001
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,364,308	$ 2,426,346
Short-term investments	10,543,876	12,764,903
Accounts receivable, net of allowance for doubtful accounts of $292,146 and $209,492	5,197,787	6,057,927
Note receivable from officer	—	75,000
Inventories	4,088,474	4,444,772
Prepaid expenses and other	925,707	1,038,511
Total current assets	25,120,152	26,807,459
PROPERTY AND EQUIPMENT, net	7,427,950	7,800,137
PATENTS AND PRODUCT RIGHTS, net	2,543,519	2,042,533
OTHER ASSETS	645,626	634,546
	$ 35,737,247	$ 37,284,675
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,065,966	$ 1,057,572
Accounts payable	1,801,952	2,874,061
Accrued expenses	3,321,509	3,111,886
Total current liabilities	6,189,427	7,043,519
LONG-TERM DEBT	3,409,362	3,586,458
OTHER LIABILITIES	119,546	114,025
COMMITMENTS AND CONTINGENCIES (Note 11)		
STOCKHOLDERS' EQUITY:		
Preferred stock, par value $.000001; 25,000,000 shares authorized, none issued	—	—
Common stock, par value $.000001; 120,000,000 shares authorized, 38,100,557 and 37,403,269 shares issued and outstanding	38	37
Additional paid-in capital	155,638,314	152,758,591
Accumulated other comprehensive loss	(184,676)	(125,664)
Accumulated deficit	(129,434,764)	(126,092,291)
Total stockholders' equity	26,018,912	26,540,673
	$ 35,737,247	$ 37,284,675

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS

	For the year ended December 31,		
	2002	2001	2000
REVENUES:			
Product	$ 31,691,495	$ 31,095,850	$ 28,095,408
Licensing and product development	318,272	1,477,494	692,808
	32,009,767	32,573,344	28,788,216
COST OF PRODUCTS SOLD	12,888,556	12,333,695	11,102,096
Gross profit	19,121,211	20,239,649	17,686,120
OPERATING EXPENSES:			
Research and development	8,274,351	9,389,313	10,399,120
Sales and marketing	8,068,879	7,980,496	6,932,068
General and administrative	6,318,513	6,752,326	6,876,516
Merger-related	—	—	7,607,158
Restructuring-related	—	450,000	—
	22,661,743	24,572,135	31,814,862
Operating loss	(3,540,532)	(4,332,486)	(14,128,742)
INTEREST EXPENSE	(284,678)	(402,686)	(490,415)
INTEREST INCOME	483,431	933,050	1,315,666
FOREIGN CURRENCY GAIN (LOSS)	(694)	3,122	(18,696)
GAIN ON SALE OF SECURITIES	—	100,000	600,000
Loss before income taxes	(3,342,473)	(3,699,000)	(12,722,187)
INCOME TAXES	—	28,789	24,363
NET LOSS	$ (3,342,473)	$ (3,727,789)	$ (12,746,550)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.09)	$ (0.10)	$ (0.36)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	37,582,780	36,868,101	35,002,283

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
Balance at December 31, 1999	32,632,911	$ 33	$ 128,115,489	$ (259,218)	$ (109,617,952)	$ 18,238,352
Common stock issued upon exercise of options	1,319,624	1	5,720,997	—	—	5,720,998
Common stock issued upon exercise of warrants	2,405,907	2	13,865,364	—	—	13,865,366
Common stock issued under Employee Stock Purchase Plan and Savings Plan	75,562	—	273,254	—	—	273,254
Compensation expense for stock option grants	—	—	792,685	—	—	792,685
Comprehensive loss:						
Net loss	—	—	—	—	(12,746,550)	(12,746,550)
Currency translation adjustment	—	—	—	(61,140)	—	(61,140)
Net unrealized gain on marketable securities	—	—	—	89,111	—	89,111
Total comprehensive loss						(12,718,579)
Balance at December 31, 2000	36,434,004	36	148,767,789	(231,247)	(122,364,502)	26,172,076
Common stock issued upon exercise of options	968,729	1	3,851,805	—	—	3,851,806
Common stock issued under Employee Stock Purchase Plan	536	—	2,123	—	—	2,123
Compensation expense for stock option grants	—	—	136,874	—	—	136,874
Comprehensive loss:						
Net loss	—	—	—	—	(3,727,789)	(3,727,789)
Currency translation adjustment	—	—	—	(75,670)	—	(75,670)
Net unrealized gain on marketable securities	—	—	—	181,253	—	181,253
Total comprehensive loss						(3,622,206)
Balance at December 31, 2001	37,403,269	37	152,758,591	(125,664)	(126,092,291)	26,540,673
Common stock issued upon exercise of options	688,454	1	2,793,742	—	—	2,793,743
Common stock issued under Employee Stock Purchase Plan	8,834	—	35,042	—	—	35,042
Compensation expense for stock option grants	—	—	50,939	—	—	50,939
Comprehensive loss:						
Net loss	—	—	—	—	(3,342,473)	(3,342,473)
Currency translation adjustment	—	—	—	(6,481)	—	(6,481)
Net unrealized loss on marketable securities	—	—	—	(52,531)	—	(52,531)
Total comprehensive loss						(3,401,485)
Balance at December 31, 2002	38,100,557	$ 38	$ 155,638,314	$ (184,676)	$ (129,434,764)	$ 26,018,912

The accompanying notes are an integral part of these statements

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

	For the year ended December 31,		
	2002	**2001**	**2000**
OPERATING ACTIVITIES:			
Net loss	$ (3,342,473)	$ (3,727,789)	$ (12,746,550)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock based compensation expense	50,939	136,874	792,685
Common stock issued as compensation for services	—	—	62,409
Amortization of deferred revenue	(107,500)	(179,167)	(143,334)
Depreciation and amortization	2,286,682	2,175,055	2,243,001
Gain on sale of securities and disposition of investment in affiliated company	—	(116,853)	(600,000)
Loss on disposition of property and equipment	2,553	173,975	10,844
Provision for excess and obsolete inventories	1,373,614	600,000	1,141,351
Changes in assets and liabilities-			
Accounts receivable	860,140	(1,118,408)	(1,853,514)
Notes receivable	75,000	100,649	
Inventories	(1,017,316)	(3,549,168)	(231,516)
Prepaid expenses and other	112,804	75,180	(153,631)
Accounts payable	(884,594)	443,050	308,789
Accrued expenses and other	72,644	(269,248)	1,125,020
Net cash used in operating activities	(517,507)	(5,255,850)	(10,044,446)
INVESTING ACTIVITIES:			
Purchases of property and equipment	(1,649,129)	(2,763,639)	(3,071,565)
Proceeds from the sale of property and equipment	2,393	33,231	—
Purchase of patents, licenses and product rights	(700,000)	—	(619,589)
Purchase of short-term investments	(9,306,439)	(21,297,303)	(24,869,468)
Proceeds from sale of short-term investments	11,474,935	23,420,432	22,339,595
Proceeds from sale of securities	—	637,500	600,000
Proceeds from disposition of investment in affiliated company	—	106,102	—
Investment in affiliated companies	—	—	(20,404)
(Increase) decrease in other assets	(52,660)	(202,819)	50,000
Net cash used in investing activities	(230,900)	(66,496)	(5,591,431)
FINANCING ACTIVITIES:			
Borrowings of term debt	4,322,854	—	—
Repayment of term debt	(4,491,556)	(1,125,206)	(1,054,194)
Net proceeds from issuance of common stock	2,828,785	3,853,929	19,797,206
Net cash provided by financing activities	2,660,083	2,728,723	18,743,012
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	26,286	(75,670)	(61,140)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,937,962	(2,669,293)	3,045,995
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	2,426,346	5,095,639	2,049,644
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 4,364,308	$ 2,426,346	$ 5,095,639

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

NOTES TO THE FINANCIAL STATEMENTS

1. BACKGROUND:

The Company

We develop, manufacture and market oral specimen collection devices using our proprietary oral fluid technologies, diagnostic products including *in vitro* diagnostic tests, and other medical devices. These products are sold in the United States and certain foreign countries to various distributors, government agencies, clinical laboratories, physicians' offices, hospitals, and commercial and industrial entities.

Merger

On September 29, 2000, STC Technologies, Inc. ("STC") and Epitope, Inc. ("Epitope") were merged (the "Merger") into OraSure Technologies, Inc., a newly formed company, incorporated under Delaware law solely for the purposes of combining the two companies and changing the state of incorporation of Epitope from Oregon to Delaware. The Merger was accounted for as a pooling of interests. There were no material adjustments required to conform the accounting policies of the two companies. In connection with the Merger, during the year ended December 31, 2000, we recorded merger-related expenses of $7.6 million, which were comprised of the following:

Cash costs:	
Transaction costs	$5,273,748
Employee costs	1,079,607
Other integration costs	608,393
Subtotal	6,961,748
Stock-based compensation	645,410
Total Merger-related expenses	$7,607,158

Transaction costs include investment banking, legal, accounting, printing and other direct costs of the Merger. Employee costs represent severance benefits paid to terminated employees whose responsibilities were deemed redundant as a result of the Merger, as well as certain relocation expenses. Other integration costs include financial system conversion costs and integration-related travel expenses. Stock-based compensation represents the amount of unamortized deferred compensation on certain nonqualified options granted by Epitope in prior years, which were immediately accelerated upon the closing of the Merger under the terms of the grants.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Use of Estimates

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

Cash and Cash Equivalents

We consider all highly liquid investments purchased with a purchased maturity of ninety days or less to be cash equivalents. As of December 31, 2002 and 2001, cash equivalents consisted of certificates of deposit, commercial paper and U.S. government and agency obligations.

Short-term Investments

We consider all short-term investments as available-for-sale securities, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are comprised of certificates of deposits, commercial paper, U.S. government and agency obligations and corporate bonds with original maturities greater than ninety days and less than one year. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses reported in stockholders' equity as a component of accumulated other comprehensive loss.

The following is a summary of our available-for-sale securities at December 31, 2002 and 2001:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2002				
Certificates of deposit	$ 3,581,734	$ —	$ —	$ 3,581,734
Commercial paper	399,017	88	—	399,105
Government and agency bonds	1,974,734	—	(3,321)	1,971,413
Corporate bonds	4,570,558	22,041	(975)	4,591,624
Total available-for-sale securities	$10,526,043	$ 22,129	$ (4,296)	$10,543,876
December 31, 2001				
Certificates of deposit	$ 2,398,963	$ 709	$ —	$ 2,399,672
Government and agency bonds	5,027,637	70,200	—	5,097,837
Corporate bonds	5,267,939	37,109	(37,654)	5,267,394
Total available-for-sale securities	$12,694,539	$ 108,018	$ (37,654)	$12,764,903

Supplemental Cash Flow Information

For 2002, 2001 and 2000, we paid interest of $268,340, $402,686 and $490,410, respectively.

For 2002, 2001 and 2000, we recorded provisions for bad debts of $295,842, $100,000, and $0, respectively. We had deductions of $213,188, $5,193 and $4,269 against the allowance for doubtful accounts in 2002, 2001 and 2000, respectively.

During 2001, the Company exchanged $337,253 of accounts receivable for an investment in a nonaffiliated entity.

Inventories

Inventories are stated at the lower of cost or market determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate quantities on hand and the carrying value of our inventories to determine the need for reserves for excess and obsolete inventories, based primarily on the estimated forecast of product sales. When factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off, as in the case of lapsing expiration dates. We currently buy our entire Histofreezer® product line from a foreign vendor, with such purchases payable in Euros. Changes in the exchange rate of the Euro could impact our product cost.

Property and Equipment

Property and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method

over the estimated useful lives of the related assets or the lease term, whichever is shorter. Buildings are depreciated over 20 years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over three to ten years. Leasehold improvements are generally amortized over the shorter of the estimated useful lives or the terms of the related leases. When assets are sold or otherwise disposed of, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the statement of operations.

Patents and Product Rights

Patents and product rights consist of costs associated with the acquisition of patents and product distribution rights and direct costs associated with patent submissions. Patents and product rights are amortized using the straight-line method over estimated useful lives of five to ten years. Amortization expense for 2002, 2001 and 2000 was $416,247, $359,853 and $816,111, respectively.

Other Assets

Included in other assets is a $337,253 investment, representing a 9.4% ownership interest in a privately-held nonaffiliated company. We do not have a controlling interest in this company, nor do we have an ownership or voting interest which allows us to exert significant influence over the operating and financial policies of this investee company. Accordingly, we have accounted for this investment using the cost method of accounting.

Impairment of Long-Lived Assets

In accordance with SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets”, if indicators of impairment exist, we assess the recoverability of the affected long-lived assets, which include property and equipment, patents and product rights, by determining whether the carrying value of such assets can be recovered through the sum of the undiscounted future operating cash flows and eventual disposition of the asset. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the assets to the fair value of these assets, generally determined based on the present value of the expected future cash flows associated with the use of the asset. We believe the future cash flows to be received from our long-lived assets will exceed the assets’ carrying value, and accordingly we have not recognized any impairment losses through December 31, 2002.

Revenue Recognition

We recognize product revenues when products are shipped. We do not grant price protection or product return rights to our customers, except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

We follow U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101 “Revenue Recognition in Financial Statements” (“SAB 101”). The bulletin draws on existing accounting rules and provides specific guidance on revenue recognition of up-front non-refundable licensing and development fees. In accordance with SAB 101, up-front licensing fees are deferred and recognized ratably over the related license period. Product development revenues are recognized over the period in which the related product development efforts are performed. Amounts received prior to the performance of product development efforts are recorded as deferred revenues. Grant revenue is recognized as the related work is performed and costs are incurred.

In accordance with Emerging Issues Task Force (“EITF”) Issue No. 00-10, “Accounting for Shipping and Handling Fees and Costs,” we record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold.

Significant Customer Concentration

In 2002, 2001 and 2000, one customer accounted for approximately 26 percent, 29 percent and 30 percent, respectively, of our total revenues. The same customer accounted for approximately 19 percent and 21 percent of accounts receivable as of December 31, 2002 and 2001, respectively.

Research and Development

Research and development costs are charged to expense as incurred.

Restructuring-related Expenses

In February 2001, we announced plans to restructure certain of our manufacturing operations. As a result of this restructuring, we incurred an infrequent charge of $450,000 for restructuring costs, primarily comprised of expenses for employee severance, travel and transport resulting from relocating and consolidating manufacturing operations. All restructuring-related expenses were paid by June 30, 2001.

Stock-Based Compensation

We account for stock-based compensation to employees and directors using the intrinsic value method in accordance with APB Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations. We account for stock-based compensation to nonemployees using the fair value method in accordance with SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123") and EITF Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring or in Conjunction with Selling, Goods or Services."

We have elected to adopt the disclosure provisions of SFAS 123, as amended by SFAS 148 "Accounting for Stock-Based Compensation — Transition and Disclosure" ("SFAS 148"). Under SFAS 123, compensation expense related to stock options granted to employees and directors is computed based on the fair value of the stock option at the date of grant using an option valuation methodology, typically the Black-Scholes option pricing model. Pursuant to the disclosure requirements of SFAS 123, had compensation expense for our common stock option plan been determined based upon the fair value of the options at the date of grant, our net loss for 2002, 2001 and 2000 would have increased as follows:

	Year ended December 31,		
	2002	2001	2000
Net loss:			
As reported	$ (3,342,473)	$ (3,727,789)	$ (12,746,550)
Add: stock-based employee compensation expense included in net loss	—	—	792,685
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards	(3,359,281)	(2,913,149)	(5,657,257)
Pro forma	$ (6,701,754)	$ (6,640,938)	$ (17,611,122)
Basic and diluted net loss per share:			
As reported	$ (0.09)	$ (0.10)	$ (0.36)
Pro forma	$ (0.18)	$ (0.18)	$ (0.50)

Income Taxes

We follow SFAS No. 109, "Accounting for Income Taxes", pursuant to which the liability method is used in accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future

tax consequences of operating loss and credit carryforwards and differences between the financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates that are expected to be in effect when the items reverse.

Foreign Currency Translation

Pursuant to SFAS No. 52, "Foreign Currency Translation," the assets and liabilities of our foreign operations are translated from Euros into U.S. dollars at current exchange rates as of the balance sheet date, and revenues and expenses are translated at average exchange rates for the period. Resulting translation adjustments are reflected as a separate component of stockholders' equity.

Gain on Sale of Securities

In December 2001, we recognized a gain of $100,000 on the sale of 50,000 shares of Lab*One*, Inc. common stock received in connection with a distribution agreement we entered into with Lab*One*, Inc. in April 1999. Our original investment associated with these shares was $537,500. We no longer hold any common shares or warrants of Lab*One*, Inc.

In December 1996, a former subsidiary of ours completed a merger with Andrew and Williamson Sales, Co. ("A&W"), which was rescinded in May 1997. We received A&W preferred stock in the recission, which had been carried at zero value due to the circumstances surrounding A&W's financial condition at the time the stock was received in 1997. In 2000, we sold the A&W preferred stock for $600,000.

Net Loss Per Common Share

We have presented basic and diluted net loss per share pursuant to SFAS No. 128, "Earnings per Share" ("SFAS 128"). In accordance with SFAS 128, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is generally computed assuming the conversion or exercise of all dilutive securities such as common stock options and warrants; however, outstanding common stock options and warrants to purchase 3,999,608, 3,915,233 and 4,677,357 shares were excluded from the computation of diluted net loss per common share for 2002, 2001 and 2000, respectively, because they were anti-dilutive due to our losses.

Other Comprehensive Income (Loss)

We follow SFAS No. 130, "Reporting Comprehensive Income." This statement requires the classification of items of other comprehensive income (loss) by their nature and disclosure of the accumulated balance of other comprehensive income (loss), separately from accumulated deficit and additional paid-in capital, in the equity section of our balance sheet.

Fair Value of Financial Instruments

As of December 31, 2002, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, accounts payable, and accrued expenses approximate their respective fair values based on their short-term nature. In addition, we believe the carrying value of our debt instruments, which do not have readily ascertainable market value, approximates their fair values, given that the interest rates on outstanding borrowings approximate market rates.

Recent Accounting Pronouncements

SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143"), which was released in August 2001, addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and their associated asset retirement costs. SFAS 143 requires an enterprise to record

the fair value of an asset retirement obligation as a liability in the period in which it incurs a legal obligation associated with the retirement of intangible long-lived assets that result from the acquisition, construction, development, or normal use of the asset. The enterprise is also required to record a corresponding increase to the carrying amount of the related long-lived asset (i.e. the associated asset retirement cost) and to depreciate that cost over the life of the asset. The liability is changed at the end of each period to reflect the passage of time (i.e. accretion expense) and changes in the estimated future cash flows underlying the initial fair value measurement. Because of the extensive use of estimates, most enterprises will record a gain or loss when they settle the obligation. We are required to adopt SFAS 143 for our fiscal year beginning January 1, 2003. We do not expect the adoption of SFAS 143 to have a material impact on our financial position or results of operations.

In April 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections" ("SFAS 145"). SFAS 145 amends existing guidance on reporting gains and losses on the extinguishment of debt to prohibit the classification of the gain or loss as extraordinary, as the use of such extinguishments have become part of the risk management strategy of many companies. SFAS 145 also amends SFAS 13 to require sale-leaseback accounting for certain lease modifications that have economic effects similar to sale-leaseback transactions. The provisions of SFAS 145 related to the rescission of SFAS 4 are applied in fiscal years beginning after May 15, 2002. Earlier application of these provisions is encouraged. The provisions of SFAS 145 related to SFAS 13 were effective for transactions occurring after May 15, 2002. The adoption of SFAS 145 is not expected to have a material effect on our financial statements.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). SFAS 146 addresses significant issues regarding the recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities. SFAS 146 also addresses recognition of certain costs related to terminating a contract that is not a capital lease, costs to consolidate facilities or relocate employees, and termination benefits provided to employees that are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract. SFAS 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 is not expected to have any impact on our financial position or results of operations.

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others, an interpretation of FASB Statements No. 5, 57 and 107 and a rescission of FASB Interpretation No. 34." This Interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees issued. The Interpretation also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of the Interpretation are applicable to guarantees issued or modified after December 31, 2002, and are not expected to have a material effect on our financial statements.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure, an amendment of FASB Statement No. 123" ("SFAS 148"). SFAS 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements. The disclosure modifications are required for fiscal years ending after December 15, 2002, and are included in the notes to our financial statements.

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities, an interpretation of ARB No. 51." This Interpretation addresses the consolidation by business enterprises of variable interest entities as defined in the Interpretation. The Interpretation applies immediately to variable interests in

variable interest entities created after January 31, 2003, and to variable interests in variable interest entities obtained after January 31, 2003. Because we have no involvement with any variable interest entities, the application of this Interpretation is not expected to have a material effect on our financial statements.

Reclassifications

Certain amounts from prior periods have been reclassified to conform to the current year presentations.

3. INVENTORIES:

	December 31,	
	2002	2001
Raw materials	$ 2,787,967	$ 2,918,825
Work in process	430,977	644,397
Finished goods	869,530	881,550
	$ 4,088,474	$ 4,444,772

4. PROPERTY AND EQUIPMENT:

	December 31,	
	2002	2001
Building and leasehold improvements	$ 5,893,702	$ 5,464,353
Machinery and equipment	10,104,511	9,935,897
Computer equipment	2,314,015	2,131,606
Furniture and fixtures	1,442,644	1,205,750
Construction in progress	656,061	698,675
	20,410,933	19,436,281
Less—Accumulated depreciation and amortization	(12,982,983)	(11,636,144)
	$ 7,427,950	$ 7,800,137

Depreciation expense was $1,828,855, $1,815,202 and $1,426,890 for 2002, 2001 and 2000, respectively.

5. PATENTS AND PRODUCT RIGHTS:

In June 1998, we acquired the patents and exclusive worldwide distribution rights to our Histofreezer® product. The purchase price of $2,548,690, including transaction costs, has been recorded as patents and product rights and is being amortized using the straight-line method over an estimated useful life of ten years. In connection with this acquisition, we also entered into a product purchase agreement with the manufacturer of the Histofreezer® product, with an initial term extending through December 31, 2006.

In October 2002, we entered into new supply and distribution agreements with bioMérieux, Inc. (“BMX”), which replaced existing agreements between the parties, for the supply by BMX of HIV-1 antigen required to manufacture our oral fluid Western Blot HIV-1 confirmatory test and for the distribution by BMX of the oral fluid Western Blot product on an exclusive worldwide basis. These agreements have an initial term ending December 31, 2005, which may be extended until December 31, 2007 under certain circumstances. As consideration for BMX entering into the new agreements, we agreed to pay BMX $750,000, of which $250,000 is included in our accompanying balance sheet at December 31, 2002 in accrued expenses and will be paid in March 2003. We recorded the $750,000 as additional Patent and Product Rights on our balance sheet and are amortizing this amount through December 2005, the initial term of the agreements.

6. ACCRUED EXPENSES:

	December 31,	
	2002	2001
Payroll and related benefits	$ 1,387,834	$ 1,728,651
Laboratory testing fees	531,921	278,305
Professional fees	296,162	271,112
Deferred revenue	316,139	401,060
Other	789,453	432,758
	$ 3,321,509	$ 3,111,886

7. CREDIT FACILITIES:

In September 2002, we entered into a new $10.9 million credit facility (“New Credit Facility”) with a new bank, pursuant to which we refinanced substantially all of our previously outstanding mortgage and term debt and increased our equipment and working capital lines of credit. The New Credit Facility is comprised of an $887,000 mortgage loan, a $3.0 million term loan, a $3.0 million non-revolving equipment line of credit and a $4.0 million revolving working capital line of credit (see Note 8).

Under the non-revolving equipment line of credit, we can borrow up to $3.0 million to finance eligible equipment purchases through September 9, 2003. Interest on outstanding borrowings accrues at a rate, selected at our option, equal to the bank’s prime rate, 180-day or 360-day LIBOR plus 2.625%, or the 4-year Treasury Note rate plus 2.30%, determined at the time of each borrowing. Borrowings are repayable in 48 consecutive, equal monthly principal installments, plus interest. As of December 31, 2002, we had $2,564,356 available for future borrowings under the non-revolving equipment line of credit.

Under the revolving working capital line of credit, we can borrow up to $4.0 million to finance working capital and other needs. Interest on outstanding borrowings shall accrue at a rate, selected at our option, equal to the bank’s prime rate less 0.25%, or 30-day LIBOR plus 2.55%, determined at the time of the initial borrowing. Borrowings are repayable by September 9, 2003, with interest payable monthly. We had no outstanding borrowings under this facility at December 31, 2002.

All borrowings under the New Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our manufacturing facility in Bethlehem, Pennsylvania. Borrowings under the equipment and working capital lines of credit are limited to commercially standard percentages of equipment purchases and accounts receivable, respectively. The New Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth and that require us to achieve positive net income for the year ending December 31, 2003 and for each year thereafter. The New Credit Facility also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of the bank.

8. LONG-TERM DEBT:

	December 31, 2002	December 31, 2001
Term loan payable to bank, interest at 4.99%, monthly principal installments of $71,429, plus interest, through March 2006, secured by a first priority security interest in all of our assets.	$ 2,785,714	$ —
Mortgage loan payable to bank, interest at an annual floating rate equal to the bank's prime rate (4.25% at December 31, 2002), fixed monthly installments of principal and interest of $7,426 through September 2007, at which time the interest rate and fixed monthly repayment amount is reset for the remaining sixty monthly installments, secured by our building.	874,186	—
Note payable to bank, interest at an annual floating rate equal to the bank's prime rate (4.25% at December 31, 2002), monthly principal installments of $5,081, plus interest, through December 2006, secured by certain equipment.	243,872	—
Note payable to bank, interest at 5.07%, monthly principal installments of $3,995, plus interest, through September 2006, secured by certain equipment.	179,786	—
Note payable to Pennsylvania Industrial Development Authority, interest at 2%, monthly installments of principal and interest of $4,895 through March 2010, secured by a second lien on our building.	391,770	442,285
Notes payable to bank, interest at 8%, refinanced in September 2002.	—	3,987,919
Note payable to bank, interest at 7.75%, monthly installments of principal and interest of $31,271 through July 2002, secured by certain property and equipment, inventory and intangible assets.	—	213,826
	4,475,328	4,644,030
Less—Current portion	(1,065,966)	(1,057,572)
	$ 3,409,362	$ 3,586,458

Long-term debt maturities as of December 31, 2002 are as follows:

2003	$1,065,966
2004	1,073,633
2005	1,077,085
2006	425,817
2007	118,313
Thereafter	714,514
	$4,475,328

These notes payable require, among other items, the maintenance of certain financial covenants (see Note 7).

9. INCOME TAXES:

At December 31, 2002, we had net operating loss carryforwards for federal income tax purposes of approximately $79.6 million that have begun to expire and will continue to expire through 2022. The Tax Reform Act of 1986 contains provisions that may limit the annual amount of net operating loss carryforwards available to be used in any given year in the event of significant changes in ownership. In connection with the Merger, a change in ownership occurred. We believe the annual limitation will not have a material effect on our ability to utilize our loss carryforwards. Given our losses in recent years, we believe a full valuation allowance is needed as of December 31, 2002.

The tax effect of temporary differences as established in accordance with SFAS No. 109 that give rise to deferred income taxes are as follows:

	December 31	
	2002	2001
Deferred tax asset:		
Net operating loss carryforwards	$ 27,358,000	$ 26,949,000
Stock based compensation	—	2,643,000
Accruals and reserves currently not deductible	1,614,000	1,696,000
Patent costs	558,000	445,000
Research and development credit carryforwards	2,252,000	1,850,000
Valuation allowance on deferred tax assets	(31,782,000)	(33,583,000)
	$ —	$ —

10. STOCKHOLDERS' EQUITY:

Stock Options

We grant stock-based awards under the OraSure Technologies, Inc. 2000 Stock Award Plan (the "2000 Plan"). The 2000 Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the 2000 Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards.

Under the terms of the 2000 Plan, qualified incentive stock options for shares of our common stock may be granted to eligible employees, including our officers. To date, options generally have been granted with ten-year exercise periods and an exercise price not less than the fair market value on the date of grant. Options generally vest over four years, with one quarter of the options vesting one year after grant and the remainder vesting on a monthly basis over the next three years. The 2000 Plan also provides that nonqualified options may be granted at a price not less than 75 percent of the fair market value of a share of common stock on the date of grant. The option term and vesting schedule of such awards may either be unlimited or have a specified period in which to vest and be exercised.

We apply APB Opinion No. 25 and the related interpretations in accounting for stock options granted to employees and directors. Accordingly, compensation expense, if any, is recognized for the intrinsic value (the difference between the exercise price and the fair value of our common stock) on the date of grant. Compensation, if any, is deferred and charged to expense over the respective vesting period. In 2000, we issued an executive an option to purchase 375,000 shares of common stock for $4.59 per share. The fair market value of our common stock at the date of issuance was $6.13. We recorded deferred compensation of $577,500 on the date of grant to be amortized over the vesting period of three years. However, the options immediately vested upon the closing of the Merger in accordance with change in control rights contained in the stock option grant. As a result, we recorded $577,500 of compensation expense in 2000 related to these options. We also recorded an additional $215,185 of compensation expense in 2000 due to the amortization of deferred compensation related to other stock options, resulting from the change in control rights provided under the applicable stock option grants.

The weighted average fair value of the options granted during 2002, 2001 and 2000 is estimated at $3.45, $7.10 and $4.96 per share, respectively, using the Black-Scholes option pricing model, with the following assumptions: dividend yield of zero; volatility of 71 percent, 65 percent and 64 percent, respectively; weighted average risk-free interest rate of 2.89 percent, 4.86 percent and 6.13 percent, respectively; and an expected life of 5.0, 7.0 and 4.3 years, respectively.

We account for stock-based compensation to non-employees using the fair value method, in accordance with SFAS No. 123 and EITF No. 96-18. In 2002 and 2001, we recorded compensation expense of $50,939 and

$136,874 related to options to purchase 20,000 shares and 19,000 shares, respectively, of our common stock granted to outside consultants or members of a non-employee advisory board. No such awards were made in 2000. Compensation expense was computed based on the estimated fair value of the stock options at the date of grant, using the Black-Scholes option pricing model.

Information with respect to the options granted under the 2000 Plan and predecessor plans is as follows:

	Shares	Price per Share	Weighted Average Exercise Price per Share
Balance, December 31, 1999	4,369,905	$0.80–$18.17	$ 3.93
Granted	1,596,142	4.59 – 15.03	6.82
Exercised	(1,319,624)	0.80 – 6.00	4.32
Canceled	(139,066)	0.80 – 18.17	3.57
Balance, December 31, 2000	4,507,357	0.80 – 15.03	4.85
Granted	357,000	7.88 – 12.95	10.51
Exercised	(968,729)	0.80 – 9.47	3.98
Canceled	(150,395)	0.80 – 14.81	6.14
Balance, December 31, 2001	3,745,233	0.80 – 15.03	5.57
Granted	1,267,275	3.83 – 7.42	5.74
Exercised	(688,454)	0.80 – 7.09	4.06
Canceled	(444,446)	0.80 – 14.84	6.14
Balance, December 31, 2002	3,879,608	$0.80–$15.03	$ 5.83

At December 31, 2002, 2,218,019 shares were available for future grants under the 2000 Plan. The following table summarizes information about stock options outstanding at December 31, 2002:

	Options outstanding			Options exercisable	
Range of exercise prices	Number outstanding	Weighted average remaining life, in years	Weighted average exercise price	Number exercisable	Weighted average exercise price
$ 0.80–$2.83	485,605	5.99	$ 1.29	368,991	$ 1.45
$ 3.22–$4.17	422,592	14.85	4.05	294,592	4.05
$ 4.18–$4.97	144,994	15.03	4.52	133,994	4.52
$ 5.04	471,573	13.05	5.04	471,573	5.04
$ 5.50–$5.81	35,313	5.15	5.77	35,313	5.77
$ 5.87	880,951	9.08	5.87	110,832	5.87
$ 6.00–$6.87	221,019	7.48	6.73	159,351	6.69
$ 7.09	688,581	7.95	7.09	399,050	7.09
$ 7.42–$10.71	415,980	8.42	9.77	202,097	9.59
$10.92–$15.03	113,000	8.00	12.68	56,123	12.72
	3,879,608	9.60	$ 5.83	2,231,916	$ 5.43

Employee Stock Purchase Plan

In 1993, Epitope's stockholders approved the adoption of the 1993 Employee Stock Purchase Plan ("1993 ESPP"). The 1993 ESPP, as subsequently amended by Epitope's stockholders, covered a maximum of 500,000 shares of common stock for subscription over established offering periods. As a result of the Merger, the 1993 ESPP was adopted and renamed by us. The Compensation Committee of the Board of Directors determines the number of offering periods, the number of shares offered, and the length of each period, provided that no more than three offering periods may be set during any given fiscal year. The purchase price for stock purchased under the 1993 ESPP for each subscription period is the lesser of 85 percent of the fair market value of a share of

common stock at the commencement of the subscription period and the fair market value at the close of the subscription period. An employee may also elect to withdraw at any time during the subscription period and receive the amounts paid plus interest at the rate of 6 percent.

As of December 31, 2002 and 2001, 0 and 8,834 shares of common stock, respectively, were subscribed for through one offering. These shares may be purchased over 24 months at an initial subscription price of $3.96. During the years ended December 31, 2002, 2001 and 2000, 8,834, 536 and 70,253 shares, respectively, were issued at prices ranging from $2.74 to $4.78 per share under the 1993 ESPP.

Common Stock Warrants

As of December 31, 2002, warrants to purchase 120,000 shares of common stock at $6.13 per share were outstanding. These warrants were issued on September 30, 1998 and expire on September 30, 2008.

11. COMMITMENTS AND CONTINGENCIES:

Phosphor Agreements

In April 1995, we entered into several research, licensing and royalty agreements (collectively the "Phosphor Agreements"), related to development and commercialization of our up-converting phosphor technology ("UPT™"). Under the terms of the Phosphor Agreements, as amended, we are obligated to make an annual license payment of $50,000 and an annual minimum royalty payment of $100,000 for usage of patented technology licensed to us. Upon the first commercial sale of a UPT™-based product or service, we are obligated to pay royalties based upon a percentage of the net sales of UPT™-based products, research and development fees and sublicensing revenues, for a period equal to the longer of ten years from the date of the first commercial sale of a UPT™-based product or service (which occurred in 2001) or the remaining life of the patents underlying the licensed technology, which expire through 2017. Royalties from the commercial sale of products or services can be credited against our minimum royalty obligation of $100,000 per year. In connection with the acquisition of certain technology related to UPT™, we are also required to pay sponsored research funds of $125,000 per year in 2003 and 2004, decreasing to $50,000 per year through 2008, as well as royalties of $25,000 per year, until 2008.

Leases

We lease office, manufacturing, warehouse and laboratory facilities under operating lease agreements. Future payments required under these leases are as follows:

2003	$1,467,879
2004	1,460,066
2005	887,585
2006	780,000
2007	783,108
Thereafter	3,978,547
	$9,357,185

Rent expense for 2002, 2001 and 2000 was $1,070,510, $805,878 and $716,748, respectively.

Purchase Commitments

As of December 31, 2002, we had outstanding non-cancelable purchase commitments in the amount of $2,097,460, of which $688,626, $351,416 and $1,057,418 are related to inventory, services and capital expenditures, respectively.

Employment Agreements

Under terms of employment agreements with certain executive officers and other employees, extending through 2003, we are required to pay each individual a base salary and for some individuals, a retention bonus, for continuing employment with our Company. The agreements require payments of $1,503,780 in 2003, which includes the severance payments discussed below.

In January 2002, we terminated an employment agreement with our former chief executive officer. During the first quarter of 2002, we recorded $480,063 in severance expenses, of which, $215,113 is payable in 2003. These expenses include continued salary and benefit premium payments to this officer, related employment taxes, and the value of certain computer equipment transferred to this individual. We also held a $75,000 note receivable from this officer, which was repaid during 2002.

Litigation

From time-to-time, we are involved in certain legal actions arising in the ordinary course of business. In management's opinion, based upon the advice of counsel, the outcome of such actions are not expected to have a material adverse effect on our future financial position or results of operations.

12. RELATED-PARTY FACILITY LEASE:

We have entered into a ten-year facility lease with Tech III Partners, LLC ("Tech Partners"), an entity owned and controlled by two of our executive officers. Under the terms of this operating lease, we began leasing a 48,000 square foot facility in October 2002, at a base rent of $780,000 per year, increasing to $858,240 per year, during the initial ten-year term. The base rental rate may be increased after the fifth year of the initial term, in order to reflect changes in the debt incurred by Tech Partners to finance construction of the leased facilities. We have not guaranteed any debt incurred by Tech Partners. This lease also provides us with options to renew our lease for an additional five years at a rental rate of $975,360 per year and to purchase the facility at any time during the initial ten year-term, based upon a formula set forth in the lease agreement.

13. RETIREMENT PLANS:

As a result of the Merger, during 2000 and a portion of 2001, we maintained two distinct retirement plans covering substantially all of our employees. Both plans permitted voluntary employee contributions to be excluded from the employees' current taxable income under the provisions of Internal Revenue Code Section 401(k) and the regulations thereunder. Generally, all employees of Epitope were eligible to participate in a profit sharing and deferred savings plan. The plan provided for us to make a matching contribution (either in cash, our common stock, or a combination of both) equal to 50 percent of an employee's contribution, not to exceed 2.5 percent of an employee's compensation. We contributed 5,309 shares valued at $62,409 during 2000 to this plan. Generally, all employees of STC were eligible to participate in a profit sharing plan. The plan provided for us, subject to the Board of Directors' discretion, to match employee contributions up to $3,000 or 8% of a participant's salary, whichever is less. Our contributions to the plan were $75,789 and $122,903 for 2001 and 2000, respectively.

On May 1, 2001, we merged the two aforementioned plans into the OraSure Technologies, Inc. 401(k) Plan (the "New Plan"). The New Plan permits voluntary employee contributions to be excluded from an employee's current taxable income under provisions of Internal Revenue Code Section 401(k) and the regulations thereunder. The New Plan also provides for us to match employee contributions up to the lesser of $4,000 or 10% of the employee's salary. Contributions to the New Plan were $443,280 and $239,402 in 2002 and 2001, respectively.

14. GEOGRAPHIC INFORMATION:

Under the disclosure requirements of SFAS No.131, "Segment Disclosures and Related Information," we operate within one segment, medical devices and products. Our products are sold principally in the United States and Europe. Segmentation of operating income and identifiable assets is not applicable since all of our revenues outside the United States are export sales.

The following table represents total revenues by geographic area (amount in thousands):

	For the year ended December 31,		
	2002	2001	2000
United States	$ 28,124	$ 27,321	$ 24,763
Europe	2,726	3,510	2,507
Other regions	1,160	1,742	1,518
	$ 32,010	$ 32,573	$ 28,788

15. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2002 and 2001. These quarterly results are unaudited, but in the opinion of management, have been prepared on the same basis as our audited financial information and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information set forth herein (all amounts in thousands, except per share amounts).

	2002 Results				
	Three months ended				
	March 31, 2002	June 30, 2002	September 30, 2002	December 31, 2002	Year ended December 31, 2002
Revenues	$ 7,725	$ 7,930	$ 8,107	$ 8,248	$ 32,010
Costs and expenses	9,387	9,285	8,508	8,371	35,551
Operating loss	(1,662)	(1,355)	(401)	(123)	(3,541)
Other income, net	69	74	14	41	198
Net loss	$ (1,593)	$ (1,281)	$ (387)	$ (82)	$ (3,343)
Basic and diluted net loss per share	$ (0.04)	$ (0.03)	$ (0.01)	$ (0.00)	$ (0.09)
Weighted average number of shares outstanding	37,434	37,494	37,536	37,863	37,583

	2001 Results				
	Three months ended				
	March 31, 2001	June 30, 2001	September 30, 2001	December 31, 2001	Year ended December 31, 2001
Revenues	$ 7,404	$ 8,508	$ 8,598	$ 8,063	$ 32,573
Costs and expenses	8,636	9,105	8,609	10,556	36,906
Operating loss	(1,232)	(597)	(11)	(2,493)	(4,333)
Other income, net	251	159	26	198	634
Income (loss) before income taxes	(981)	(438)	15	(2,295)	(3,699)
Income taxes (benefit)	16	6	(1)	8	29
Net income (loss)	$ (997)	$ (444)	$ 16	$ (2,303)	$ (3,728)
Basic and diluted net loss per share	$ (0.03)	$ (0.01)	$ 0.00	$ (0.06)	$ (0.10)
Weighted average number of shares outstanding	36,457	36,702	39,009	37,246	36,868

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INDEX TO EXHIBITS

Exhibit Number	Exhibit
2.1	Agreement and Plan of Merger, dated as of May 6, 2000, by and among Epitope, Inc., the Company and STC Technologies, Inc., including the Epitope Stockholders Agreement and the STC Stockholders Agreement attached as Exhibits A and B thereto and the other exhibits attached thereto, is incorporated by reference to Exhibit 2 to the Current Report on Form 8-K of Epitope, Inc. dated May 9, 2000.
3.1	Certificate of Incorporation of OraSure Technologies is incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
3.1.1	Certificate of Amendment to Certificate of Incorporation dated May 23, 2000 is incorporated by reference to Exhibit 3.1.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
3.1.2	Certificate of Designation of Series A Preferred Stock of OraSure Technologies (filed as Exhibit A to the Rights Agreement referred to in Exhibit 4.2).
3.2	Amended and Restated Bylaws of OraSure Technologies, effective as of February 4, 2003.
4.1	Specimen certificate representing shares of OraSure Technologies $.000001 par value Common Stock is incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 8, 2000.
4.2	Rights Agreement, dated as of May 6, 2000, between OraSure Technologies and ChaseMellon Shareholder Service, L.L.C. (now called Mellon Investor Services LLC), as Rights Agent, is incorporated by reference to Exhibit 4.2 to Amendment No. 1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 8, 2000.
4.3	Stockholders' Agreement among STC Technologies, Inc., HealthCare Ventures V, L.P., RHO Management Trust II, Hudson Trust and Pennsylvania Early Stage Partners, L.P., dated March 30, 1999, is incorporated by reference to Exhibit 4.3 to Amendment No. 3 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 30, 2000.
4.4	Amendment to Stockholders' Agreement filed is Exhibit 4.3 is incorporated by reference to Exhibit 4.4 to Amendment No. 3 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 30, 2000.
4.5	Second Amendment to Stockholders' Agreement filed as Exhibit 4.3 is incorporated by reference to Exhibit 4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
10.1	Form of Indemnification Agreement (and list of parties to such agreement) is incorporated by reference to Exhibit 10.1 to Amendment No. 3 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 30, 2000.*
10.2	Separation Agreement and Release dated as of February 14, 2002 between OraSure Technologies and Robert D. Thompson is incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001.*
10.3	Employment Agreement dated as of September 29, 2000 between OraSure Technologies and Robert D. Thompson is incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*
10.4	Employment Agreement dated as of September 29, 2000 between OraSure Technologies and Michael J. Gausling is incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*

Exhibit Number	Exhibit
10.5	Employment Agreement dated as of November 1, 2001 between OraSure Technologies and Ronald H. Spair is incorporated be reference to Exhibit 10 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.*
10.6	Employment Agreement dated as of September 29, 2000 between OraSure Technologies and Dr. R. Sam Niedbala is incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*
10.7	Employment Agreement dated as of September 29, 2000 between OraSure Technologies and P. Michael Formica is incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001.*
10.8	Description of Non-Employee Director Compensation Policy, as amended effective as of February 4, 2003.*
10.9	Amended and Restated Epitope, Inc. 1991 Stock Award Plan.*
10.10	OraSure Technologies, Inc. Employee Incentive and Non-Qualified Stock Option Plan, as amended and restated effective September 29, 2000, is incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*
10.11	OraSure Technologies, Inc. 2000 Stock Award Plan, as amended effective as of May 20, 2002, is incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.*
10.12	Nonqualified Stock Option Agreement For Discounted Non-Plan Option between Epitope, Inc. and Robert D. Thompson is incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*
10.13	Description of OraSure Technologies, Inc. 2002 Employee Cash Bonus Plan is incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the Company's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2002.*
10.14	Description of OraSure Technologies, Inc. 2003 Self-Funding Annual Incentive Plan.*
10.15	Description of OraSure Technologies, Inc. Management Stock Option Award Guidelines.*
10.16	Production Agreement with Koninklinjke Utermöhlen, N.V. dated June 9, 1998 is incorporated by reference to Exhibit 10.8 to Amendment No. 3 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 30, 2000.
10.17	Amendment No. 1 to Production Agreement, dated as of December 11, 2001, between the Company and Koninklijke Utermöhlen N.V., is incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001.
10.18	Research and License Agreement with SRI International and David Sarnoff Research Center dated April 26, 1995 is incorporated by reference to Exhibit 10.9 to Amendment No. 4 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 31, 2000.
10.19	First Amendment to Research and License Agreement among SRI International and David Sarnoff Research Center and the Company dated September 1, 1995 is incorporated by reference to Exhibit 10.10 to Amendment No. 3 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 30, 2000.

Exhibit Number	Exhibit
10.20	Third Amendment to Research and License Agreement dated August 30, 2000 among SRI International, Sarnoff Corporation (formerly David Sarnoff Research Center) and the Company is incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.
10.21	Commercial Lease between Northampton County New Jobs Corp., as Landlord, and STC Technologies, Inc., as Tenant, dated April 30, 1999, is incorporated by reference to Exhibit 10.11 to Amendment No. 1 to the Company's Registration Statement on Form S-4 (No 333-39210), filed August 8, 2000.
10.22	Lease dated October 25, 1999 between PS Business Parks, L.P., a California Limited Partnership, and Epitope, Inc., is incorporated by reference to Exhibit 10.6 to the Epitope, Inc. Annual Report on Form 10-K for 1999.
10.23	Commercial Lease between Tech III Partners, LLC and OraSure Technologies, dated March 1, 2002, is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001.
10.24	Amendment No. 1 to Commercial Lease, dated as of October 21, 2002, between Tech III Partners, LLC and OraSure Technologies, Inc., is incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
10.25	Loan and Security Agreement, dated as of September 10, 2002, between Comerica Bank – California and OraSure Technologies, Inc., is incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
10.26	Distribution Agreement, dated as of October 11. 2002, between OraSure Technologies, Inc. and bioMérieux, Inc., is incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
10.27	Supply Agreement, dated as of October 11, 2002, between OraSure Technologies, Inc. and bioMérieux, Inc., is incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
23	Consent of KPMG LLP.
24	Powers of Attorney.
99.1	Certification pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.2	Certification pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management contract or compensatory plan or arrangement.

Exhibit 3.2

AMENDED AND RESTATED BYLAWS
OF
ORASURE TECHNOLOGIES, INC.

Effective as of February 4, 2003

ARTICLE I
Name and Location

SECTION 1. Name.

The name of the Corporation shall be the name set forth in the Certificate of Incorporation.

SECTION 2. Principal Office.

The principal office of the Corporation is located at 220 East First Street, Bethlehem, Pennsylvania 18015-1360.

SECTION 3. Additional Offices.

Other offices for the transaction of business of the Corporation may be located at such place or places as the Board of Directors may from time to time determine.

ARTICLE II
Capital Stock

SECTION 1. Stock Certificates.

All certificates of stock shall be signed by the Chairman of the Board of Directors, the Chief Executive Officer, the President or a Vice President and the Secretary or an Assistant Secretary, and sealed with the corporate seal.

SECTION 2. Stock Transfers.

Transfers of stock shall be made on the books of the Corporation upon the surrender of the old certificate properly endorsed, and said old certificate shall be canceled before a new certificate is issued.

SECTION 3. Lost or Destroyed Stock Certificates.

A new certificate of stock may be issued in the place of any certificate theretofore issued, alleged to have been lost or destroyed, and the Corporation may, in its discretion, require the owner of the lost or destroyed certificate, or its legal representative, to give a bond sufficient to indemnify the Corporation against any claim that may be made against it on account of the alleged loss of any certificate.

SECTION 4. Preemptive Rights Denied.

No holder of shares of any class of the Corporation, or holder of any securities or obligations convertible into shares of any class of the Corporation, shall have any preemptive right whatsoever to subscribe for, purchase or otherwise acquire shares of the Corporation of any class, whether now or hereafter authorized; provided, however, that nothing in this Section 4 shall prohibit the Corporation from granting, contractually or otherwise, to any such holder, the right to purchase additional securities of the Corporation.

ARTICLE III
Stockholders' Meetings

SECTION 1. Annual Meeting.

The annual meeting of the stockholders of the Corporation shall be held, either within or without the State of Delaware, on such date and at such time as may from time to time be determined by the Board of Directors. At such meeting the stockholders shall elect directors in the manner provided in the Certificate of Incorporation of the Corporation. The stockholders may transact such other business at such annual meetings as may properly come before the meeting.

SECTION 2. Special Meeting.

A special meeting of the holders of any one or more classes of the capital stock of the Corporation entitled to vote as a class or classes with respect to any matter, as required by law or as provided by the Certificate of Incorporation, may be called at any time and place, either within or without the state of Delaware, only by the Chairman of the Board, the Chief Executive Officer, the President or the Board of Directors.

SECTION 3. Notice.

Notice of the time and place of all annual meetings and of the time, place and purpose of all special meetings shall be mailed by the Secretary to each stockholder at his or her last known post office address as it appears on the records of the Corporation at least ten (10) days before the date set for such meeting.

SECTION 4. Nomination of Directors.

Nomination of persons for election to the Board of Directors of the Corporation at a meeting of the stockholders may be made by or at the direction of the Board of Directors or may be made at a meeting of stockholders by any stockholder of the Corporation entitled to vote for the election of Directors at the meeting in compliance with the notice procedures set forth in this Section 4 of ARTICLE III. Such nomination, other than those made by or at the direction of the Board, shall be made pursuant to timely notice in writing to the Secretary of the Corporation. To be timely, a stockholder's notice shall be delivered to or mailed and received at the principal executive offices of the Corporation not less than ninety (90) days nor more than one hundred twenty (120) days prior to the

meeting; provided, however, that in the event that less than one hundred (100) days' notice or prior public disclosure of the date of the meeting is given or made to stockholders, notice by the stockholder to be timely must be so received no later than the close of business on the tenth (10th) day following the day on which such notice of the date of the meeting was mailed or such public disclosure was made, whichever first occurs. Such stockholder's notice to the Secretary shall set forth: (a) as to each person whom the stockholder proposes to nominate for election or re- election as a Director, (i) the name, age, business address and residence address of the person, (ii) the principal occupation or employment of the person, (iii) the class and number of shares of capital stock of the Corporation which are beneficially owned by the person, and (iv) any other information relating to the person that is required to be disclosed in solicitations for proxies for election of Directors pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and (b) as to the stockholder giving the notice; (i) the name and record address of the stockholder; and (ii) the class and number of shares of capital stock of the Corporation which are beneficially owned by the stockholder. The Corporation may require any proposed nominee to furnish such other information as may reasonably be required by the Corporation to determine the eligibility of such proposed nominee to serve as a Director of the Corporation. No person shall be eligible for election as a Director of the Corporation at a meeting of the stockholders unless such person has been nominated in accordance with the procedures set forth herein. If the facts warrant, the Chairman of the meeting shall determine and declare to the meeting that a nomination does not satisfy the requirements set forth in the preceding sentence and the defective nomination shall be disregarded. Nothing in this Section 42 shall be construed to affect the requirements for proxy statements of the Corporation under Regulation 14A of the Exchange Act.

SECTION 5. Presentation of Business at Stockholders' Meetings.

At any meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before a meeting, business must be: (a) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors, (b) otherwise properly brought before the meeting by or at the direction of the Board of Directors, or (c) otherwise properly brought before the meeting by a stockholder. For business to be properly brought before a meeting by a stockholder, the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation. To be timely, a stockholder's notice shall be delivered to or mailed and received at the principal executive offices of the Corporation not less than ninety (90) days nor more than one hundred twenty (120) days prior to the meeting; provided, however, that in the event that less than one hundred (100) days' notice or prior public disclosure of the date of the meeting is given or made to stockholders, notice by the stockholder to be timely must be so received no later than the close of business on the tenth (10th) day following the day on which such notice of the date of the meeting was mailed or such public disclosure was made, whichever first occurs. Such stockholder's notice to the Secretary shall set forth: (a) as to each matter the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting and the reasons for conducting such business at the meeting, and (b) as to the stockholder giving the notice, (i) the name and record

address of the stockholder, (ii) the class and number of shares of capital stock of the Corporation which are beneficially owned by the stockholder and (iii) any material interest of the stockholder in such business. No business shall be conducted at a meeting of the stockholders unless proposed in accordance with the procedures set forth herein. The Chairman of the meeting shall, if the facts warrant, determine and declare to the meeting that business was not properly brought before the meeting in accordance with the foregoing procedure and such business shall not be transacted. To the extent this Section 5 shall be deemed by the Board of Directors or the Securities and Exchange Commission, or finally adjudged by a court of competent jurisdiction, to be inconsistent with the right of stockholders to request inclusion of a proposal in the Corporation's proxy statement pursuant to Rule 14a-8 promulgated under the Exchange Act, such rule shall prevail.

SECTION 6. Presiding Officials.

The Chairman of the Board of Directors, or in his or her absence or inability to act, the Chief Executive Officer, or in his or her absence or inability to act, the President, or in his or her absence or inability to act, any Vice President, shall preside at all stockholders' meetings.

SECTION 7. Voting.

Except as otherwise provided in the Certificate of Incorporation of the Corporation, at each meeting of the stockholders, each stockholder shall be entitled to cast one vote for each share of voting stock standing of record on the books of the Corporation, in his or her name, and may cast such vote either in person or by proxy. All proxies shall be in writing and filed with the Secretary of the meeting.

SECTION 8. Quorum; Adjournment.

At any meeting held for the purpose of electing directors, the presence in person or by proxy of the holders of at least a majority of the then outstanding voting shares of the Corporation shall be required and be sufficient to constitute a quorum for the election of directors. At a meeting held for any purpose other than the election of directors, shares representing a majority of the votes entitled to be cast on such matter, present in person or represented by proxy, shall constitute a quorum. In the absence of the required quorum at any meeting of stockholders, a majority of such holders present in person or by proxy shall have the power to adjourn the meeting, from time to time, without notice (except as required by law) other than an announcement at the meeting, until a quorum shall be present.

SECTION 9. Annual Statement of Business.

At each of the annual stockholders' meetings, one of the executive officers of the Corporation shall submit a statement of the business done during the preceding year, together with a report of the general financial condition of the Corporation.

ARTICLE IV
Directors

SECTION 1. Powers of the Board.

The business and property of the Corporation shall be managed by a Board consisting of such number of Directors as is determined from time to time in accordance with the provisions of the Certificate of Incorporation of the Corporation. The Board of Directors may elect one of their number to act as Chairman of the Board.

SECTION 2. Qualification.

Each Director upon his or her election shall qualify by filing his or her written acceptance with the Secretary or an Assistant Secretary and by fulfilling any prerequisite to qualification that may be set forth in the Certificate of Incorporation of the Corporation.

SECTION 3. Annual Meetings.

The annual meeting of the Board of Directors shall be held immediately after the adjournment of each annual meeting of the stockholders and in the event a quorum is not present, said meeting shall be held within ten (10) days after adjournment upon proper notice by the Chairman of the Board of Directors, the Chief Executive Officer, the President or a Vice President.

SECTION 4. Special Meetings.

Special meetings of the Board of Directors may be called at any time or place by the Chairman of the Board, the Chief Executive Officer, or by the President, and in the absence or inability of all of them to act, by any Vice President, and may also be called by any two members of the Board of Directors. By unanimous consent of the Directors, special meetings of the Board may be held without notice, at any time and place.

SECTION 5. Notice; Telephonic Attendance; Unanimous Consent.

Notice of all regular and special meetings of the Board of Directors or the Executive Committee or any committee established pursuant to this ARTICLE IV (an "Other Committee") shall be sent to each Director or member of such committee, as the case may be, by the Secretary or any Assistant Secretary, by a means reasonably calculated to be received at least seven (7) days prior to the time fixed for such meeting, or notice of special meetings of the Board of Directors or the Executive Committee or any Other Committee may be given by telephone, telegraph, telefax or telex to each Director or member of such committee, as the case may be, at least twenty-four (24) hours prior to the time fixed for such meeting, or on such shorter notice as the person or persons calling the meeting may reasonably deem necessary or appropriate in the circumstances. To the extent provided in the notice of the meeting or as otherwise determined by the Chairman of the Board or the Board of Directors, Directors may participate in any regular or special meeting by means of conference telephone, videoconference or similar communications equipment which allows all persons participating in such meeting to hear each other, and

participation in such meeting by means of such a device shall constitute presence in person at such meeting. Attendance of a director at any meeting shall constitute a waiver of notice of such meeting except where a director attends a meeting for the express purpose of objecting to the transaction of any business because the meeting is not lawfully called or convened.

If all the directors shall severally or collectively consent in writing to any action to be taken by the directors, such consents shall have the same force and effect as a unanimous vote of the directors at a meeting duly held. The Secretary shall file such consents with the minutes of the meetings of the Board of Directors.

SECTION 6. Quorum; Adjournment.

Except as otherwise provided in the Certificate of Incorporation of the Corporation, a quorum for the transaction of business at any meeting of the directors shall consist of a majority of the members of the Board, but the directors present, although less than a quorum, shall have the power to adjourn the meeting from time to time or to some future date.

SECTION 7. Election of Officers.

The directors shall elect the officers of the Corporation and fix their salaries and other compensation. Such election shall be made at the Directors' meeting following each annual stockholders' meeting.

SECTION 8. Advisers to the Board of Directors.

The Board of Directors from time to time, as they may deem proper, shall have authority to appoint a general manager, counsel or attorneys and other employees for such length of time and upon such terms and conditions and at such salaries and other compensation as they may deem necessary and/or advisable.

SECTION 9. Compensation; Reimbursement of Expenses.

The members of the Board of Directors shall receive compensation for their services in such amount as may be reasonable and proper and consistent with the time and service rendered. The members of the Board of Directors shall receive the reasonable expenses necessarily incurred in the attendance of meetings and in the transaction of business for the Corporation.

SECTION 10. Indemnification; Insurance.

(a) Indemnification.

(1) Actions Other than Those by or in the Right of the Corporation. To the extent permitted by Delaware law from time to time in effect and subject to the provisions of paragraph (c) of this Section 10, the Corporation shall indemnify any person who was or is a party or is threatened to be made a party to any

threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation (or such other corporation or organization), and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person's conduct was unlawful.

(2) Action by or in the Right of the Corporation. To the extent permitted by Delaware law from time to time in effect and subject to the provisions of paragraph (c) of this Section 10, the Corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that such person is or was a director, officer, employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation (or such other corporation or organization) and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Corporation (or such other corporation or organization) unless and only to the extent that the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which such court shall deem proper.

(3) Successful Defense of Action. Notwithstanding, and without limitation of, any other provision of this Section 10, to the extent that a director, officer, employee or agent of the Corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in sub-paragraph (1) or (2) of this paragraph (a), or in defense of any claim, issue or matter therein, such director, officer, employee or agent shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

(4) Determination Required. Any indemnification under sub-paragraph (1) or (2) of this paragraph (a) (unless ordered by a court) shall be made by the Corporation only as authorized in the specific case upon a determination that indemnification of the director, officer, employee or agent is proper in the circumstances because such director, officer, employee or agent has met the applicable standard of conduct set forth in said sub-paragraph. Such determination shall be made: (i) by the Board of Directors by a majority vote of a quorum consisting of directors who were not parties to the particular action, suit or proceeding, or (ii) if such a quorum is not obtainable, or, even if obtainable, a quorum of disinterested directors so directs, by independent legal counsel in a written opinion, or (iii) by the stockholders.

(b) Insurance. The Corporation may, when authorized by the Board of Directors, purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify him against such liability under the provisions of this Section 10. The risks insured under any insurance policies purchased and maintained on behalf of any person as aforesaid or on behalf of the Corporation shall not be limited in any way by the terms of this Section 10 and to the extent compatible with the provisions of such policies, the risks insured shall extend to the fullest extent permitted by law, common or statutory.

(c) Advancement of Expenses; Nonexclusivity; Duration. Expenses (including attorneys' fees) incurred by an officer or director in defending any civil, criminal, administrative or investigative action, suit or proceeding shall be paid by the Corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such officer or director to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the Corporation as authorized in this Section 10. Such expenses (including attorneys' fees) incurred by other employees and agents may be so paid by the Corporation upon such terms and conditions, if any, as the Board of Directors deems appropriate. The indemnifications, advancement of expenses and rights provided by, or granted pursuant to, this Section 10 shall not be deemed exclusive of any other indemnifications, advancement of expenses, rights or limitations of liability to which any person seeking indemnification or advancement of expenses may be entitled under any Bylaw, agreement, vote of stockholders or disinterested directors, or otherwise, either as to action in such person's official capacity or as to action in another capacity while holding office, and they shall continue although such person has ceased to be a director, officer, employee or agent and shall inure to the benefit of such person's heirs, executors and administrators. The authorization to purchase and maintain insurance set forth in paragraph (b) shall likewise not be deemed exclusive.

SECTION 11. Committees.

(a) The Board of Directors may, by resolution or resolutions adopted by a majority of the whole Board, designate one or more committees, each of which shall consist of two or more directors of the Corporation. Each such committee, to the extent provided in such resolution or resolutions or in a Charter adopted by the Board, shall have and may exercise all of the authority of the Board in the management of the Corporation and may authorize the seal of the Corporation to be affixed to all papers which may require it; provided, however, that the designation of each such committee and the delegation thereto of authority shall not operate to relieve the Board, or any member thereof, of any responsibility imposed upon it or such member by law.

(b) The Board of Directors, by resolution adopted by a majority of the whole Board, may designate one or more additional directors as alternate members of any committee to replace any absent or disqualified member at any meeting of that committee, and at any time may change the membership of any committee or amend or rescind the resolution designating the committee or any Charter adopted for such committee. In the absence or disqualification of a member or alternate member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not the member or members constitute a quorum, may unanimously appoint another director to act at the meeting in the place of any such absent or disqualified member, provided that the director so appointed meets any qualifications stated in these Bylaws, the Charter (if any) approved by the Board for the committee or the resolutions designating the committee or any amendment thereto.

(c) Notwithstanding any other provision of these Bylaws, no committee of the Board of Directors shall have the power or authority of the Board with respect to (i) amending the Certificate of Incorporation, (ii) approving or recommending to stockholders any type or form of "business combination" (as defined in Section 203 of the General Corporation Law of Delaware as in effect on January 1, 1996), (iii) approving or recommending to stockholders an agreement of merger or consolidation or the sale, lease or exchange of all or substantially all of the Corporation's property or assets, (iv) approving or recommending to the stockholders a dissolution of the Corporation or a revocation of a dissolution, (v) amending these Bylaws, (vi) declaring a dividend or making any other distribution to the stockholders, or (vii) authorizing the issuance of stock otherwise than pursuant to the grant or exercise of a stock option under employee stock options of the Corporation..

(d) Each such committee shall keep regular minutes of its proceedings, which minutes shall be recorded in the minute book of the Corporation. The Secretary or an Assistant Secretary of the Corporation may act as Secretary for each such committee if the committee so requests.

(e) Unless otherwise provided in these Bylaws, or in the resolutions designating any committee or the Charter (if any) approved by the Board for the

committee, any committee may fix its rules or procedures, fix the time and place of its meetings and specify what notice of meetings, if any, shall be given.

ARTICLE V
Officers

SECTION 1. Designations.

The officers of this Corporation shall be a Chairman of the Board of Directors, a Chief Executive Officer, a President, as many Vice Presidents as the Board of Directors may from time to time deem advisable and one or more of which may be designated Executive Vice President or Senior Vice President, a Secretary, a Treasurer, and such Assistant Secretaries and Assistant Treasurers as the Board of Directors may from time to time deem advisable, and such other officers as the Board of Directors may from time to time deem advisable and designate. The Chairman of the Board of Directors shall be a member of and be elected by the Board of Directors. All other officers shall be elected by the Board of Directors. All officers shall hold office until their respective successors are elected and shall have qualified. Any two offices may be held by one person except the office of President and Vice President.

SECTION 2. Chairman of the Board.

The Chairman of the Board of Directors shall preside at all meetings of the Directors and stockholders at which he or she is present and shall have such other duties, power and authority as may be prescribed by the Board of Directors from time to time or elsewhere in these Bylaws.

SECTION 3. Chief Executive Officer.

The Chief Executive Officer shall have such general executive powers and duties as are usually vested in the office of the chief executive officer and shall perform such other duties as are authorized by the Board of Directors. Unless the Board of Directors otherwise provides, the Chief Executive Officer, or any person designated in writing by the Chief Executive Officer, shall have full power and authority on behalf of the Corporation to: (i) attend and to vote or take action at any meeting of the holders of securities of corporations in which the Corporation may hold securities, and at such meetings shall possess and may exercise any and all rights and powers incident to being a holder of such securities, and (ii) execute and deliver waivers of notice and proxies for and in the name of this Corporation with respect to securities of any such corporation held by this Corporation.

SECTION 4. President.

The President shall have such general executive powers and duties of supervision and management as are usually vested in such office and shall perform such other duties as are authorized by the Board of Directors or the Chief Executive Officer. The Chairman

of the Board, the Chief Executive Officer, or the President shall sign contracts, certificates and other instruments of the Corporation as authorized by the Board of Directors.

SECTION 5. Vice Presidents.

A Vice President shall have the right and power to perform all duties and exercise all authority of the President, in case of the absence of the President or upon vacancy in the office of President or delegation by the Board of Directors, until the Board of Directors otherwise provides, and shall have all power and authority usually enjoyed by a person holding the office of Vice President.

SECTION 6. Secretary and Assistant Secretaries.

The Secretary shall issue notices of all directors' and stockholders' meetings, and shall attend and keep the minutes of the same; shall have charge of all corporate books, records and papers; shall be custodian of the corporate seal; shall attest with his or her signature, which may be a facsimile signature if authorized by the Board of Directors, and impress with the corporate seal, all stock certificates and written contracts of the Corporation; and shall perform all other duties as are incident to his or her office. Any Assistant Secretary, in the absence or inability of the Secretary, shall perform all duties of the Secretary and such other duties as may be required.

SECTION 7. Treasurer and Assistant Treasurers.

The Treasurer shall have custody of all money and securities of the Corporation and shall give bond in such sum and with such sureties as the directors may specify, conditioned upon the faithful performance of the duties of his or her office. He or she shall keep regular books of account and shall submit them, together with all of his or her records and other papers, to the directors for their examination and approval annually; and quarterly or as and when directed by the Board of Directors, he or she shall submit to each director a statement of the condition of the business and accounts of the Corporation; and shall perform all such other duties as are incident to his or her office. An Assistant Treasurer, in the absence or inability of the Treasurer, shall perform all the duties of the Treasurer and such other duties as may be required.

SECTION 8. Bonding.

Any officer or employee of the Corporation shall give such bond for the faithful performance of his or her duties in such sum, as and when the Board of Directors may direct.

ARTICLE VI
Dividends

SECTION 1. Dividends shall be paid out of the net income or earned surplus of the Corporation, determined after making proper provision for required sinking fund deposits for debt obligations and proper provisions for working capital and such reserves as may

be required by good and generally accepted accounting practice, when declared from time to time by resolution of the Board of Directors. No such dividends shall be declared or paid which will impair the capital of the Corporation.

ARTICLE VII
Amendments

SECTION 1. Except as otherwise provided in the Certificate of Incorporation of the Corporation, these Bylaws may be amended, altered or repealed by the affirmative vote of a majority of the Board of Directors, subject to the power of stockholders to amend, alter or repeal the Bylaws, or as otherwise may from time to time be authorized by the laws of the State of Delaware.

ARTICLE VIII
Corporate Seal

SECTION 1. The corporate seal of this Corporation shall have inscribed thereon the name of the Corporation and its state of incorporation.

Exhibit 10.8

Description of Nonemployee Director Compensation Policy

The following describes the Company's Compensation Policy for Nonemployee Directors, as amended effective as of February 4, 2003 (the "Policy").

Pursuant to the Policy, the Chairman of the Company's Board of Directors (the "Board") receives an annual fee of $25,000, the Chairman of the Audit Committee of the Board receives an annual fee of $17,000, the Chairmen of the Compensation and Strategic Planning Committees of the Board each receive an annual fee of $16,000, and all other nonemployee Directors receive an annual fee of $12,000. Annual fees are payable quarterly in advance.

In addition, each nonemployee Director receives a $1,000 fee for each Board meeting attended, and each member of a Board Committee receives an additional $1,000 fee for each Committee meeting attended. A payment will be made only for a meeting where minutes of that meeting are prepared. Nonemployee Directors also receive reimbursement for their reasonable out-of-pocket costs of attending Board and Committee meetings.

Nonemployee Directors receive an initial grant of 40,000 stock options upon joining the Board (the "Initial Grant"). An additional grant of 40,000 stock options is also made to any nonemployee Director who becomes Chairman of the Board (the "Chairman Grant"). Each nonemployee Director receives an annual grant of 20,000 stock options (the "Annual Grant") on the annual option grant date for officers and employees of the Company, except for the Chairman of the Board, who receives an annual grant of 30,000 stock options.

The options granted to nonemployee Directors are nonqualified stock options, and have an exercise price equal to the mean between the high and low sales prices of the Company's Common Stock as quoted on The Nasdaq Stock Market on the grant date. Each Initial Grant and Chairman Grant generally vests on a monthly basis over the 24 months immediately following the grant date, and each Annual Grant generally vests on a monthly basis over the 12 months immediately following the grant date. All vesting of the options will cease 90 days after the nonemployee Director ceases to serve on the Board. Options become exercisable in full immediately upon the occurrence of a change in control of the Company. A change in control of the Company would occur on the happening of such events as the beneficial ownership by a person or group of 30 percent or more of the outstanding Common Stock of the Company, certain changes in Board membership affecting a majority of positions, certain mergers or consolidations, a sale or other transfer of all or substantially all the Company's assets, or approval by the stockholders of a plan of liquidation or dissolution of the Company, as well as any change in control required to be reported by the proxy disclosure rules of the Securities and Exchange Commission. Payment of the exercise price may be made in cash or by delivery of previously acquired shares of Common Stock having a fair market value equal to the aggregate exercise price.

EXHIBIT 10.9

EPITOPE, INC.

AMENDED AND RESTATED 1991 STOCK AWARD PLAN

ARTICLE 1
ESTABLISHMENT AND PURPOSE

1.1 Establishment; Amendment and Restatement. Epitope, Inc. ("Corporation"), hereby establishes the Epitope, Inc., 1991 Stock Award Plan (the "Plan"), effective as of January 8, 1991, subject to shareholder approval as provided in Article 17. The Plan was previously amended and restated effective March 25, 1991, December 8, 1992, December 14, 1993, and December 13, 1994, and is further amended and restated as set forth herein effective December 17, 1996.

1.2 Purpose. The purpose of the Plan is to promote and advance the interests of Corporation and its shareholders by enabling Corporation to attract, retain, and reward key employees, outside advisors, and directors of Corporation and its subsidiaries. It is also intended to strengthen the mutuality of interests between such employees, advisors, and directors and Corporation's shareholders. The Plan is designed to meet this intent by offering stock options and other equity-based incentive awards, thereby providing a proprietary interest in pursuing the long-term growth, profitability, and financial success of Corporation.

ARTICLE 2
DEFINITIONS

2.1 Defined Terms. For purposes of the Plan, the following terms shall have the meanings set forth below:

"Advisor" means a member of an Advisory Committee of Corporation or a Subsidiary, or any other consultant selected by the Committee, who is neither an employee of Corporation or a Subsidiary nor a Non-Employee Director.

"Advisory Committee" means a scientific advisory committee to Corporation or a Subsidiary.

"Agritope Share" means a share of Agritope Stock.

"Agritope Stock Proposal Date" means the effective date of the amendment of Corporation's Articles of Incorporation to create Agritope Stock and to redesignate Corporation's previously existing common stock as Medical Products Stock.

"Agritope Stock" means the Agritope Common Stock, no par value, of Corporation or any security of Corporation issued in substitution, exchange, or in lieu of such stock.

"Award" means an award or grant made to a Participant of Options, Stock Appreciation Rights, Restricted Awards, Performance Awards, or Other Stock-Based Awards pursuant to the Plan.

"Award Agreement" means an agreement as described in Section 6.4.

"Board" means the Board of Directors of Corporation.

"Code" means the Internal Revenue Code of 1986, as amended and in effect from time to time, or any successor thereto, together with rules, regulations, and interpretations promulgated thereunder. Where the context so requires, any reference to a particular Code section shall be construed to refer to the successor provision to such Code section.

"Committee" means the committee appointed by the Board to administer the Plan as provided in Article 3 of the Plan.

"Common Stock" means the Common Stock, no par value, of Corporation or any security of Corporation issued in substitution, exchange, or in lieu of such stock. For all periods after the Agritope Stock Proposal Date, references in this Plan to Common Stock include either Agritope Stock, Medical Products Stock, or both, as the context may require.

"Continuing Restriction" means a Restriction contained in Sections 6.5(h), 16.4, 16.5, and 16.7 of the Plan and any other Restrictions expressly designated by the Committee in an Award Agreement as a Continuing Restriction.

"Corporation" means Epitope, Inc., an Oregon corporation, or any successor corporation.

"Deferred Compensation Option" means a Nonqualified Option granted with an option price less than Fair Market Value on the date of grant pursuant to Section 7.9 of the Plan.

"Disability" means the condition of being "disabled" within the meaning of Section 422(c)(7) of the Code. However, the Committee may change the foregoing definition of "Disability" or may adopt a different definition for purposes of specific Awards.

"Exchange Act" means the Securities Exchange Act of 1934, as amended and in effect from time to time, or any successor statute. Where the context so requires, any reference to a particular section of the Exchange Act, or to any rule promulgated under the Exchange Act, shall be construed to refer to successor provisions to such section or rule.

"Fair Market Value" means with respect to either Agritope Shares or Medical Products Shares, on a particular day, without regard to any restrictions (other than a restriction which, by its terms, will never lapse), the mean between the reported high and low sale prices, or, if there is no sale on such day, the mean between the reported bid and asked prices, of Shares of the applicable class on that day or, if that day is not a trading day, the last prior trading day, on the securities exchange or automated securities interdealer quotation system on which such Shares shall have been traded.

"Incentive Stock Option" or "ISO" means any Option granted pursuant to the Plan that is intended to be and is specifically designated in its Award Agreement as an "incentive stock option" within the meaning of Section 422 of the Code.

"Medical Products Share" means a share of Medical Products Stock.

"Medical Products Stock" means the Epitope Medical Products Common Stock, no par value, of Corporation or any security of Corporation issued in substitution, exchange, or in lieu of such stock.

"Non-Employee Director" means a member of the Board who is not an employee of Corporation or any Subsidiary.

"Nonqualified Option" or "NQO" means any Option, including a Deferred Compensation Option, granted pursuant to the Plan that is not an Incentive Stock Option.

"Option" means an ISO, an NQO, or a Deferred Compensation Option.

"Other Stock-Based Award" means an Award as defined in Section 11.1.

"Participant" means an employee of Corporation or a Subsidiary, an Advisor, or a Non-Employee Director who is granted an Award under the Plan.

"Performance Award" means an Award granted pursuant to the provisions of Article 10 of the Plan, the Vesting of which is contingent on performance attainment.

"Performance Cycle" means a designated performance period pursuant to the provisions of Section 10.3 of the Plan.

"Performance Goal" means a designated performance objective pursuant to the provisions of Section 10.4 of the Plan.

"Plan" means this Epitope, Inc., 1991 Stock Award Plan, as amended and restated and set forth herein and as it may be hereafter amended from time to time.

"Reporting Person" means a Participant who is subject to the reporting requirements of Section 16(a) of the Exchange Act.

"Restricted Award" means a Restricted Share or a Restricted Unit granted pursuant to Article 9 of the Plan.

"Restricted Share" means an Award described in Section 9.1(a) of the Plan.

"Restricted Unit" means an Award of units representing Shares described in Section 9.1(b) of the Plan.

"Restriction" means a provision in the Plan or in an Award Agreement which limits the exercisability or transferability, or which governs the forfeiture, of an Award or the Shares, cash, or other property payable pursuant to an Award.

"Retirement" means:

(a) For Participants who are employees, retirement from active employment with Corporation and its Subsidiaries at or after age 50, or such earlier retirement date as approved by the Committee for purposes of the Plan;

(b) For Participants who are Non-Employee Directors, termination of membership on the Board after attaining age 50, or such earlier retirement date as approved by the Committee for purposes of the Plan; and

(c) For Participants who are Advisors, termination of service as an Advisor after attaining age 50, or such earlier retirement date as approved by the Committee for purposes of the Plan.

However, the Committee may change the foregoing definition of "Retirement" or may adopt a different definition for purposes of specific Awards.

"Share" means a share of Common Stock. For all periods after the Agritope Stock Proposal Date, references in this Plan to Shares include either Agritope Shares, Medical Products Shares, or both, as the context may require.

"Stock Appreciation Right" or "SAR" means an Award to benefit from the appreciation of Common Stock granted pursuant to the provisions of Article 8 of the Plan.

"Subsidiary" means a "subsidiary corporation" of Corporation within the meaning of Section 425 of the Code, namely any corporation in which Corporation directly or indirectly controls 50 percent or more of the total combined voting power of all classes of stock having voting power.

"Vest" or "Vested" means:

(a) In the case of an Award that requires exercise, to be or to become immediately and fully exercisable and free of all Restrictions (other than Continuing Restrictions);

(b) In the case of an Award that is subject to forfeiture, to be or to become nonforfeitable, freely transferable, and free of all Restrictions (other than Continuing Restrictions);

(c) In the case of an Award that is required to be earned by attaining specified Performance Goals, to be or to become earned and nonforfeitable, freely transferable, and free of all Restrictions (other than Continuing Restrictions); or

(d) In the case of any other Award as to which payment is not dependent solely upon the exercise of a right, election, exercise, or option, to be or to become immediately payable and free of all Restrictions (except Continuing Restrictions).

2.2 Gender and Number. Except where otherwise indicated by the context, any masculine or feminine terminology used in the Plan shall also include the opposite gender; and the definition of any term in Section 2.1 in the singular shall also include the plural, and vice versa.

ARTICLE 3
ADMINISTRATION

3.1 General. Except as provided in Section 3.7, the Plan shall be administered by a Committee composed as described in Section 3.2.

3.2 Composition of the Committee. The Committee shall be appointed by the Board from among its members in a number and with such qualifications as will meet the requirements for approval by a committee pursuant to Rule 16b-3 under the Exchange Act. The Board may from time to time remove members from, or add members to, the Committee. Vacancies on the Committee, however caused, shall be filled by the Board. The initial members of the Committee shall be the members of Corporation's existing Executive Compensation Committee. The Board may at any time replace the Executive Compensation Committee with another Committee. In the event that the Executive Compensation Committee shall cease to satisfy the requirements of Rule 16b-3, the Board shall appoint another Committee satisfying such requirements.

3.3 Authority of the Committee. The Committee shall have full power and authority (subject to such orders or resolutions as may be issued or adopted from time to time by the Board) to administer the Plan in its sole discretion, including the authority to:

(a) Construe and interpret the Plan and any Award Agreement;

(b) Promulgate, amend, and rescind rules and procedures relating to the implementation of the Plan;

(c) With respect to employees and Advisors:

(i) Select the employees and Advisors who shall be granted Awards;

(ii) Determine the number and types of Awards to be granted to each such Participant;

(iii) Determine the number of Shares, or Share equivalents, to be subject to each Award and whether the Shares subject to an Award are to be Agritope Shares, Medical Products Shares, or a combination of both;

(iv) Determine the option price, purchase price, base price, or similar feature for any Award; and

(v) Determine all the terms and conditions of all Award Agreements, consistent with the requirements of the Plan.

Decisions of the Committee, or any delegate as permitted by the Plan, shall be final, conclusive, and binding on all Participants.

3.4 Action by the Committee. A majority of the members of the Committee shall constitute a quorum for the transaction of business. Action approved by a majority of the members present at any meeting at which a quorum is present, or action in writing by all the members of the Committee, shall be the valid acts of the Committee.

3.5 Delegation. Notwithstanding the foregoing, the Committee may delegate to one or more officers of Corporation the authority to determine the recipients, types, amounts, and terms of Awards granted to Participants who are not Reporting Persons.

3.6 Liability of Committee Members. No member of the Committee shall be liable for any action or determination made in good faith with respect to the Plan, any Award, or any Participant.

3.7 Awards to Non-Employee Directors. The Board may grant Awards from time to time to Non-Employee Directors. Awards to Non-Employee Directors shall be governed by and shall be subject to the terms and conditions set forth in an Award Agreement in a form approved by the Board.

3.8 Costs of Plan. The costs and expenses of administering the Plan shall be borne by Corporation.

ARTICLE 4
DURATION OF THE PLAN AND SHARES SUBJECT TO THE PLAN

4.1 Duration of the Plan. The Plan is effective January 8, 1991, subject to approval by Corporation's shareholders as provided in Article 17. The Plan shall remain in effect until Awards have been granted covering all the available Shares or the Plan is otherwise terminated by the Board. Termination of the Plan shall not affect outstanding Awards.

4.2 Shares Subject to the Plan.

4.2.1 General. The shares which may be made subject to Awards under the Plan shall be Shares of Common Stock, which may be either authorized and unissued Shares or reacquired Shares. No fractional Shares shall be issued under the Plan. If an Award under the Plan is canceled or expires for any reason prior to having been fully Vested or exercised by a Participant or is settled in cash in lieu of Shares or is exchanged for other Awards, all Shares covered by such Awards shall be made available for future Awards under the Plan. Furthermore, any Shares used as full or partial payment to Corporation by a Participant of the option, purchase, or other exercise price of an Award and any Shares covered by a Stock Appreciation Right which are not issued upon exercise shall become available for future Awards.

4.2.2 Medical Products Shares. The maximum number of Medical Products Shares for which Awards may be granted under the Plan shall be 3,400,000 Medical Products Shares, plus the number of Shares which were available for grant under Corporation's Incentive Stock Option Plan for Key Employees of Epitope, Inc. (the "ISOP"), on January 8, 1991, subject to adjustment pursuant to Article 14.

4.2.3 Agritope Shares. The maximum number of Agritope Shares for which Awards may be granted under the Plan shall be (i) 1,000,000 Agritope Shares plus (ii) that number of Agritope Shares which is one-half of the number of shares of Epitope Common Stock (rounded down to the nearest whole number) subject to outstanding Options under the Plan on the Agritope Stock Proposal Date, in each case subject to adjustment pursuant to Article 14.

4.2.4 Availability of Shares for Future Awards. If an Award under the Plan or under the ISOP is canceled or expires for any reason prior to having been fully Vested or exercised by a Participant or is settled in cash in lieu of Shares or is exchanged for other Awards, all Shares covered by such Awards shall be made available for future Awards under the Plan. Furthermore, any Shares used as full or partial payment to Corporation by a Participant of the option, purchase, or other exercise price of an Award and any Shares covered by a Stock Appreciation Right which are not issued upon exercise shall become available for future Awards.

ARTICLE 5
ELIGIBILITY

5.1 Employees and Advisors. Officers and other key employees of Corporation and its Subsidiaries (who may also be directors of Corporation or a Subsidiary) and Advisors who, in the Committee's judgment, are or will be contributors to the long-term success of Corporation shall be eligible to receive Awards under the Plan.

5.2 Non-Employee Directors. All Non-Employee Directors shall be eligible to receive Awards as provided in Section 3.7 of the Plan.

ARTICLE 6
AWARDS

6.1 Types of Awards. The types of Awards that may be granted under the Plan are:

(a) Options governed by Article 7 of the Plan;

(b) Stock Appreciation Rights governed by Article 8 of the Plan;

(c) Restricted Awards governed by Article 9 of the Plan;

(d) Performance Awards governed by Article 10 of the Plan; and

(e) Other Stock-Based Awards or combination awards governed by Article 11 of the Plan.

In the discretion of the Committee, any Award may be granted alone, in addition to, or in tandem with other Awards under the Plan.

6.2 General. Subject to the limitations of the Plan, the Committee may cause Corporation to grant Awards to such Participants, at such times, of such types, in such amounts, for such periods, with such option prices, purchase prices, or base prices, and subject to such terms, conditions, limitations, and restrictions as the Committee, in its discretion, shall deem appropriate. Awards may be granted as additional compensation to a Participant or in lieu of other compensation to such Participant. A Participant may receive more than one Award and more than one type of Award under the Plan.

6.3 Nonuniform Determinations. The Committee's determinations under the Plan or under one or more Award Agreements, including without limitation, (a) the selection of Participants to

receive Awards, (b) the type, form, amount, and timing of Awards, (c) the terms of specific Award Agreements, and (d) elections and determinations made by the Committee with respect to exercise or payments of Awards, need not be uniform and may be made by the Committee selectively among Participants and Awards, whether or not Participants are similarly situated.

6.4 Award Agreements. Each Award shall be evidenced by a written Award Agreement between Corporation and the Participant. Award Agreements may, subject to the provisions of the Plan, contain any provision approved by the Committee.

6.5 Provisions Governing All Awards. All Awards shall be subject to the following provisions:

(a) Type of Shares. Each Award Agreement shall specify whether the Award covers Agritope Shares, Medical Products Shares, or a specified combination of both.

(b) Alternative Awards. If any Awards are designated in their Award Agreements as alternative to each other, the exercise of all or part of one Award automatically shall cause an immediate equal (or pro rata) corresponding termination of the other alternative Award or Awards.

(c) Rights as Shareholders. No Participant shall have any rights of a shareholder with respect to Shares subject to an Award until such Shares are issued in the name of the Participant.

(d) Employment Rights. Neither the adoption of the Plan nor the granting of any Award shall confer on any person the right to continued employment with Corporation or any Subsidiary or the right to remain as a director of Corporation or a member of any Advisory Committee, as the case may be, nor shall it interfere in any way with the right of Corporation or a Subsidiary to terminate such person's employment or to remove such person as an Advisor or as a director at any time for any reason, with or without cause.

(e) Termination Of Employment. The terms and conditions under which an Award may be exercised, if at all, after a Participant's termination of employment or service as an Advisor or as a Non-Employee Director shall be determined by the Committee and specified in the applicable Award Agreement.

(f) Change in Control. The Committee, in its discretion, may provide in any Award Agreement that in the event of a change in control of Corporation (as the Committee may define such term in the Award Agreement), as of the date of such change in control:

(i) All, or a specified portion of, Awards requiring exercise shall become fully and immediately exercisable, notwithstanding any other limitations on exercise;

(ii) All, or a specified portion of, Awards subject to Restrictions shall become fully Vested; and

(iii) All, or a specified portion of, Awards subject to Performance Goals shall be deemed to have been fully earned.

The Committee, in its discretion, may include change in control provisions in some Award Agreements and not in others, may include different change in control provisions in different Award Agreements, and may include change in control provisions for some Awards or some Participants and not for others.

(g) Reporting Persons. With respect to all Awards granted to Reporting Persons, the Award Agreement shall provide that:

(i) Awards requiring exercise shall not be exercisable until at least six months after the date the Award was granted, except in the case of the death or Disability of the Participant; and

(ii) Shares issued pursuant to any other Award may not be sold by the Participant for at least six months after acquisition, except in the case of the death or Disability of the Participant;

provided, however, that (unless an Award Agreement provides otherwise) the limitation of this Section 6.5(g) shall apply only if or to the extent required by Rule 16b-3 under the Exchange Act or any applicable successor provision. Award Agreements for Awards to Reporting Persons shall also comply with any future restrictions imposed by such Rule 16b-3.

(h) Service Periods. At the time of granting Awards, the Committee may specify, by resolution or in the Award Agreement, the period or periods of service performed or to be performed by the Participant in connection with the grant of the Award.

ARTICLE 7
OPTIONS

7.1 Types of Options. Options granted under the Plan may be in the form of Incentive Stock Options or Nonqualified Options (including Deferred Compensation Options). The grant of each Option and the Award Agreement governing each Option shall identify the Option as an ISO or an NQO. In the event the Code is amended to provide for tax-favored forms of stock options other than or in addition to Incentive Stock Options, the Committee may grant Options under the Plan meeting the requirements of such forms of options.

7.2 General. Options shall be subject to the terms and conditions set forth in Article 6 and this Article 7 and shall contain such additional terms and conditions, not inconsistent with the express provisions of the Plan, as the Committee (or the Board with respect to Awards to Non-Employee Directors) shall deem desirable.

7.3 Option Price. Each Award Agreement for Options shall state the option exercise price per Share of Common Stock purchasable under the Option, which shall not be less than:

(a) $1 per share in the case of a Deferred Compensation Option;

(b) 75 percent of the Fair Market Value of a Share on the date of grant for all other Nonqualified Options; or

(c) 100 percent of the Fair Market Value of a Share on the date of grant for all Incentive Stock Options.

7.4 Option Term. The Award Agreement for each Option shall specify the term of each Option, which may be unlimited or may have a specified period during which the Option may be exercised, as determined by the Committee.

7.5 Time of Exercise. The Award Agreement for each Option shall specify, as determined by the Committee:

(a) The time or times when the Option shall become exercisable and whether the Option shall become exercisable in full or in graduated amounts over a period specified in the Award Agreement;

(b) Such other terms, conditions, and restrictions as to when the Option may be exercised as shall be determined by the Committee; and

(c) The extent, if any, to which the Option shall remain exercisable after the Participant ceases to be an employee, Advisor, or director of Corporation or a Subsidiary.

An Award Agreement for an Option may, in the discretion of the Committee, provide whether, and to what extent, the Option will become immediately and fully exercisable (i) in the event of the death, Disability, or Retirement of the Participant, or (ii) upon the occurrence of a change in control of Corporation.

7.6 Method of Exercise. The Award Agreement for each Option shall specify the method or methods of payment acceptable upon exercise of an Option. An Award Agreement may provide that the option price is payable in full in cash or, at the discretion of the Committee:

(a) In installments on such terms and over such period as the Committee shall determine;

(b) In previously acquired Shares (including Restricted Shares);

(c) By surrendering outstanding Awards under the Plan denominated in Shares or in Share-equivalent units;

(d) By delivery (in a form approved by the Committee) of an irrevocable direction to a securities broker acceptable to the Committee:

(i) To sell Shares subject to the Option and to deliver all or a part of the sales proceeds to Corporation in payment of all or a part of the option price and withholding taxes due; or

(ii) To pledge Shares subject to the Option to the broker as security for a loan and to deliver all or a part of the loan proceeds to Corporation in payment of all or a part of the option price and withholding taxes due; or

(e) In any combination of the foregoing or in any other form approved by the Committee.

If Restricted Shares are surrendered in full or partial payment of an Option price, a corresponding number of the Shares issued upon exercise of the Option shall be Restricted Shares subject to the same Restrictions as the surrendered Restricted Shares.

7.7 Special Rules for Incentive Stock Options. In the case of an Option designated as an Incentive Stock Option, the terms of the Option and the Award Agreement shall be in conformance with the statutory and regulatory requirements specified in Section 422 of the Code, as in effect on the date such ISO is granted. ISOs may be granted only to employees of Corporation or a Subsidiary. ISOs may not be granted under the Plan after January 8, 2001, unless the ten-year limitation of Section 422(b)(2) of the Code is removed or extended.

7.8 Restricted Shares. In the discretion of the Committee, the Shares issuable upon exercise of an Option may be Restricted Shares if so provided in the Award Agreement.

7.9 Deferred Compensation Options. The Committee may, in its discretion, grant Deferred Compensation Options with an option price less than Fair Market Value to provide a means for deferral of compensation to future dates. The option price shall be determined by the Committee subject to Section 7.3(a) of the Plan. The number of Shares subject to a Deferred Compensation Option shall be determined by the Committee, in its discretion, by dividing the amount of compensation to be deferred by the difference between the Fair Market Value of a Share on the date of grant and the option price of the Deferred Compensation Option. Amounts of compensation deferred with Deferred Compensation Options may include amounts earned under Awards granted under the Plan or under any other compensation program or arrangement of Corporation as permitted by the Committee. The Committee shall grant Deferred Compensation Options only if it reasonably determines that the recipient of such an Option is not likely to be deemed to be in constructive receipt for income tax purposes of the income being deferred.

7.10 Reload Options. The Committee, in its discretion, may provide in an Award Agreement for an Option that in the event all or a portion of the Option is exercised by the Participant using previously acquired Shares, the Participant shall automatically be granted a replacement Option (with an option price equal to the Fair Market Value of a Share on the date of such exercise) for a number of Shares equal to (or equal to a portion of) the number of shares surrendered upon exercise of the Option. Such reload Option features may be subject to such terms and conditions as the Committee shall determine, including without limitation, a condition that the Participant retain the Shares issued upon exercise of the Option for a specified period of time.

7.11 Limitation on Number of Shares Subject to Options. In no event may options for more than 500,000 Shares be granted to any individual under the Plan during any fiscal year period.

ARTICLE 8
STOCK APPRECIATION RIGHTS

8.1 General. Stock Appreciation Rights shall be subject to the terms and conditions set forth in Article 6 and this Article 8 and shall contain such additional terms and conditions, not inconsistent with the express terms of the Plan, as the Committee (or the Board with respect to Awards to Non-Employee Directors) shall deem desirable.

8.2 Nature of Stock Appreciation Right. A Stock Appreciation Right is an Award entitling a Participant to receive an amount equal to the excess (or if the Committee shall determine at the time of grant, a portion of the excess) of the Fair Market Value of a Share of Common Stock on the date of exercise of the SAR over the base price, as described below, on the date of grant of the SAR, multiplied by the number of Shares with respect to which the SAR shall have been exercised. The base price shall be designated by the Committee in the Award Agreement for the SAR and may be the Fair Market Value of a Share on the grant date of the SAR or such other higher or lower price as the Committee shall determine.

8.3 Exercise. A Stock Appreciation Right may be exercised by a Participant in accordance with procedures established by the Committee. The Committee may also provide that a SAR shall be automatically exercised on one or more specified dates or upon the satisfaction of one or more specified conditions. In the case of SARs granted to Reporting Persons, exercise of the SAR shall be limited by the Committee to the extent required to comply with the applicable requirements of Rule 16b-3 under the Exchange Act.

8.4 Form of Payment. Payment upon exercise of a Stock Appreciation Right may be made in cash, in installments, in Shares, by issuance of a Deferred Compensation Option, or in any combination of the foregoing, or in any other form as the Committee shall determine.

ARTICLE 9
RESTRICTED AWARDS

9.1 Types of Restricted Awards. Restricted Awards granted under the Plan may be in the form of either Restricted Shares or Restricted Units.

(a) Restricted Shares. A Restricted Share is an Award of Shares transferred to a Participant subject to such terms and conditions as the Committee deems appropriate, including, without limitation, restrictions on the sale, assignment, transfer, or other disposition of such Restricted Shares and may include a requirement that the Participant forfeit such Restricted Shares back to Corporation upon termination of Participant's employment (or service as an Advisor) for specified reasons within a specified period of time or upon other conditions, as set forth in the Award Agreement for such Restricted Shares. Each Participant receiving a Restricted Share shall be issued a stock certificate in respect of such Shares, registered in the name of such Participant, and shall execute a stock power in blank with respect to the Shares evidenced by such certificate. The certificate

evidencing such Restricted Shares and the stock power shall be held in custody by Corporation until the Restrictions thereon shall have lapsed.

(b) Restricted Units. A Restricted Unit is an Award of units (with each unit having a value equivalent to one Share) granted to a Participant subject to such terms and conditions as the Committee deems appropriate, and may include a requirement that the Participant forfeit such Restricted Units upon termination of Participant's employment (or service as an Advisor) for specified reasons within a specified period of time or upon other conditions, as set forth in the Award Agreement for such Restricted Units.

9.2 General. Restricted Awards shall be subject to the terms and conditions of Article 6 and this Article 9 and shall contain such additional terms and conditions, not inconsistent with the express provisions of the Plan, as the Committee (or the Board with respect to Awards to Non-Employee Directors) shall deem desirable.

9.3 Restriction Period. Restricted Awards shall provide that such Awards, and the Shares subject to such Awards, may not be transferred, and may provide that, in order for a Participant to Vest in such Awards, the Participant must remain in the employment (or remain as an Advisor) of Corporation or its Subsidiaries, subject to relief for reasons specified in the Award Agreement, for a period commencing on the date of the Award and ending on such later date or dates as the Committee may designate at the time of the Award (the "Restriction Period"). During the Restriction Period, a Participant may not sell, assign, transfer, pledge, encumber, or otherwise dispose of Shares received under or governed by a Restricted Award grant. The Committee, in its sole discretion, may provide for the lapse of restrictions in installments during the Restriction Period. Upon expiration of the applicable Restriction Period (or lapse of Restrictions during the Restriction Period where the Restrictions lapse in installments) the Participant shall be entitled to settlement of the Restricted Award or portion thereof, as the case may be. Although Restricted Awards shall usually Vest based on continued employment (or service as an Advisor) and Performance Awards under Article 10 shall usually Vest based on attainment of Performance Goals, the Committee, in its discretion, may condition Vesting of Restricted Awards on attainment of Performance Goals as well as continued employment (or service as an Advisor). In such case, the Restriction Period for such a Restricted Award shall include the period prior to satisfaction of the Performance Goals.

9.4 Forfeiture. If a Participant ceases to be an employee or Advisor of Corporation or a Subsidiary during the Restriction Period for any reason other than reasons which may be specified in an Award Agreement (such as death, Disability, or Retirement) the Award Agreement may require that all non-Vested Restricted Awards previously granted to the Participant be forfeited and returned to Corporation.

9.5 Settlement of Restricted Awards.

(a) Restricted Shares. Upon Vesting of a Restricted Share Award, the legend on such Shares will be removed and the Participant's stock power will be returned and the Shares will no longer be Restricted Shares. The Committee may also, in its discretion, permit a Participant to receive, in lieu of unrestricted Shares at the

conclusion of the Restriction Period, payment in cash, installments, or by issuance of a Deferred Compensation Option equal to the Fair Market Value of the Restricted Shares as of the date the Restrictions lapse.

(b) Restricted Units. Upon Vesting of a Restricted Unit Award, a Participant shall be entitled to receive payment for Restricted Units in an amount equal to the aggregate Fair Market Value of the Shares covered by such Restricted Units at the expiration of the Applicable Restriction Period. Payment in settlement of a Restricted Unit shall be made as soon as practicable following the conclusion of the applicable Restriction Period in cash, in installments, in Shares equal to the number of Restricted Units, by issuance of a Deferred Compensation Option, or in any other manner or combination of such methods as the Committee, in its sole discretion, shall determine.

9.6 Rights as a Shareholder. A Participant shall have, with respect to unforfeited Shares received under a grant of Restricted Shares, all the rights of a shareholder of Corporation, including the right to vote the shares, and the right to receive any cash dividends. Stock dividends issued with respect to Restricted Shares shall be treated as additional Shares covered by the grant of Restricted Shares and shall be subject to the same Restrictions.

ARTICLE 10
PERFORMANCE AWARDS

10.1 General. Performance Awards shall be subject to the terms and conditions set forth in Article 6 and this Article 10 and shall contain such other terms and conditions not inconsistent with the express provisions of the Plan, as the Committee (or the Board with respect to Awards to Non-Employee Directors) shall deem desirable.

10.2 Nature of Performance Awards. A Performance Award is an Award of units (with each unit having a value equivalent to one Share) granted to a Participant subject to such terms and conditions as the Committee deems appropriate, including, without limitation, the requirement that the Participant forfeit such Performance Award or a portion thereof in the event specified performance criteria are not met within a designated period of time.

10.3 Performance Cycles. For each Performance Award, the Committee shall designate a performance period (the "Performance Cycle") with a duration to be determined by the Committee in its discretion within which specified Performance Goals are to be attained. There may be several Performance Cycles in existence at any one time and the duration of Performance Cycles may differ from each other.

10.4 Performance Goals. The Committee shall establish Performance Goals for each Performance Cycle on the basis of such criteria and to accomplish such objectives as the Committee may from time to time select. Performance Goals may be based on performance criteria for Corporation, a Subsidiary, or an operating group, or based on a Participant's individual performance. Performance Goals may include objective and subjective criteria. During any Performance Cycle, the Committee may adjust the Performance Goals for such Performance Cycle as it deems equitable in recognition of unusual or nonrecurring events

affecting Corporation, changes in applicable tax laws or accounting principles, or such other factors as the Committee may determine.

10.5 Determination of Awards. As soon as practicable after the end of a Performance Cycle, the Committee shall determine the extent to which Performance Awards have been earned on the basis of performance in relation to the established Performance Goals.

10.6 Timing and Form of Payment. Settlement of earned Performance Awards shall be made to the Participant as soon as practicable after the expiration of the Performance Cycle and the Committee's determination under Section 10.5, in the form of cash, installments, Shares, Deferred Compensation Options, or any combination of the foregoing or in any other form as the Committee shall determine.

ARTICLE 11
OTHER STOCK-BASED AND COMBINATION AWARDS

11.1 Other Stock-Based Awards. The Committee (or the Board with respect to Awards to Non-Employee Directors) may grant other Awards under the Plan pursuant to which Shares are or may in the future be acquired, or Awards denominated in or measured by Share equivalent units, including Awards valued using measures other than the market value of Shares. Such Other Stock-Based Awards may be granted either alone, in addition to, or in tandem with, any other type of Award granted under the Plan.

11.2 Combination Awards. The Committee may also grant Awards under the Plan in tandem or combination with other Awards or in exchange of Awards, or in tandem or combination with, or as alternatives to, grants or rights under any other employee plan of Corporation, including the plan of any acquired entity. No action authorized by this section shall reduce the amount of any existing benefits or change the terms and conditions thereof without the Participant's consent.

ARTICLE 12
DEFERRAL ELECTIONS

The Committee may permit a Participant to elect to defer receipt of the payment of cash or the delivery of Shares that would otherwise be due to such Participant by virtue of the exercise, earn-out, or Vesting of an Award made under the Plan. If any such election is permitted, the Committee shall establish rules and procedures for such payment deferrals, including, but not limited to: (a) payment or crediting of reasonable interest on such deferred amounts credited in cash, (b) the payment or crediting of dividend equivalents in respect of deferrals credited in Share equivalent units, or (c) granting of Deferred Compensation Options.

ARTICLE 13
DIVIDEND EQUIVALENTS

Any Awards may, at the discretion of the Committee, earn dividend equivalents. In respect of any such Award which is outstanding on a dividend record date for Common Stock, the Participant may be credited with an amount equal to the amount of cash or stock dividends that would have been paid on the Shares covered by such Award, had such covered Shares been issued and outstanding on such dividend record date. The Committee shall establish such rules

and procedures governing the crediting of dividend equivalents, including the timing, form of payment, and payment contingencies of such dividend equivalents, as it deems are appropriate or necessary.

ARTICLE 14
ADJUSTMENTS UPON CHANGES IN CAPITALIZATION, ETC.

14.1 Plan Does Not Restrict Corporation. The existence of the Plan and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Board or the shareholders of Corporation to make or authorize any adjustment, recapitalization, reorganization, or other change in Corporation's capital structure or its business, any merger or consolidation of the Corporation, any issue of bonds, debentures, preferred or prior preference stocks ahead of or affecting Corporation's capital stock or the rights thereof, the dissolution or liquidation of Corporation or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding.

14.2 Adjustments by the Committee. In the event of any change in capitalization affecting the Common Stock of Corporation, such as a stock dividend, stock split, recapitalization, merger, consolidation, split-up, combination or exchange of shares or other form of reorganization, or any other change affecting the Common Stock, such proportionate adjustments, if any, as the Committee, in its sole discretion, may deem appropriate to reflect such change, shall be made with respect to the aggregate number of Shares for which Awards in respect thereof may be granted under the Plan, the maximum number of Shares which may be sold or awarded to any Participant, the number of Shares covered by each outstanding Award, and the price per Share in respect of outstanding Awards. The Committee may also make such adjustments in the number of Shares covered by, and price or other value of any outstanding Awards in the event of a spin-off or other distribution (other than normal cash dividends), of Corporation assets to shareholders.

ARTICLE 15
AMENDMENT AND TERMINATION

Without further approval of Corporation's shareholders, the Board may at any time terminate the Plan, or may amend it from time to time in such respects as the Board may deem advisable, except that the Board may not, without approval of the shareholders, make any amendment that would materially increase the aggregate number of shares of Common Stock that may be issued under the Plan (except for adjustments pursuant to Article 14 of the Plan). Without further shareholder approval, the Board may amend the Plan to take into account changes in applicable securities, federal income tax laws, and other applicable laws. Further, should the provisions of Rule 16b-3, or any successor rule, under the Exchange Act be amended, the Board, without further shareholder approval, may amend the Plan as necessary to comply with any modifications to such rule.

ARTICLE 16
MISCELLANEOUS

16.1 Tax Withholding.

16.1.1 General. Corporation shall have the right to deduct from any settlement, including the delivery or vesting of Shares, made under the Plan any federal, state, or local taxes of any kind required by law to be withheld with respect to such payments or to take such other action as may be necessary in the opinion of Corporation to satisfy all obligations for the payment of such taxes. The recipient of any payment or distribution under the Plan shall make arrangements satisfactory to Corporation for the satisfaction of any such withholding tax obligations. Corporation shall not be required to make any such payment or distribution under the Plan until such obligations are satisfied.

16.1.2 Stock Withholding. The Committee, in its sole discretion, may permit a Participant to satisfy all or a part of the withholding tax obligations incident to the settlement of an Award involving payment or delivery of Shares to the Participant by having Corporation withhold a portion of the Shares that would otherwise be issuable to the Participant. Such Shares shall be valued based on their Fair Market Value on the date the tax withholding is required to be made. Any stock withholding with respect to a Reporting Person shall be subject to such limitations as the Committee may impose to comply with the requirements of the Exchange Act.

16.2 Unfunded Plan. The Plan shall be unfunded and Corporation shall not be required to segregate any assets that may at any time be represented by Awards under the Plan. Any liability of Corporation to any person with respect to any Award under the Plan shall be based solely upon any contractual obligations that may be effected pursuant to the Plan. No such obligation of Corporation shall be deemed to be secured by any pledge of, or other encumbrance on, any property of Corporation.

16.3 Payments to Trust. The Committee is authorized to cause to be established a trust agreement or several trust agreements whereunder the Committee may make payments of amounts due or to become due to Participants in the Plan.

16.4 Annulment of Awards. Any Award Agreement may provide that the grant of an Award payable in cash is provisional until cash is paid in settlement thereof or that grant of an Award payable in Shares is provisional until the Participant becomes entitled to the certificate in settlement thereof. In the event the employment (or service as an Advisor or membership on the Board) of a Participant is terminated for cause (as defined below), any Award which is provisional shall be annulled as of the date of such termination for cause. For the purpose of this Section 16.4, the term "for cause" shall have the meaning set forth in the Participant's employment agreement, if any, or otherwise means any discharge (or removal) for material or flagrant violation of the policies and procedures of Corporation or for other job performance or conduct which is materially detrimental to the best interests of Corporation, as determined by the Committee.

16.5 Engaging in Competition With Corporation. Any Award Agreement may provide that, if a Participant terminates employment with Corporation or a Subsidiary for any reason whatsoever, and within 18 months after the date thereof accepts employment with any competitor of (or otherwise engages in competition with) Corporation, the Committee, in its sole discretion, may require such Participant to return to Corporation the economic value of any Award that is realized or obtained (measured at the date of exercise, Vesting, or payment) by

such Participant at any time during the period beginning on the date that is six months prior to the date of such Participant's termination of employment with Corporation.

16.6 Other Corporation Benefit and Compensation Programs. Payments and other benefits received by a Participant under an Award made pursuant to the Plan shall not be deemed a part of a Participant's regular, recurring compensation for purposes of the termination indemnity or severance pay law of any state or country and shall not be included in, or have any effect on, the determination of benefits under any other employee benefit plan or similar arrangement provided by Corporation or a Subsidiary unless expressly so provided by such other plan or arrangements, or except where the Committee expressly determines that an Award or portion of an Award should be included to accurately reflect competitive compensation practices or to recognize that an Award has been made in lieu of a portion of cash compensation. Awards under the Plan may be made in combination with or in tandem with, or as alternatives to, grants, awards, or payments under any other Corporation or Subsidiary plans, arrangements, or programs. The Plan notwithstanding, Corporation or any Subsidiary may adopt such other compensation programs and additional compensation arrangements as it deems necessary to attract, retain, and reward employees and directors for their service with Corporation and its Subsidiaries.

16.7 Securities Law Restrictions. No Shares shall be issued under the Plan unless counsel for Corporation shall be satisfied that such issuance will be in compliance with applicable federal and state securities laws. Certificates for Shares delivered under the Plan may be subject to such stop-transfer orders and other restrictions as the Committee may deem advisable under the rules, regulations, and other requirements of the Securities and Exchange Commission, any stock exchange upon which the Common Stock is then listed, and any applicable federal or state securities law. The Committee may cause a legend or legends to be put on any such certificates to make appropriate reference to such restrictions.

16.8 Governing Law. Except with respect to references to the Code or federal securities laws, the Plan and all actions taken thereunder shall be governed by and construed in accordance with the laws of the state of Oregon.

ARTICLE 17
SHAREHOLDER APPROVAL

The amendment and restatement of the Plan is expressly subject to the approval of the Plan by the shareholders at the 1997 annual meeting of Corporation's shareholders.

Exhibit 10.14

Description of OraSure Technologies, Inc. 2003 Self-Funding Annual Incentive Plan

On February 4, 2003, the Company's Board of Directors authorized the Company to implement the 2003 Self-Funding Annual Incentive Plan (the "Bonus Plan"). The purpose of the Bonus Plan is to reward outstanding individual performance by management with cash bonuses. All employees, except for sales employees (who are covered by a separate commission plan) at the level of director and above, will be eligible to participate in the Bonus Plan.

Pursuant to the Bonus Plan, cash bonuses may be paid out of a cash bonus pool to be funded based on the Company's achievement of certain financial objectives regarding revenues, net income, cash flow from operations and gross margin for 2003. If the Company achieves 100% of these financial targets, the bonus pool would be funded in the amount of $900,000.

Payments from the bonus pool will depend on an employee's achievement of individual performance objectives. Bonus payments will be based on the target payouts set forth below, which are expressed as a percentage of base salary. No individual participating in the Bonus Plan can receive a bonus greater than 150% of his or her target amount, and the aggregate of all bonuses cannot exceed the funded amount of the bonus pool.

Title	Target Payouts
Chief Executive Officer	50%
Executive Vice President	40%
Senior Vice President	30%
Vice President	20%
Director	10%

Performance criteria for individual employees will be derived from the Company's 2003 corporate objectives concerning financial performance, strategic planning, research and development, business development, regulatory affairs and quality control, manufacturing, engineering, information systems, sales and marketing, human resources, investor relations matters and/or such other objectives chosen by the Board or Compensation Committee in their sole discretion. Awards are expected to reflect a weighted average measurement of an employee's achievement of his or her individual performance objectives.

Employees must be employed by the Company as of December 31, 2003 and at the time of the bonus award in order to participate in the Bonus Plan, and awards will be adjusted on a pro rata basis to the extent any employee is employed for only a portion of the year 2003. The Chief Executive Officer will recommend individual awards for all participating employees (except for the Chief Executive Officer) for approval by the Compensation Committee of the Board based on an assessment of each individual's performance against his or her applicable performance objectives. The Compensation Committee may approve or disapprove any recommended bonus award in whole or in part in its sole discretion. The Compensation Committee shall recommend for Board approval any bonus award for the Chief Executive Officer based on an assessment of his performance against his individual performance objectives. The Board may approve or disapprove any recommended bonus award for the Chief Executive Officer in whole or in part in its sole discretion.

The Compensation Committee and the Board shall have the right in their sole discretion to reject any or all of the recommended bonus awards, even if the bonus pool has been funded and any and all applicable performance criteria have been satisfied, based on the business conditions of the Company at or immediately after the end of 2003.

Exhibit 10.15

Description of OraSure Technologies, Inc.
Management Stock Option Award Guidelines

On February 4, 2003, the Company's Board of Directors adopted Stock Option Award Guidelines for the Company's management (the "Option Guidelines"). The purpose of the Option Guidelines is to establish a framework for granting stock options in order to reward outstanding performance by the Company's management team. Employees covered by the Option Guidelines are at the director level and above, and include all Company officers.

Awards under the Option Guidelines in any year will depend on an employee's achievement of individual performance objectives. Each employee's individual performance will be evaluated against his or her performance to determine if that individual meets expectations, exceeds expectations or has performed in an outstanding manner. Set forth below are annual award targets assuming that the participating employees are evaluated as having met expectations for the year in question:

Title	Award Target (No.of Shares)
Chief Executive Officer	150,000
Executive Vice President	60,000
Senior Vice President	40,000
Vice President	25,000
Director	Up to 7,500

If an employee's performance is evaluated to exceed expectations or to be outstanding, the amount of that employee's award could be up to 150% of the applicable annual target set forth above. If an employee's performance is evaluated to be below expectations, his or her award could be 50-75% of the applicable target set forth above. Any employee whose performance is evaluated to be unsatisfactory would receive no stock option award.

Performance criteria for individual employees will be derived from the Company's corporate objectives for the applicable year, concerning financial performance, strategic planning, research and development, business development, regulatory affairs and quality control, manufacturing, engineering, information systems, sales and marketing, human resources, investor relations matters and/or such other objectives chosen by the Board or the Compensation Committee in their sole discretion. Awards are expected to reflect a weighted average measurement of an employee's achievement of his or her individual performance objectives.

Employees must be employed by the Company as of December 31, 2003 and at the time of grant in order to receive a stock option award, and awards will be adjusted on a pro rata basis to the extent any employee is employed for only a portion of a year. The Chief Executive Officer will recommend individual awards for all covered employees (other than the Chief Executive Officer) to the Compensation Committee of the Board of Directors based on an assessment of each individual's performance against his or her applicable performance objectives. The Compensation Committee may approve or disapprove any recommended option award in whole or in part in its sole discretion. The Compensation Committee will evaluate the performance of the Chief Executive Officer and determine an appropriate option award in accordance with the Option Guidelines and such evaluation.

The Compensation Committee shall have the right in its sole discretion to reject any or all of the recommended bonus awards, even if any and all applicable performance criteria have been satisfied, based on the business conditions of the Company at or immediately after the end of 2003.

Exhibit 23

Independent Auditors' Consent

The Board of Directors
OraSure Technologies, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-102235, No. 333-50340 and No. 333-48662) on Form S-8 and the registration statement (No. 333-73498) on Form S-3 of OraSure Technologies, Inc. of our report dated January 27, 2003, with respect to the balance sheet of OraSure Technologies, Inc. as of December 31, 2002, and the related statements of operations, stockholders' equity and comprehensive loss, and cash flows for the year then ended, which report appears in the December 31, 2002 annual report on Form 10-K of OraSure Technologies, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 31, 2003

Exhibit 24

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2002, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 24, 2003.

/s/ Carter H. Eckert

Signature

Carter H. Eckert

Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2002, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2003.

/s/ Michael J. Gausling

Signature

Michael J. Gausling

Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2002, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2003.

/s/ Frank G. Hausmann

Signature

Frank G. Hausmann

Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2002, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2003.

/s/ Richard J. Lane

Signature

Richard J. Lane

Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2002, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2003.

/s/ Gregory B. Lawless

Signature

Gregory B. Lawless

Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2002, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2003.

/s/ Roger L. Pringle

Signature

Roger L. Pringle

Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2002, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of February 26, 2003.

/s/ Douglas G. Watson

Signature

Douglas G. Watson

Print Name

Exhibit 99.1

CERTIFICATION PURSUANT TO
18 U.S.C.ss.1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of OraSure Technologies, Inc. (the "Company") on Form 10-K for the year ended December 31, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael J. Gausling, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Michael J. Gausling

Michael J. Gausling
President and Chief Executive Officer

March 31, 2003

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to OraSure Technologies, Inc. and will be retained by OraSure Technologies, Inc. and furnished to the Securities and Exchange Commission or its Staff upon request.

Exhibit 99.2

CERTIFICATION PURSUANT TO
18 U.S.C.ss.1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of OraSure Technologies, Inc. (the "Company") on Form 10-K for the year ended December 31, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Ronald H. Spair

Ronald H. Spair
Executive Vice President and
Chief Financial Officer

March 31, 2003

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to OraSure Technologies, Inc. and will be retained by OraSure Technologies, Inc. and furnished to the Securities and Exchange Commission or its Staff upon request.