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

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the fiscal year ended December 31, 2004

OR

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

For the transition period from _____ to _____

Commission File 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 nonaffiliates, 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 30, 2004)**:** $417,434,893

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of March 1, 2005: 44,639,664 shares.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement for the 2005 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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Statements contained in this Annual 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 Annual 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 business principally involves the development, manufacture, marketing and sale of oral fluid specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types, and other medical devices. Our diagnostic products include tests which are processed in a laboratory and tests which are performed on a rapid basis at the point of care. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. One of our products is also sold in the United States over-the-counter or consumer retail market.

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 infectious diseases, drugs of abuse 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 is 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.

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.

Additional information about us 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. These 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 Annual Report.

Products

The following is a summary of our principal products and their existing and pending approvals/clearances by the U.S. Food and Drug Administration ("FDA") and commercial status:

Product	Description	FDA Approval Status	Commercial Status
OraQuick® *ADVANCE*™	A rapid, point-of-care test for antibodies to the Human Immunodeficiency Virus Type 1 and Type 2 ("HIV-1/2") that can be visually read at the point of care in approximately 20 minutes.	Premarket approval ("PMA") approved by the FDA (March 2004 – June 2004) for use with oral fluid, fingerstick and venous whole blood and plasma. CLIA (Clinical Laboratory Improvement Amendments of 1988) waived for use with oral fluid, fingerstick and venous whole blood (June 2004).	Marketed
OraQuick® HIV-1	A rapid, point-of-care test for antibodies to the Human Immunodeficiency Virus Type 1 ("HIV-1") that can be visually read at the point of care in approximately 20 minutes.	PMA approved by the FDA (November 2002 – September 2003) for use with fingerstick and venous whole blood. CLIA waived for use with fingerstick and venous whole blood (January 2003).	Marketed
OraSure®	Oral fluid collection device for the detection of antibodies to HIV-1 in an oral fluid sample in a laboratory setting.	PMA approved by FDA in December 1994. Also have FDA 510(k) clearance for use of this device in detecting cocaine and cotinine (an indicator of nicotine) in oral fluid.	Marketed Marketed
Intercept®	Oral fluid collection device, along with nine related immunoassays, for oral fluid drug testing in a laboratory setting.	Collection device—FDA 510(k) cleared in 2000.	Marketed
	Used to detect the following drugs in an oral fluid sample: marijuana, cocaine, opiates, amphetamines, methamphetamines, PCP, benzodiazepines, barbiturates and methadone.	Nine drug assays—FDA 510(k) cleared during 2000-2001.	Marketed
Histofreezer®Rx	A cryosurgical (freezing) system for the removal of warts and other benign skin lesions, marketed primarily to the physicians' office market.	Nine indications—FDA 510(k) cleared during 1991 – 1999.	Marketed
Freeze Off™	A cryosurgical (freezing) system for the removal of common and plantar warts, sold under the Freeze Off™ and Compound W® tradenames in the over-the-counter market in the U.S.	Two indications—FDA 510(k) cleared in February 2003.	Marketed
UP*link*®	A rapid, point-of-care oral fluid drug detection system.	510(k) application filed with FDA in September 2003; withdrawn in March 2004 due to need to submit additional performance data.	Marketed Internationally

In addition to the above products, we also sell certain immunoassay tests and reagents for insurance risk assessment, substance abuse testing and forensic toxicology applications; an oral fluid Western blot HIV-1 confirmatory test approved by the FDA for confirming positive HIV-1 test results obtained from the use of our OraSure® device; and the FDA 510(k) cleared Q.E.D.® saliva alcohol test.

OraQuick® Rapid Test

OraQuick® is our rapid test platform designed to test an oral fluid, whole blood (i.e., both fingerstick and venous) or 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 or plasma is to be tested, a loop collection device is used to collect a drop of blood or plasma and mix it in the developer solution, after which the collection pad is inserted into the solution. In all cases, 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 was the OraQuick® rapid HIV-1 antibody test, a rapid test for the presence of antibodies against HIV-1. In 2002, we received premarket approval of this test from the FDA for detecting HIV-1 in finger-stick whole blood samples and in 2003 we received FDA approval for use of the OraQuick® test with venous whole blood samples. These approvals were based on data from clinical studies we performed, which indicated that the OraQuick® test has sensitivity of 99.6% and specificity of 100%. 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 has been made available for use by nearly 40,000 locations in the United States certified under the Clinical Laboratory Improvements Amendments of 1988, or CLIA, to perform moderately complex diagnostic tests. Additionally, in January 2003, we received a waiver under CLIA for OraQuick® which permits the use of this 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 the period March to June 2004, we received FDA approval for use of our new OraQuick® test to detect antibodies to both HIV-1 and a second type of the HIV virus, known as HIV-2, in finger-stick and venous whole blood, oral fluid and plasma. In June 2004, we also received a CLIA waiver of this test for oral fluid, fingerstick whole blood and venous whole blood. We named this new test OraQuick® *ADVANCE*™.

In mid-July 2004, we received data from an investigational clinical trial suggesting a higher rate of unconfirmed positive results from the use of our OraQuick® HIV-1/2 test in oral fluid samples than was shown in the clinical data that we compiled in support of our FDA approval of an oral fluid claim, including data from Company-sponsored trials and independent Centers for Disease Control and Prevention ("CDC") studies. Similar results were not indicated for blood samples tested with the device. We performed a technical and procedural assessment to understand this situation and delayed the launch of the OraQuick® *ADVANCE*™ HIV-1/2 test, which was originally scheduled for August of 2004, until the assessment was completed. Based on the results of this assessment, we determined that the OraQuick® *ADVANCE*™ test performed within specifications, and we commercially launched this product in October 2004.

We believe that the OraQuick® ADVANCE™ device, because it is approved for detecting antibodies to both HIV-1 and 2 in fingerstick and venous whole blood, oral fluid and plasma samples, will provide a significant competitive advantage in the market for rapid HIV testing in the United States. Demand for OraQuick® *ADVANCE*™ has quickly grown since the launch of that product, and it is our intent to convert all customers to this product and ultimately stop manufacturing and selling the OraQuick® HIV-1 test.

In April 2003, the CDC announced a new four-part initiative for HIV testing and diagnosis, which is intended to increase the use of rapid HIV testing as part of routine medical care. Under this program, the CDC purchased 250,000 OraQuick® devices during 2003, 250,000 devices during 2004, and 209,000 additional devices for delivery in 2005.

In August 2004, the Substance Abuse and Mental Health Services Administration ("SAMHSA") placed an order to purchase $4.0 million of our OraQuick® *ADVANCE*™ tests and HIV confirmatory test services. The OraQuick® tests are expected to be deployed by SAMHSA to over 22,000 substance abuse treatment and prevention sites throughout the United States. We are discussing an amendment to this contract with SAMHSA, which is expected to increase the number of OraQuick® *ADVANCE*™ tests purchased and eliminate the confirmatory test component of the order. We expect that all tests ordered by SAMHSA will be fully deployed in 2005.

The OraQuick® device is also 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 transmission. In September 2003, the CDC reported that, based on data from the MIRIAD study, the use of the OraQuick® test at the point of care provided test results four times faster than when the OraQuick® test was used in a laboratory setting. As a result, the study found that rapid HIV testing enables healthcare professionals to determine the HIV status of a mother and administer antiretroviral drugs to both mother and child more quickly than traditional laboratory tests, thereby reducing the chances of mother-to-child transmission of HIV.

Finally, the OraQuick® device has been selected for use in the CDC's LIFE Initiative, an international effort to address the AIDS epidemic in certain African countries. This initiative focuses on areas such as preventing mother-to-child transmission, secondary transmitted disease prevention, HIV prevention for youth, and blood safety systems.

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 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 systems for infectious disease testing, 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 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 bioMerieux, Inc. ("BMX"). During 2004, we completed clinical trials with BMX as part of an application to obtain FDA approval of the use of a new EIA screening test for HIV-1 with an OraSure® device. The FDA submission is expected to be made by BMX during the first quarter of 2005.

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 primarily for insurance risk assessment purposes.

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. Each of these EIA's is also FDA 510(k) cleared for use with the Intercept® device.

We believe that the Intercept® device has several advantages over competing urine and other drugs of abuse testing products, including its lower total testing 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 thereby streamline the testing process.

Histofreezer® and Freeze Off™

The Histofreezer® cryosurgical removal system is a low-cost alternative to liquid nitrogen and other methods for removal of warts and other benign skin lesions by physicians. 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 by freezing. We have received 510(k) clearance for use of the Histofreezer® product to remove common warts and eight other types of benign skin lesions.

In February 2003, we received FDA 510(k) clearance to market and sell a cryosurgical product similar to Histofreezer® in the retail or over-the-counter market for the removal of common and plantar warts only. This product is being distributed under the name Freeze Off™ by Medtech Holdings, Inc., the owner of the Compound W® line of wart removal products.

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.

In a 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.

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.

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 sell 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 BMX.

Q.E.D.® Saliva Alcohol Test

Our Q.E.D.® saliva alcohol test is a point-of-care test device that is a cost-effective 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 1998, 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.

UPlink®

Based on our proprietary Up-Converting Phosphor Technology (UPT™), UP*link*® is a point-of-care system comprised of an oral fluid sample collector, test cassette, and analyzer, which is designed to deliver instrument-read results for simultaneously detecting the full NIDA-5 panel of tests – cocaine, methamphetamines/amphetamines, PCP, opiates and marijuana, in a single oral fluid sample. The Company believes the UP*link*® point-of-care oral fluid detection system could offer several important advantages over traditional lab-based urine drug tests, including reduced costs and turn around time, the ability to perform accurate drug testing for a full NIDA-5 panel virtually anywhere, treatment of test subjects with greater dignity, and reduced risk of sample adulteration.

In September 2003, we filed an application with the FDA for 510(k) clearance of our UP*link*® rapid oral fluid drugs of abuse detection system. In March 2004, the FDA responded to our application by indicating that additional performance data would be needed in order to obtain clearance. We are evaluating the FDA's requirements and whether any modifications to our UP*link*® system will be required in order to provide that data. At this time, we cannot predict if or when we will be able to resubmit an application for 510(k) clearance of the UP*link*® system. However, the absence of 510(k) clearance does not affect our ability to sell the UP*link*® system internationally.

In March 2000, we signed a research and development agreement with Dräger Safety AG & Co. KGaA ("Dräger"), 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. Under this agreement, Dräger has exercised an 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. In April 2004, we commercially launched the UP*link*® system with Dräger in the roadside market in Europe and other countries.

As part of a recent strategic review of our business, we concluded that the roadside drugs of abuse testing market may not be as attractive as a number of our other opportunities we can pursue. Consequently, we are exploring our options with respect to the UP*link*® system, including transferring the manufacturing of the product to Dräger, which is permitted under our agreement. If we enter into such an arrangement with Dräger, we would expect to receive royalties on future sales of the product by Dräger while retaining the rights to the workplace testing and possibly other markets.

Products Under Development

OraQuick® Platform

We believe that OraQuick® has significant potential as a point-of-care testing platform for physicians' offices, hospitals, and other markets. 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 certain sexually transmitted diseases. We are currently in negotiations with Ortho-Clinical Diagnostics and Chiron Corporation to obtain patent license rights that would enable us to develop and sell a test for detecting antibodies to the Hepatitis C virus using the OraQuick® platform.

OraSure®/Intercept® Applications

Oral mucosal transudate, or OMT, 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 collection of a variety of antibodies or markers for infectious diseases or conditions in addition to HIV-1, such as antibodies to viral hepatitis.

In 2004, SAMHSA issued proposed regulations for oral fluid drug testing for federal workers. When issued in final form, these regulations may require certain modifications to our Intercept® product in order to permit its use by federal workers. As a result, we are attempting to develop modifications to the Intercept® collection device that we anticipate may be required by these regulations or are otherwise likely to be desired by our customers. We are also currently developing additional drugs of abuse assays for use with our Intercept® collection device.

UPT™ Development

During 2004 and for several prior years, much of our research and development efforts were focused on UPT™ and the first UPT™ application to be commercialized, our UP*link*® rapid, point-of-care system for detecting drugs of abuse in oral fluid.

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 may be a label technology with broad applications. During 2004, research was conducted to decrease particle size and increase the light-emitting efficiency of the particles.

We are participating in the third year of 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 covers 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 was approximately $400,000 in the first year, $350,000 in the second year, and $308,000 in the third year and if the grant is renewed by the NIH as we expect, approximately $300,000 in the last year. Payments under the grant are subject to availability of funding from the NIH and satisfactory progress of the research and development project.

Although we believe that UPT™ may have several potential applications for *in vitro* diagnostics, we have not been able to successfully develop potential UPT™ applications other than the UP*link*® application for rapid detection of drugs of abuse in oral fluid. We are evaluating the viability of UPT™ as a technology platform, and a final decision as to the future of UPT™ has not been made. Accordingly, there can be no assurance that we will develop additional UPT™ applications or continue to invest in research and development for UPT™.

Business Strategy

During the fourth quarter of 2004, we completed an intensive review and refinement of our strategic business plans. As a result, we have adopted a multi-part growth strategy, pursuant to which we intend to leverage our extensive diagnostic experience in order to maximize the available opportunities from our existing products and technologies, and supplement our existing product pipeline by accessing other technologies and products. We intend to follow a disciplined approach to maximize the value of our business for the benefit of our stockholders.

Our overall vision is to become a recognized global leader focused on providing innovative diagnostic solutions that add substantial value to existing and emerging healthcare needs. In order to achieve this vision, our business strategy will include the following key elements:

- *Extension of Base Businesses*. We intend to maximize the sales potential of our existing product lines and technologies in the markets where they are currently sold, with a focus on expanding, where possible, the number of our oral fluid product offerings. Under this part of the strategy, we intend to fully capitalize on the potential market reach of our OraQuick®, OraSure®, Intercept®, Histofreezer® and Freeze Off™ products by investing in our sales and marketing efforts where appropriate, making product improvements and enhancements, and optimizing our distribution channels. We also intend to expand the reach of our existing products and technology platforms into new markets and will focus specifically on expanding into international markets.
- *Infectious Disease Testing*. We will pursue new products and technology platforms in the infectious disease, point-of-care testing business to supplement our existing product pipeline. This may include either the development of new infectious disease products or the acquisition of new technologies or products. One new product we are pursuing is the development of a rapid Hepatitis C test on our OraQuick® platform.
- *OTC Opportunities*. We intend to identify or develop products that can be sold in the over-the-counter ("OTC") or retail marketplace. One potential opportunity under this part of our strategy is to determine

the feasibility of selling our OraQuick®*ADVANCE*™ rapid HIV-1/2 antibody test in the United States OTC market. We are also seeking a partner for distributing our cryosurgical wart removal product in the European OTC market.

- *Operational Improvements*. We intend to create a culture focused on the continuous improvement of our operations. These improvements will include, but not be limited to, expanding the use of automated manufacturing for our product lines as demand increases, expanding the global sourcing of components and assemblies to achieve efficiencies and cost improvements, making infrastructure and information technology investments as needed to improve effectiveness and productivity, and modifying our processes in order to continuously improve quality and the effectiveness of our operations.

Research and Development

In 2004, 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 assays, clinical trials and regulatory efforts related to claims for HIV-2, oral fluid and plasma for our OraQuick® *ADVANCE*™ test, CLIA waiver of our OraQuick® *ADVANCE*™ HIV-1/2 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 may continue funding external research.

Research and development expenses totaled approximately $6.1 million in 2004, $8.0 million in 2003 and $8.3 million in 2002. These expenses include the costs associated with research and development, regulatory affairs and clinical trials.

Sales and Marketing

We attempt to reach our major target markets through a combination of direct sales, strategic partnerships, and independent distributors. Our marketing strategy is to raise awareness through a full array of marketing activities, which include trade shows, print advertising, special programs 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 $47.8 million, $35.9 million and $28.1 million in 2004, 2003 and 2002, respectively. Revenues attributable to international customers amounted to $6.2 million, $4.6 million and $3.9 million, or 11%, 11% and 12% of our total revenues, in 2004, 2003 and 2002, 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*, Inc., Heritage Labs and Clinical Reference Laboratory. 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 for life insurance risk assessment. 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. One large insurance customer uses the OraSure® device with policies having face amounts up to $3 million.

Our sales force continues to encourage additional insurance companies to use OraSure® and to extend the use of the product by existing customers. We believe there are several factors which will help expand the use of our device, 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, the ease of use of the OraSure® device, and the development of new oral fluid assays for use with our OraSure® device for detecting substances or conditions that affect life insurance risk assessment.

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 and Clinical Reference Laboratory.

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 both the OraQuick® *ADVANCE*™ HIV-1/2 and OraQuick® HIV-1 antibody tests directly to customers in the public health market for HIV testing. This market consists of a broad range of clinics and laboratories and includes states, counties, and other governmental agencies, the CDC, SAMHSA, 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 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, focusing primarily on the hospital and physicians' office markets. This relationship was later converted to a non-exclusive distributorship in early 2004. In February 2005, we entered into a new agreement for the distribution of the OraQuick® *ADVANCE*™ HIV-1/2 test, appointing Abbott as our exclusive distributor in the U.S. hospital market and as a non-exclusive distributor in the U.S. physicians' office marketplace. As our exclusive distributor to hospitals, Abbott will sell OraQuick® *ADVANCE*™ to federal hospitals under the terms of our Federal Supply Schedule on file with the General Services Administration. Under this new agreement, we have retained exclusive rights for all other markets including sales to the public health and criminal justice markets, the military, the CDC, SAMHSA and other governmental agencies. In February 2005, we terminated the distribution agreement with Abbott for the OraQuick® rapid HIV-1 antibody test and expect Abbott to transition its customers to OraQuick® *ADVANCE*™.

In 2004, we deployed a small sales force that provided direct access to and marketing support for the hospital market for our OraQuick® test. This sales force successfully sold our OraQuick® tests into the hospital market and will now support and work with Abbott to maximize the penetration of OraQuick® *ADVANCE*™ in this market.

Substance Abuse Testing

Our substance abuse testing products are marketed to laboratories serving the workplace testing, forensic toxicology, criminal justice, and drug rehabilitation markets. 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 devices and associated MICRO-PLATE assays 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 and Clinical Reference Laboratory, 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 and quantitative testing method. Typical usage situations include pre-employment, random, post-accident, reasonable-cause, and return-to-duty testing.

Cryosurgical Systems

We sell Freeze Off™, a product similar to Histofreezer®, in the over-the-counter market in the U.S. pursuant to a distribution agreement with Medtech, the owner of the Compound W® line of wart removal products and a wholly-owned subsidiary of Prestige Brands Holdings, Inc.

Most of our Histofreezer® sales occur in the United States to distributors that, in turn, resell the product 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 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.

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, substance abuse, 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® and Freeze Off™ products, immunoassay tests and reagents, and OraQuick® rapid HIV tests accounted for total revenues of approximately $14.6 million, $20.2 million, $6.4 million and $10.2 million in 2004, $14.5 million, $10.8 million, $6.6 million and $6.3 million in 2003 and $14.3 million, $7.2 million, $7.6 million and $400,000 in 2002, respectively. As new products are developed and commercialized, we expect to reduce our dependence on these existing products.

We currently have two customers, Lab*One* and Medtech Holdings, Inc., which accounted for 12% and 25% of our total revenues, respectively, during 2004.

Lab*One* stopped purchasing our AUTO-LYTE® urine assays as of June 2003, and our oral fluid assays as of June 2004. As a result, our assay revenues in the insurance risk assessment market in 2004 were reduced by approximately $1.2 million when compared to 2003. Similarly, our assay revenues in the insurance risk assessment market in 2003 were reduced by approximately $1.8 million when compared to 2002.

The loss of Lab*One* or Medtech, or a significant decrease in the volume of products purchased by either customer, could have a material adverse effect on our results.

Supply and Manufacturing

During 2004, we successfully transferred manufacturing of both the OraSure® and Intercept® collection devices and the oral fluid Western Blot HIV-1 confirmatory test to our Bethlehem, Pennsylvania facility. The transfer of the OraSure® device and the Western Blot required FDA approval and, in August 2003, we completed the required equivalency and validation studies and filed a submission with the FDA seeking approval of the transfers. The FDA granted approval for the transfer of the Western Blot test in January 2004 and for the OraSure® device in March 2004, after an inspection of our Bethlehem manufacturing facility. The transfer of the manufacturing of our Intercept® device required only that we notify the FDA of the transfer. We expect the transfer of these products will lower our manufacturing costs and help assure that we can maintain our quality control for these products in the future.

We manufacture the OraQuick® test in our Bethlehem, Pennsylvania facility. 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 supply agreement had an initial term of one year, and automatically renews 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 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, under a supply agreement with a five-year term ending in 2009. 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. This in turn 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 currently manufactured in 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 our 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 believe 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.

Histofreezer® is assembled 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. Utermöhlen also manufactures Freeze Off™, the over-the-counter version of Histofreezer® for the U.S. market. We believe that additional manufacturers of the Histofreezer® and Freeze Off™ products 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 these products.

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.

We assemble analyzers, test cassettes and collectors used in our UP*link*® oral fluid drugs of abuse rapid detection system and package this product for shipment at our Bethlehem, Pennsylvania facility.

Employees

As of December 31, 2004, we had 194 full-time employees, including 61 in sales, marketing, and client services; 27 in research and development; 73 in operations, manufacturing, quality control, quality assurance, regulatory affairs, clinical trials, information systems, purchasing and shipping; and 33 in administration and finance. This compares to 171 employees as of December 31, 2003. As of December 31, 2004, eight of our employees held Ph.D. degrees. Our employees are not currently represented by a collective bargaining agreement.

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;
- The ability to develop and market products and processes;
- The ability to obtain FDA or other regulatory approvals;
- The ability to manufacture products that meet applicable FDA requirements (i.e., good manufacturing practices);
- Access to adequate capital;
- 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 rapid blood 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 tests, 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. Abbott Laboratories sells a competing rapid HIV test internationally, but during 2003 terminated the manufacture of a rapid HIV test sold primarily into the United States hospital market. In addition, MedMira and Trinity Biotech have each received FDA approval to sell competing rapid HIV-1 blood tests, and Bio-Rad Laboratories has received FDA approval to sell a competing rapid HIV-1/2 blood test in the United States. We believe these tests, under their current FDA approvals, will compete with our OraQuick® tests in the hospital or other laboratory settings. In addition, Trinity Biotech has received CLIA waiver for its rapid HIV test, and we believe that this test will compete with our OraQuick® tests in the markets outside of the traditional hospital and laboratory settings. These companies, or others, may continue to expand the bodily fluids with which a rapid HIV test may be performed, or develop and commercialize new rapid HIV tests, which would provide further competition for our OraQuick® tests. We believe other companies may also seek FDA approval to sell competing rapid HIV tests in the future.

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 thiazides as well as MICRO-PLATE heterogeneous assays specifically designed for the detection of cocaine, cotinine, and Immunoglobulin G, or IgG, in oral fluid are the only assays available in the marketplace. In urine chemistries, our significant competitors include The Diagnostics Systems Group of Olympus America Inc. and Diagnostic Reagents International. However, the most significant competition facing our AUTO-LYTE® assays is from assays developed internally by our laboratory customers (i.e., “home brews”), which can be produced at a cost lower than the price typically paid for our products. For example, effective June 30, 2003, Lab*One*, Inc. ceased purchasing our AUTO-LYTE® urine assays for insurance risk assessment testing, in order, we believe, to use internally-developed assays. As a result, revenues from these products were substantially lower in 2004.

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 MICRO-PLATE oral fluid drug assays, which are sold for use with the Intercept® and OraSure® collection devices, are expected to come under increasing competitive pressure from "home-brew" assays developed internally by our laboratory customers. In fact, on June 30, 2004 Lab*One*, Inc. ceased purchasing our MICRO-PLATE oral fluid assays for use with our OraSure® collection device in the insurance risk assessment testing market and is now, we believe, using internally-developed home-brew assays instead.

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. Wartner may also eventually compete with Histofreezer® in the physician market in the United States.

The Freeze Off™ product, sold by Medtech under its Compound W® tradename, competes with other over-the-counter wart removal products in the United States. Wartner currently sells a competing cryosurgical wart removal product in the over-the-counter market, and Schering-Plough began selling a competing cryosurgical wart removal product under its Dr. Scholl's brand in 2004. In July 2004, we filed a lawsuit against Schering-Plough alleging that Schering-Plough's manufacture and sale of its Dr. Scholl's® Freeze Away™ cryosurgical wart removal product in the over-the-counter market infringes three patents relating to our cryosurgical products. For a further discussion of this dispute with Schering-Plough, see the Section of this Annual Report entitled "Legal Proceedings."

Q.E.D.® has two direct competitors, Ansys Technologies, Inc. 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, 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 provide fewer benefits than our Q.E.D.® test.

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, 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.

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 16 United States patents and numerous foreign patents for the OraSure® and Intercept® collection devices and 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 for lateral flow diagnostic tests that covers our OraQuick® rapid HIV antibody tests in the United States, and we 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® tests. In June 2004, we received a worldwide, non-exclusive sublicense from Bio-Rad Laboratories under patents relating to the HIV-2 virus. Bio-Rad is the exclusive licensee of these patents, which are held by the Institute Pasteur of Paris, France. The non-exclusive rights to the HIV-2 patents obtained from Bio-Rad will permit us to sell a rapid test for both HIV-1 and HIV-2 using our OraQuick® technology platform on a worldwide basis. We obtained these licenses through the payment of certain upfront fees and an agreement to pay ongoing royalties. We believe these fees and royalties are comparable to those generally paid by other companies under similar arrangements.

We may need to obtain licenses or other rights under, or enter into distribution or other business arrangements in connection with certain other intellectual property patents, in order to manufacture and sell the OraQuick® HIV tests. 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 five United States patents and numerous foreign patents issued for apparatuses and methods for the topical removal of skin lesions relating to our Histofreezer® and Freeze Off™ products. We have also licensed another patent relating to apparatuses and methods for the topical removal of skin lesions relating to our Histofreezer® and Freeze Off™ products.

We have or have licensed rights under 16 United States patents and numerous foreign patents for methods, compositions, and apparatuses relating to our UPT™ and UP*link*® technologies. Several additional UPT™ and UP*link*® patent applications remain pending in the United States and abroad.

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

We have four United States 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®, OraQuick® *ADVANCE*™, Histofreezer®, Q.E.D.® and AUTO-LYTE® trademarks. We also own many of these marks and others in several foreign countries. The tradename, Freeze Off™, is owned by Medtech Holdings, Inc., in the U.S. and Canada.

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.

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 regulated environment 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 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 products are regulated in the United States as medical devices.

There are two mechanisms by which regulated medical devices can be placed on the market in the United States. Some products may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act. To obtain this clearance from the FDA, 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 premarket application), the FDA must approve a premarket application, or 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 before approval is granted, if at all.

Some of our 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 assurance 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 (i.e., UL approval).

The Clinical Laboratory Improvements Amendments of 1988, or CLIA, prohibit laboratories from performing 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 both our OraQuick®

rapid HIV-1 and OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody tests and our 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 the 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 a pre-requisite to use of 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. The CE mark is a European Union ("EU") requirement to sell products that fall under the scope of the Medical Devices Directive ("MDD") and the In Vitro Diagnostic Device Directive ("IVDD"). The CE mark is evidence that the manufacturer meets the requirements of all applicable directives, including the MDD and IVDD.

On June 14, 1998, compliance with the MDD became mandatory for all manufacturers selling medical devices in the EU. 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 former Beaverton, Oregon facility, and we subsequently transferred this authorization to our Bethlehem, Pennsylvania facility in November 2003. In December 2000, our Bethlehem facility received final certification under the MDD and various ISO standards, enabling use of the CE mark for our Histofreezer® product line. In November 2003, we updated our certification to the MDD and ISO standards, and obtained additional certification under the Canadian Medical Devices Conformity Assessment System ("CMDCAS"), as discussed below.

In addition, we are currently in the process of preparing the information to demonstrate that we meet the essential requirements of the IVDD in order to receive authorization to affix a CE mark to our OraQuick® HIV products. A CE mark indicates compliance with this directive and is required for distribution of *in vitro* diagnostic products in the EU.

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 various international standards and directives applicable to such equipment.

We must also comply with certain registration requirements as dictated by Health Canada, prior to commencing sales in Canada. We have completed this process for several of our current products and may do so with respect to other products in the future. In addition, Canadian law requires manufacturers of medical devices

to have a quality management system that meets various ISO requirements in order to obtain a license to sell their devices in Canada. The CMDCAS was developed by Health Canada in collaboration with the Standards Council of Canada ("SCC") to support the Canadian Medical Devices Regulations.

In July 2003, Canada adopted a new ISO standard and will require all ISO certificate holders to transition to the new standard by March 14, 2006. The EU has a similar requirement with a compliance date of July 2006. We will need to do additional work and receive an updated certification in order to meet these deadlines.

Anti-Kickback Laws

The Federal Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation, or receipt of any form of remuneration in return for, or to induce:

- The referral of a person;
- The furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other governmental programs; or
- The purchase, lease, or order of, or the arrangement or recommendation of the purchasing, leasing, or ordering of any item or service reimbursable under Medicare, Medicaid, or other governmental programs.

Our products are or may be purchased by customers that will seek or receive reimbursement under Medicare, Medicaid or other governmental programs. Noncompliance with the federal anti-kickback legislation can result in exclusion from Medicare, Medicaid, or other governmental programs, restrictions on our ability to operate in certain jurisdictions, as well as civil and criminal penalties, any of which could have an adverse effect on our business and results of operations.

The Federal Civil Monetary Penalties Law prohibits the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance can result in civil money penalties of up to $10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the Federal healthcare programs.

Many states have also adopted some form of anti-kickback laws. A determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

We believe that we are operating in compliance with these laws.

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 other new products or technology; ability to fund research and development and other projects and operations; ability to obtain or 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; uncertainty and costs of litigation relating to our patents or other intellectual property; 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 our agreements with financial institutions; ability to retain qualified personnel; exposure to product liability, patent infringement 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; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks, war and civil unrest; 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.

Regulatory Risks

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

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. In addition, we are often required to obtain approval or registration with foreign governments or regulatory bodies before we can import and sell our products in foreign countries.

The process of obtaining required approvals or clearances from governmental or public health agencies can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities and other costly, time-consuming procedures. For example, during 2004, we received several FDA approvals for our new OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test, including approval for use of the test on oral fluid samples. These approvals required the submission of clinical data and required significant time to obtain. The submission of an application to the FDA or other regulatory authority 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 or by another agency.

Moreover, the approval or clearance process for a new product can be complex and lengthy. This time span increases our costs to develop new products as well as the risk that we will not succeed in introducing or selling them in the United States or other countries.

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, during 2004 the Substance Abuse and Mental Health Services Administration ("SAMHSA"), which is part of the U.S. Department of Health and Human Services, issued proposed regulations for the use of oral fluid drug testing for federal workers. The SAMHSA regulations, when issued in final form, could permit us to market and sell our oral fluid drug tests for use with federal workers only if certain modifications are made to our products. If we are unable to make these modifications, or if the modifications require significant time to develop, our ability to sell our oral fluid drug testing products in that market could be limited. In addition, the extent to which the final SAMHSA regulations permit the sale of our oral fluid drug tests for use with federal workers may influence whether customers in the workplace, criminal justice or other unregulated markets use our products.

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, or IVDD. We are not permitted to sell our products in the EU without a CE mark, which could lead to the termination of strategic alliances and agreements for sales of those products in the EU. We have obtained the CE mark for many of our existing products, and we intend to CE mark certain of our future products and are not aware of any material reason why we will be unable to do so. However, there can be no assurance that compliance with all provisions of the IVDD will be demonstrated and the CE mark obtained for all products that we desire to sell in the EU.

Failure to Comply With FDA or Other Requirements May Require Us to Suspend Production of Our Products or Institute a Recall Which Could Result in Higher Costs and 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.

Although we believe that we have adequate processes in place to ensure compliance with these requirements, the FDA could force us to stop manufacturing our products if it concludes that we are 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 applicable regulatory requirements.

Risks Relating to Our Financial Results, Structure and Need for Financing

We Have a History of Losses.

We have not achieved full-year profitability. We incurred net losses of approximately $0.6 million, $1.1 million and $3.3 million, in 2004, 2003 and 2002, respectively. As of December 31, 2004, the Company had an accumulated deficit of approximately $131.1 million.

In order to achieve sustainable profitability, our revenues will have to continue to grow at a significant rate. 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® drug testing product, and the OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test;
- The degree to which certain of our new products may replace sales of our existing products and the financial impact of that change, including the degree to which our OraQuick® test will replace our OraSure® collection device for HIV-1 testing or sales of the Freeze Off® wart removal product in the over-the-counter market will replace sales of our Histofreezer® product to physicians' offices or other professional markets;
- Achieving growth in sales of the Freeze Off® wart removal product in the over-the-counter market;
- Achieving growth in international markets with our OraQuick® test, Freeze Off™ product and other products;
- Changes in the level of competition, such as would occur if any larger and financially stronger competitors introduced new or lower priced products to compete with our products;
- Changes in economic conditions in domestic or international markets, such as economic downturns, reduced demand, inflation and currency fluctuations;
- Failure to achieve our targets for growth in revenues;
- Changes in distributor buying patterns or a buildup of significant quantities in our distributors' inventories or distribution channels; and
- Commercially developing, and obtaining regulatory approvals and creating market acceptance for new products in a time frame consistent with our objectives.

We have not yet fully achieved our financial and business 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.

We May Require Future Additional Capital to Fund Our Operations.

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 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;
- The scope and results of clinical testing;
- 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.

An Economic Downturn or Terrorist Attacks May Adversely Affect Our Business.

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 or the issuance of fewer life insurance policies. 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.

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.

Our Stock Price Could Continue to be Volatile.

Our stock price has been volatile, has fluctuated substantially in the past and may be volatile in the future and could experience substantial declines. The following factors, among others, could have a significant impact on the market for our Common Stock:

- Future announcements concerning us;
- Future announcements concerning our competitors or industry;
- Governmental regulation;
- Clinical results with respect to our products in development or those of our competitors;
- Developments in patent or other proprietary rights;
- Litigation or threatened litigation;
- Public concern as to the safety of products that we or others have developed;
- Changes in the level of competition;
- Loss of or declines in sales to major distributors or customers;
- The relatively low trading volume for our Common Stock;
- Period to period fluctuations in our operating results;
- Failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by securities analysts or major stockholders;

- General market and economic conditions; and
- Terrorist attacks, civil unrest and war.

Future Sales by Existing Stockholders Could Depress the Market Price of Our Common Stock and Make It More Difficult For Us to Sell Stock in the Future.

Sales of our Common Stock in the public market, or the perception that such sales could occur, could negatively impact the market price of our Common Stock. We are unable to estimate the number of shares of our Common Stock that may actually be resold in the public market since this will depend on the market price for our Common Stock, the individual circumstances of the sellers and other factors. We also have a number of institutional stockholders that own significant blocks of our Common Stock. If one or more of these stockholders sell large portions of their holdings in a relatively short time, for liquidity or other reasons, the prevailing market price of our Common Stock could be negatively affected.

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 creation or 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 principles. A change in these principles 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.

Risks Relating to Our Industry, Business and Strategy

Our Ability to Sell Products Could be Affected by Competition From New and Existing Diagnostic Products and by Treatment or Other Non-Diagnostic Products Which May be Developed.

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. Many of our principal competitors 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.

We also face competition from products which may be sold at a lower price. To the extent this competition arises, customers may choose to buy lower cost products from third parties or we may be forced to sell our products at a lower price, both of which could result in a loss of revenues or a lower gross margin contribution from the sale of our products. In addition, the development and commercialization of products outside of the diagnostics industry could adversely affect sales of our product. For example, the development of a safe and effective vaccine to HIV or treatments for other diseases or conditions that our products are designed to detect, could reduce, or eventually eliminate, the demand for our HIV or other diagnostic products and thereby result in a loss of revenues.

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

In order to remain competitive, we must regularly commit substantial resources to research and development and the commercialization of new products.

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, or at all, and we may have to abandon a product in which we have invested substantial amounts.

During 2004, 2003 and 2002, we incurred $6.1 million, $8.0 million and $8.3 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 research and development efforts in recent years has been our UPT™ technology and the related UP*link*® rapid detection system; however, we are reevaluating the feasibility and market potential of this technology, and there can be no assurance that we will succeed or continue in our research and development efforts with respect to UPT™, UP*link*® or other technologies or products.

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, 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 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, operations 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 manufacture, 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. 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.

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

We have obtained the required regulatory approvals to sell a cryosurgical wart removal product, called Freeze Off™, in the consumer or over-the-counter market. We believe the sale of this or other products in the over-the-counter market could increase the risk of potential product liability exposure and the required level of insurance coverage that we will need to maintain. 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 and our results of operations.

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 2004 we completed the restructuring of our manufacturing operations, which included the transfer of the manufacturing of our Intercept®, OraSure® and oral fluid Western Blot products from our Beaverton, Oregon facility and a contract manufacturer in Oregon to Bethlehem, Pennsylvania. We obtained FDA approval to transfer the operations to Pennsylvania. This type of transfer and the need to obtain FDA approval could interfere with or delay our manufacturing processes and disrupt continued operations. Any delay in 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, but not limited to, foreign currency exposure, liability under foreign laws or regulations, and not being able to successfully assimilate differences in foreign business practices or overcome language or cultural barriers.

The occurrence 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 or otherwise achieve our financial or strategic objectives.

Our Net Sales Could be Affected by Third-Party Reimbursement Policies and Potential Cost Constraints.

The end-users of our products are expected to increasingly include hospitals, physicians and other healthcare providers. Use of our products could be adversely impacted if these end-users do not receive reimbursement for the cost of our products by their patients' healthcare insurers or payors. Our net sales could also be adversely affected by changes in reimbursement policies of these governmental or private healthcare payors, including in particular the level of reimbursement for our products. In the United States, healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third-party payors, principally private health insurance plans, Medicare and Medicaid, to reimburse all or part of the cost of the product and

procedure. We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the United States in recent years, currently available levels of reimbursement may not continue to be available in the future for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the United States or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, regulation or reimbursement policies of third-party payors may reduce the demand for our products or our ability to sell our products on a profitable basis.

Unexpected Increases in Demand for Our Products Could Require Us to Spend Considerable Resources to Meet the Demand or Harm Our Customer Relationships if We are Unable to Meet Demand.

If we experience unexpected increases in the demand for our products, we may be required to expend additional capital resources to meet these demands. These capital resources could involve the cost of new machinery or even the cost of new manufacturing facilities. This would increase our capital costs, which could adversely affect our earnings. If we are unable to develop necessary manufacturing capabilities in a timely manner, our net sales could be adversely affected. Failure to cost-effectively increase production volumes, if required, or lower than anticipated yields or production problems encountered as a result of changes that we make in our manufacturing processes to meet increased demand, could result in shipment delays and increased manufacturing costs, which could also have a material adverse effect on our revenues and profitability.

Our inability to meet customer demand for our products could also harm our customer relationships and impair our reputation within the industry. This, in turn, could have a material adverse effect on our business and prospects.

Risks Relating to Collaborators

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 consolidated in recent years, 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*, Inc., acquired another large insurance laboratory customer, Osborne Group, Inc., in 2001 and our revenues decreased because of efficiencies resulting from that acquisition.

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 are using lower cost “home brew” insurance testing assays that they have developed internally or purchased from our competitors. As a result, Lab*One* has stopped purchasing our urine assays and certain of our MICRO-PLATE oral fluid assays. This has reduced our sales and is expected to lower sales of these products in 2005 and beyond.

In addition, during the fourth quarter of 2003, Lab*One* acquired the Insurance Testing Laboratory of MetLife, which was another large purchaser of our urine assays and in early 2004 acquired NWT, Inc., a laboratory that distributed the Company’s Intercept® drug test into the workplace testing market. These acquisitions could further reduce sales of our products.

Finally, some of our distributors may not fulfill their contractual obligations. Although we will try to maintain and expand our business with our distributors and require that they fulfill their contractual obligations, there can be no assurance that such companies will continue to purchase or distribute our products, maintain historic order volumes or otherwise meet their purchase or other obligations, 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 antigen and nitrocellulose required to make our OraQuick® rapid HIV-1 antibody test is 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. The availability of critical components from sole supply sources could also reduce our control over pricing, quality and timely delivery. These events could either disrupt our ability to manufacture and sell certain of our products, or completely prevent us from doing so or increase our costs. Any such event could 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 in the United States, 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 HIV-1 confirmatory test, which has also been approved by the FDA for use with our OraSure® device, to confirm that positive indication.

BMX 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 has 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 $11.0 million and $12.2 million, or 20% and 30% of our total revenues, in 2004 and 2003, respectively.

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. Our strategy for development and commercialization of products may entail entering into 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, there is no assurance that they will do so and 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.

Risks Relating to Intellectual Property

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 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 amounts. 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.

We are Involved in Pending, and May Become Involved in Future, Intellectual Property Infringement Disputes, Which are Costly and Could Limit or Eliminate Our Ability to Sell Our Products or Use Certain of Our Technologies in the Future.

From time to time, we may seek to enforce our patents or other intellectual property rights through litigation. In addition, there are a large number of patents and patent applications in our product areas, and additional patents may issue to third parties relating to our product areas. Litigation in our industry regarding patent and other intellectual property rights is prevalent and is expected to continue.

Our involvement in litigation to enforce our patents or other intellectual property or to determine rights in proprietary technology could adversely affect our revenues, market share, results of operations and business because:

- As is common with major litigation, it could consume a substantial portion of managerial and financial resources;
- Its outcome would be uncertain and a court may find that our patents are invalid or unenforceable in response to claims by another party or that the third-party patent claims are valid and infringed by our products;
- An adverse outcome could subject us to the loss of the protection of our patents or to liability in the form of past royalty payments, penalties, special and punitive damages, or future royalty payments significantly affecting our future earnings;
- Failure to obtain a necessary license upon an adverse outcome could prevent us from selling our current products or other products we may develop; and
- A court could award a preliminary and/or permanent injunction which would prevent us from selling our current or future products.

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

Our OraQuick® test 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 or sell the OraQuick® test in the United States or other countries where these patents are in force.

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 and it is possible that a third party could seek to enforce one or more lateral flow patents against us. In the event that we are unable to successfully defend against such litigation or it is determined that a license is required and it is not possible to negotiate or otherwise obtain a license agreement on reasonable terms under a necessary patent, our ability to manufacture and sell the OraQuick® device could be limited. In such case, we may be able to modify the OraQuick® test such that a license would not be necessary. However, this alternative could delay or limit our ability to sell the OraQuick® test in the United States and other markets, which would adversely affect our results of operations, cash flows and business.

Risks Relating to Product Marketing and Sales

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 test, the OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test and other new

products or technologies that may be developed or acquired. 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 obtain market acceptance and fill the market need that is perceived to exist.

If Acceptance and Adoption of Our Oral Fluid Testing 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. However, the ultimate degree of acceptance in these markets is uncertain, and other markets 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 or the rapid, point-of-care testing for HIV. As a result, 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 Increasing International Presence May be Affected by Regulatory, Cultural or Other Restraints.

We intend to increase revenue derived from international sales of our products. Our international sales accounted for approximately $6.2 million or 11% of total revenues for 2004, approximately $4.6 million or 11% of total revenues for 2003, and approximately $3.9 million or 12% of total revenues for 2002.

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 countries;
- 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 ability 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 countries;
- 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 for 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 addition, we have entered into a contract for the manufacture and supply of the OraQuick® rapid HIV antibody test in Thailand, and our Histofreezer® and Freeze Off® cryosurgical products are currently

manufactured in The Netherlands. In addition, we may enter into agreements to manufacture other products in foreign countries as well. However, 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. In addition, foreign currency fluctuations and economic conditions in foreign countries could increase the costs of manufacturing our products in foreign countries.

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 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 approximately $780,000 and increasing to approximately $858,000 per year over that initial term. The lease also has a five-year renewal option at an annual base rental rate of approximately $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 recently exercised our option to extend this lease for the five-year renewal term, which expires in March 2010.

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

We leased approximately 30,500 square feet of office, manufacturing, and laboratory space in Beaverton, Oregon, under a lease that expired on January 31, 2005. During 2004, we transferred the manufacturing operations that were conducted at our Oregon facility to our Bethlehem facilities. We did not renew the lease in January 2005.

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.

Patent Infringement Litigation

On July 23, 2004, we filed a lawsuit against Schering-Plough Healthcare Products, Inc. for infringement of several of our patents relating to technology for the cryosurgical removal (i.e., freezing) of warts and other benign skin lesions. The suit was commenced in the United States District Court for the Eastern District of Pennsylvania, and alleges that Schering-Plough's manufacture and sale of its Dr. Scholls® Freeze Away™ cryosurgical wart removal product in the United States over-the-counter market infringes the following United States patents: Nos. 5,738,682; 6,092,527 and 4,865,028. We are requesting permanent injunctive relief and the payment of damages. Schering-Plough has asserted various defenses in this matter, including that its Dr. Scholls® Freeze Away™ product does not infringe our patents and that one or more of our patents are invalid and unenforceable.

In August 2004, we filed an application for a preliminary injunction against Schering-Plough. In September 2004, the Court scheduled an early trial in this matter for February 2005. Because such a trial would include a final determination of our request for permanent injunctive relief in lieu of our previously-filed request for a preliminary injunction, we withdrew our request for a preliminary injunction.

In November 2004, a Court held a Markman hearing in order to determine as a matter of law the meaning of certain terms and phrases in the claims in our patents which are relevant to an infringement determination. A Markman hearing is a normal part of any patent infringement litigation. However, the Court has not yet issued a decision from the Markman hearing and, as a result, recently vacated the original trial schedule. The period for fact discovery in this matter has closed, although the period for discovery from expert witnesses remains open, and it is expected that a new trial schedule will be established after the Court issues its Markman decision.

Abbott Arbitration

In June 2002, Abbott Laboratories became a co-exclusive distributor of our OraQuick® rapid HIV-1 antibody test in the United States under a five-year agreement, which required minimum monthly purchases totaling approximately $4.0 million during a 15-month period following initial FDA approval of the product. The OraQuick® test received initial FDA approval in November 2002.

Abbott failed to meet its minimum purchase obligations under the agreement, and we asserted that the agreement was therefore terminated. Abbott disputed the termination, and in October 2003, it invoked the arbitration procedure for resolution of disputes under the agreement. In February 2004, the arbitrator ruled that the agreement did not terminate and would continue in effect, and that our remedy was limited to revoking Abbott's status as a co-exclusive distributor. We subsequently exercised that remedy by notifying Abbott that, based on the magnitude of its purchases, Abbott's distribution rights were converted to non-exclusive. This agreement with Abbott was eventually terminated in February 2005.

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, 2004.

PART II

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

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,			
	2004		2003	
	High	Low	High	Low
First Quarter	$12.00	$7.20	$ 8.62	$5.05
Second Quarter	10.63	6.65	8.29	5.47
Third Quarter	9.73	5.19	10.92	7.36
Fourth Quarter	7.52	5.54	10.30	7.55

On March 1, 2005, there were 607 holders of record and approximately 14,500 holders in street name of the Common Stock, and the closing price of the Common Stock was $7.05 per share. We have never paid any cash dividends, and our 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. 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,				
	2004	2003	2002	2001	2000
Operating Results:					
Revenues	$ 54,008	$ 40,451	$ 32,010	$ 32,573	$ 28,788
Costs and expenses	55,365	41,737	35,550	36,906	42,917
Other income (expense), net	797	177	198	634	1,407
Net loss	(560)	(1,136)	(3,342)	(3,728)	(12,747)
Basic and diluted net loss per share	$ (0.01)	$ (0.03)	$ (0.09)	$ (0.10)	$ (0.36)
Weighted average number of shares outstanding	44,464	39,794	37,583	36,868	35,002

	December 31,				
	2004	2003	2002	2001	2000
Financial position:					
Cash, cash equivalents, and short-term investments	$ 66,723	$ 64,024	$ 14,908	$ 15,191	$ 20,052
Working capital	68,910	67,171	18,931	19,764	21,440
Total assets	88,064	86,151	35,737	37,285	37,736
Long-term debt, excluding current portion	1,334	2,456	3,409	3,586	4,644
Accumulated deficit	(131,130)	(130,570)	(129,435)	(126,092)	(122,365)
Stockholders' equity	75,577	73,509	26,019	26,541	26,172

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 Annual 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.

Overview

Our Company operates primarily in the worldwide $22 billion *in vitro* diagnostics business. 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. We also manufacture and sell medical devices for the removal of warts and other benign skin lesions by cryosurgery, or freezing.

Our diagnostic product offerings primarily target the infectious disease and substance abuse testing segments of the larger *in vitro* diagnostic market, and are used in both laboratories as well as the emerging, and rapidly growing, point-of-care marketplace. Our OraSure® and Intercept® oral fluid collection devices, and their related assays, are processed in a laboratory, while the OraQuick® rapid HIV antibody tests and the UP*link*® oral fluid rapid drug detection system are designed for use at the point-of-care. Our cryosurgical products, which are sold under the names Histofreezer® and Freeze Off™, are also used at the point-of care.

In vitro diagnostics have traditionally used blood or urine as the bodily fluids upon which tests are conducted. However, we have targeted the use of oral fluid in our products as a differentiating factor, and believe that it provides a significant competitive advantage over blood and urine. Our oral fluid tests have sensitivity and specificity comparable to blood and/or urine tests and, when combined with their ease of use, non-invasive and dignified nature, and cost effectiveness, represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

We have made significant progress in increasing our sales and gaining market acceptance for our products. As a result, we reported strong financial results for 2004. Our total revenues were $54.0 million, or an increase of 34% over 2003, and our net loss for the year was $0.6 million, representing an improvement of more than $0.5 million over 2003. Our liquidity also improved, as we reported $3.4 million in cash flow from operations in 2004 and we had $66.7 million in cash, cash equivalents and short-term investments as of December 31, 2004.

Sales into the infectious disease testing market segment increased significantly in 2004 due to the continued market acceptance of our OraQuick® device. This increase resulted largely from sales directly to various public health organizations, sales to the Centers for Disease Control and Prevention ("CDC") for further distribution in the public health market, and sales to Abbott Laboratories for distribution primarily to hospitals.

During the period March-June 2004, we received FDA approval of our new OraQuick® *ADVANCE*™ test to detect antibodies to both HIV-1 and HIV-2 in oral fluid, fingerstick whole blood, venous whole blood, and plasma samples, In June 2004, we also obtained a CLIA waiver for the OraQuick® *ADVANCE*™ HIV-1/2 test for all specimen types except plasma. This new product was officially launched commercially in October 2004. Since that time, the demand for OraQuick® *ADVANCE*™ has grown quickly, and we are working to convert all OraQuick® customers to this new product and expect eventually to cease selling our original OraQuick® HIV-1 test.

In June 2004, we received a nonexclusive, worldwide sublicense to certain HIV-2 patents held by Bio-Rad Laboratories. We believe that the recently approved OraQuick® *ADVANCE*™ test, together with the sublicense from Bio-Rad, will provide a significant competitive advantage by allowing us to sell a versatile rapid HIV test that is capable of detecting antibodies to both the HIV-1 and HIV-2 strains of the virus in oral fluids, finger stick whole blood, venous whole blood and plasma.

In 2004, the CDC and SAMHSA placed purchase orders totaling $6.3 million for OraQuick® devices and related testing materials. Both of these orders were for OraQuick® *ADVANCE*™. We expect that these agencies, and perhaps other federal governmental agencies, will make future bulk purchases of OraQuick® *ADVANCE*™ for further distribution to the public health and other markets throughout the United States.

In February 2005, we entered into a new agreement for the distribution of OraQuick® *ADVANCE*™ with Abbott Laboratories. Under this agreement, Abbott was appointed as our exclusive distributor in the U.S. hospital market and as a non-exclusive distributor in the U.S. physicians' office marketplace. As our exclusive distributor to hospitals, Abbott will sell OraQuick® *ADVANCE*™ to federal hospitals under the terms and conditions of our Federal Supply Schedule that is filed with the U.S. General Services Administration. We have retained exclusive rights to all other markets, including the public health and criminal justice markets, the military, the CDC, SAMHSA and other government agencies. In 2004, we deployed a small sales force that provided direct access to and marketing support for the sales of our OraQuick® test into the hospital market. This sales force will now support Abbott and will work together with them to maximize the penetration of OraQuick® *ADVANCE*™ in the hospital market.

The markets for rapid HIV testing are very competitive and the level of competition is expected to increase, which could affect sales of our OraQuick® tests. For example, the Ortho Diagnostics division of Johnson & Johnson and Bio-Rad Laboratories each sell competing laboratory-based HIV-1 EIAs, and Calypte, Inc. sells an HIV-1 screening test for urine, in the United States. In addition, MedMira and Trinity Biotech have each received FDA approval to sell competing rapid HIV-1 blood tests and Bio-Rad recently received FDA approval for a rapid HIV-1/2 blood test. We believe these tests, under their current FDA approvals, will compete with our OraQuick® tests in the hospital or other laboratory settings. In addition, Trinity Biotech has received CLIA waiver for its rapid fingerstick HIV-1 blood test, and we believe that this test will compete with our OraQuick® tests in the public health and other markets outside of the traditional hospital and laboratory settings. These companies, or others, may continue to expand the bodily fluids with which a rapid HIV test may be performed or develop and commercialize new rapid tests, either of which would provide further competition for our OraQuick® tests.

Sales to the substance abuse testing market also increased during 2004, reflecting the growing acceptance of our Intercept® collection device and related oral fluid drug assays, as corporate and criminal justice customers continued to shift to oral fluid and away from traditional urine-based drug testing. This increase was partially offset by lower sales of our drug assays to the forensic toxicology market. We expect continuing growth in the utilization of our Intercept® product line, primarily in the United States and United Kingdom.

In March 2004, the FDA responded to our application for 510(k) clearance of the UP*link*® rapid oral fluid drugs of abuse detection system, by indicating that additional performance data would be needed in order to obtain clearance. We are evaluating the FDA's requirements and whether any modifications to our UP*link*® system will be required in order to provide that data. At this time, we cannot predict if or when we will resubmit an application for 510(k) clearance of the UP*link*® system. However, the absence of 510(k) clearance will not affect our ability to sell the UP*link*® system internationally. In April 2004, we launched our UP*link*® system in Germany and other European countries, primarily in the roadside testing market, with our partner, Dräger Safety.

In April 2004, SAMHSA published proposed guidelines that would, if adopted, include oral fluid testing as an accepted drug testing method for federal employees. We have responded to SAMHSA's proposed guidelines with a comment letter and await the final guidelines that will apply to both our Intercept® and UP*link*® drugs of abuse test. We are unable to predict at this time whether additional modifications may be required to bring our

UP*link*® or Intercept® drug testing systems into compliance with the guidelines when finally adopted or what effect, if any, non-compliance with the final guidelines will have on our product offerings. Compliance with the guidelines will be required in order for us to sell our drug testing products to federal employees and possibly other industries that are influenced by the federal guidelines in structuring their drug testing programs.

Sales to the cryosurgical systems market during 2004 have grown substantially. The cryosurgical systems market represents sales of Histofreezer® into both the domestic and international physicians' office markets and sales of the over-the-counter ("OTC") formulation of this product, called Freeze Off™, to our partner, Medtech Holdings, Inc. ("Medtech"), a wholly-owned subsidiary of Prestige Brands Holdings, Inc. Medtech distributes Freeze Off™ to consumers under its Compound W® trademark in the OTC market in the United States.

In July 2004, we filed a lawsuit against Schering-Plough Healthcare Products, Inc. ("Schering-Plough") for infringement of several of our patents relating to the technology for the cryosurgical removal (i.e., freezing) of warts and other benign skin lesions. The suit was commenced in the United States District Court for the Eastern District of Pennsylvania, and alleges that Schering-Plough's manufacture and sale of its Dr. Scholl's® Freeze Away™ cryosurgical wart removal product in the over-the-counter market infringes three of our patents. We are seeking injunctive relief and the payment of damages, and Schering-Plough has raised several defenses, including that their Freeze Away™ device does not infringe our patents and that one or more of our patents are either invalid or unenforceable. We currently expect that a final trial on the merits in this matter will occur in the spring of 2005.

Sales to the insurance risk assessment market continued to decline in 2004, primarily as a result of lower device and assay sales to our largest customer, Lab*One*, Inc. The assays have experienced substantial competitive pressure from "home-brew" assays internally developed by this customer. Sales of these products are not expected to recover. We anticipate little growth in the insurance risk assessment market until we are successful in developing new oral fluid based diagnostic tests for additional predictive health markers desired by the insurance industry.

During 2004, we received all necessary FDA approvals to transfer the manufacture of our Intercept® and OraSure® collection devices and our oral fluid Western blot HIV-1 confirmatory test from Oregon to our facilities in Bethlehem, Pennsylvania. This transfer has been completed and is expected to reduce our annual operating expenses and improve our ability to control the quality of the transferred products. In January 2005, the lease on our Oregon facility expired and all operations at that location have now ceased. The absence of this lease will reduce our operating expenses.

Because of the regulatory approvals needed for most of our products, we often are required to rely on sole source providers for critical components and materials. This is particularly true for our OraQuick® tests and oral fluid Western blot HIV-1 confirmatory product. If we are unable to obtain necessary components or materials from these sole sources, the time required to develop replacements and obtain the required FDA approvals could disrupt our ability to sell the affected products. In addition, any delay or interruption in our ability to manufacture the oral fluid Western blot HIV-1 confirmatory test would adversely affect sales of our OraSure® oral fluid collection device, as our customers are not expected to purchase OraSure® devices if an oral fluid Western blot HIV-1 confirmatory test is not readily available.

We generated approximately 89% of our 2004 revenues in the U.S. marketplace. Consequently, we are evaluating strategies to increase our sales penetration in markets outside the U.S. As our business in foreign countries increases, we will be exposed to additional risks, including economic, political, exchange rate, regulatory and cultural risks.

Results of Operations

Twelve Months Ended December 31, 2004 Compared to December 31, 2003

Total revenues increased 34% to approximately $54.0 million in 2004 from approximately $40.5 million in 2003, primarily as a result of increased sales of our Freeze Off™ wart removal product, OraQuick® rapid HIV-1 antibody test and Intercept® oral fluid collection device and related drug assays, partially offset by a decline in assay revenues in the insurance risk assessment market. Revenues derived from products sold in countries outside the U.S. were approximately $6.2 million and $4.6 million, or 11% and 11% of total revenues for the years ended December 31, 2004 and 2003, respectively.

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.

	Years ended December 31,				
	Dollars			Percentage of Total Revenues	
	2004	2003	% Change	2004	2003
Market Revenues					
Insurance risk assessment	$ 7,777	$ 9,708	(20)%	14%	24%
Infectious disease testing	15,526	11,909	30	29	29
Substance abuse testing	10,108	7,295	39	19	18
Cryosurgical systems	20,193	10,828	86	37	27
Product revenues	53,604	39,740	35	99	98
Licensing and product development	404	711	(43)	1	2
Total revenues	$54,008	$40,451	34%	100%	100%

Sales to the insurance risk assessment market declined by 20% to approximately $7.8 million in 2004 from approximately $9.7 million in 2003, primarily as a result of lower insurance testing assay sales. We expect that sales of our urine assays will continue to come under competitive pressure because of sluggish sales and competitive conditions in the life insurance testing market. As a result of these conditions, our laboratory customers have eliminated or reduced their purchases of these products and instead use lower cost, internally-developed (i.e., “home-brew”) assays or testing products purchased from our competitors. We currently expect that our 2005 revenues in this market segment will remain at approximately the levels attained in 2004.

Sales to the infectious disease testing market increased 30% to approximately $15.5 million in 2004, primarily as a result of higher sales of our OraQuick® rapid HIV-1 antibody test. OraQuick® and OraSure® sales during 2004 totaled approximately $10.2 million and $5.3 million, respectively, as compared to approximately $6.3 million and $5.6 million, respectively, for 2003.

During 2004, we recorded approximately $4.1 million in direct sales of OraQuick® to the U.S. public health market and approximately $2.3 million to the CDC. We also had OraQuick® sales of approximately $2.0 million to Abbott, approximately $650,000 directly to hospital customers, and approximately $1.2 million to the international marketplace. During 2003, we recorded approximately $1.9 million in direct sales of OraQuick® to the U.S. public health market and approximately $2.0 million to the CDC. We also had OraQuick® sales of approximately $1.8 million to Abbott and approximately $700,000 to the international marketplace in 2003.

As previously indicated, during 2004 we received a total of $6.3 million in purchase orders from the CDC and SAMHSA for OraQuick® *ADVANCE* rapid HIV-1/2 antibody tests, of which approximately $72,000 were shipped in 2004. We expect to complete shipment of the remaining devices pursuant to these purchase orders in 2005.

We believe that our OraQuick® *ADVANCE*™ device, which is approved for detecting antibodies to both HIV-1 and 2 in oral fluid, fingerstick and venous whole blood, and plasma samples, and is CLIA-waived for use

with all sample types except plasma, provides a significant competitive advantage and will allow us to more fully implement a strategy to sell OraQuick® internationally. This new test was commercially launched in late October 2004, and initial shipments of this product began in early November 2004. We are currently pursuing CE marking for our OraQuick® *ADVANCE*™ product which would allow us to sell our product in Europe. Our goal is to obtain a CE mark for OraQuick® *ADVANCE*™ by the summer of 2005, and obtain several country-specific registrations to allow us to launch the product in Europe later this year.

Although sales of OraQuick® are expected to increase, such sales may negatively impact sales of our OraSure® oral fluid collection device in the infectious disease testing market. Customers who now or in the future may purchase our OraSure® device for HIV-1 testing may elect instead to purchase our OraQuick® tests. It is not possible at this time, however, to estimate the timing or extent of such change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick® tests, if it occurs at all.

Sales to the substance abuse testing market increased 39% to approximately $10.1 million in 2004 as a result of higher sales of our Intercept® oral fluid collection device and related drug assays in the workplace, criminal justice and international marketplaces. Sales of our Intercept® device and related drug assays in 2004 increased 53%, or by approximately $2.4 million over the comparable period in 2003. We expect continued growth in Intercept® sales in 2005 as customers continue to shift from urine-based to oral-fluid based testing methods.

In April 2004, we launched our UP*link*® rapid oral fluid drug detection system, including assays for the detection of drugs of abuse commonly identified by the National Institute for Drug Abuse (“NIDA”) as the NIDA-5 (i.e., cocaine, opiates, amphetamines/methamphetamines, PCP and marijuana) with our partner, Dräger Safety. This product is being initially sold to the roadside testing market in Europe. Revenues from this product were approximately $564,000 in 2004. As part of our recently concluded strategic review of the business, we concluded that the roadside drugs of abuse market may not be as attractive as a number of other opportunities. Consequently, we are exploring our options with respect to this product including transitioning the manufacturing of the product to Dräger, which is permitted under our agreement with Dräger. In exchange, we would expect to receive a royalty on future sales by Dräger while retaining the right to sell UP*link*® in the workplace testing and other markets.

Sales of our products in the cryosurgical systems market (which includes both the physicians’ office and OTC markets) increased 86% to approximately $20.2 million in 2004. This increase was primarily the result of an increase of $8.3 million in sales of our OTC cryosurgical product, called Freeze Off™, to Medtech, the owner of the Compound W® line of wart removal products. In 2003, we entered into a distribution agreement with Medtech following receipt of FDA 510(k) clearance for the sale of our cryosurgical system in the OTC market in the U.S. Medtech launched the Freeze Off™ product in the third quarter of 2003, and there were $5.0 million of sales to Medtech during 2003.

Freeze Off™ is being sold under Medtech’s Compound W® trademark. Our five-year distribution agreement requires minimum purchases by Medtech of at least $2.0 million each year over the life of the contract in order for Medtech to maintain its exclusive distribution rights to the OTC market in the U.S. However, based on additional purchase orders received to date, we expect sales of product to Medtech to reach at least $4.0 million during the first quarter of 2005. We have concluded a review of the market potential for over-the-counter cryosurgical product in the European Union and have entered negotiations with a select number of top-tier distribution partners. We expect to announce a distributor in the near future and intend to launch an OTC product in selected European countries later in 2005.

Sales of our Histofreezer® product to physicians’ offices in the U.S. and international markets increased 21% and 7% to approximately $5.2 million and $1.7 million, respectively, in 2004, when compared to 2003, primarily as a result of higher distributor purchases. We anticipate that U.S. sales of Histofreezer® in the professional market will continue to increase in 2005. Sales in the international market are expected to increase above 2004 levels as we secure additional distributors in countries where the product is currently not sold.

Although not our experience to date in the U.S. professional marketplace, it is possible that sales of the Freeze Off™ product in the U.S. OTC market may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the professional market. However, it is not possible at this time to estimate the timing or financial impact of such a change, if it occurs at all.

Medtech, our largest customer, accounted for approximately 25% and 12% of total revenues for 2004 and 2003, respectively. Lab*One* accounted for approximately 12% and 17% of total revenues for 2004 and 2003, respectively.

Licensing and product development revenues decreased 43% to approximately $404,000 in 2004, from approximately $711,000 in the comparable period in 2003. Licensing and product development revenues in 2004 were primarily related to our collaborative UP*link*® and oral fluid research project with the University of Pennsylvania, under a grant awarded by the National Institutes of Health. The current annual phase of this grant expires in June 2005 and our share of funding is expected to be approximately $308,000 for that period. Further revenues beyond June 2005 will depend on progress achieved in the research and future funding awarded by the National Institutes of Health.

The Company's gross margin was 59% in 2004, compared to 60% in 2003. Our 2004 gross margin was positively impacted by more efficient utilization of the Company's manufacturing capacity, offset by higher production costs associated with the Company's UP*link*® rapid oral fluid drug detection system, a less favorable product sales mix, and higher scrap as a result of the transfer of production from Oregon.

Research and development expenses decreased 24% to approximately $6.1 million in 2004, from approximately $8.0 million for the comparable period in 2003, primarily as a result of lower staffing costs and costs associated with transferring our manufacturing operations from Oregon to Bethlehem. Research and development costs are expected to increase in 2005 primarily as a result of costs associated with the development of new product offerings and product enhancements for the infectious disease and substance abuse markets.

Sales and marketing expenses increased 41% to approximately $15.2 million in 2004 from approximately $10.8 million in 2003. This increase was primarily the result of higher product advertising expenditures, costs associated with our hospital sales force and increased staffing related expenses. Included in advertising expenses was $2.9 million and $1.1 million for 2004 and 2003, respectively, paid to Medtech as reimbursement for marketing expenses incurred for the Compound W® Freeze Off™ product. We expect that sales and marketing expense will increase in 2005 at a more moderate rate compared to 2004. As we attempt to increase our presence in the international marketplace, we will incur additional expenses related to this effort. Promotional expenses are also expected to increase as we continue in our efforts to expand market awareness and acceptance for our OraQuick®, Intercept® and Histofreezer® products. Pursuant to our agreement with Medtech, we will also continue to co-invest in Medtech's marketing activities for the Compound W® Freeze Off™ product, and we will reimburse Medtech, on a declining basis over the next two years of the agreement, for a portion of Medtech's out-of-pocket costs of advertising and promoting this product in the OTC market.

General and administrative expenses increased 74% to approximately $12.0 million in 2004 from approximately $6.9 million in 2003. This increase was primarily attributable to legal fees associated with the Schering-Plough litigation, transition costs for the retirement of our former Chief Executive Officer and the additional costs of hiring our new Chief Executive Officer, consulting fees for strategic planning, increased staffing related expenses and increased professional fees related to compliance with the requirements of the Sarbanes-Oxley Act of 2002. General and administrative expenses are expected to increase further in 2005 versus 2004 as a result of legal fees associated with the Schering-Plough patent litigation.

Interest expense decreased to approximately $134,000 in 2004 from approximately $190,000 in 2003, as a result of lower outstanding debt balances. Interest income increased to approximately $984,000 in 2004 from approximately $425,000 in 2003, as a result of substantially larger balances available for investment.

Losses on foreign currency transactions of $53,000 and $59,000 were recorded for the years ended December 31, 2004 and 2003, respectively.

During the year ended December 31, 2004, no provision for income taxes was recorded, while we had a provision of $27,000 in 2003 related to foreign income taxes.

Twelve Months Ended December 31, 2003 Compared to December 31, 2002

Total revenues increased 26% to approximately $40.5 million in 2003 from approximately $32.0 million in 2002, primarily as a result of increased sales of our OraQuick® rapid HIV-1 antibody test, the successful launch of the Freeze Off™ wart removal product, and higher sales of our Intercept® oral fluid collection device and related drug assays, partially offset by a decline in assay revenues in the insurance risk assessment market and lower sales of Histofreezer® in the physicians' office market in the U.S. Revenues derived from products sold in countries outside the U.S. were approximately $4.6 million and $3.9 million, or 11% and 12% of total revenues for the years ended December 31, 2003 and 2002, respectively.

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.

	Years ended December 31,				
	Dollars			Percentage of Total Revenues	
	2003	2002	% Change	2003	2002
Market Revenues					
Insurance risk assessment	$ 9,708	$12,030	(19)%	24%	38%
Infectious disease testing	11,909	6,063	96	29	19
Substance abuse testing	7,295	6,434	13	18	20
Cryosurgical systems	10,828	7,165	51	27	22
Product revenues	39,740	31,692	25	98	99
Licensing and product development	711	318	124	2	1
Total revenues	$40,451	$32,010	26 %	100%	100%

Sales to the insurance risk assessment market declined by 19% to approximately $9.7 million in 2003 from approximately $12.0 million in 2002, primarily as a result of lower insurance testing assay sales. Our laboratory customers eliminated or reduced their purchases of these products and instead used lower cost, internally-developed (i.e., "home-brew") assays or testing products purchased from our competitors.

Sales to the infectious disease testing market increased 96% to approximately $11.9 million in 2003, primarily as a result of higher sales of our OraQuick® rapid HIV-1 antibody test. OraQuick® and OraSure® sales in 2003 totaled approximately $6.3 million and $5.6 million, respectively, as compared to approximately $350,000 and $5.7 million, respectively, for the comparable period in 2002.

Abbott Laboratories purchased approximately 400,000 OraQuick® devices in 2003, representing approximately 40% of the total OraQuick® sales in that year. In addition, we received a total of $4.0 million in purchase orders from the CDC for approximately 500,000 of our OraQuick® rapid HIV-1 antibody tests. Pursuant to the first such order, we sold 250,000 devices to the CDC in 2003. The second purchase order, for an additional $2.0 million, was received in late 2003, and was completed with the remaining shipment of 250,000 devices to the CDC by September 1, 2004.

Sales to the substance abuse testing market increased 13% to approximately $7.3 million in 2003 as a result of higher sales of our Intercept® oral fluid collection device and related drug assays in the workplace, criminal

justice and international marketplaces. These increases more than offset the absence of approximately $400,000 in laboratory equipment sales included in our substance abuse testing market revenues in 2002. Sales of our Intercept® device and related drug assays in 2003 increased 37%, or by approximately $1.2 million, over the comparable period in 2002.

Sales of our products in the cryosurgical systems market (which included both the physicians' office and OTC markets) increased 51% to approximately $10.8 million in 2003. This increase was primarily the result of $5.0 million of sales of our OTC cryosurgical system to Medtech, partially offset by lower sales of Histofreezer® in the professional markets in both the U.S. and international markets. Sales of our Histofreezer® product to physicians' offices in the U.S. and international markets declined 23% and 2% to approximately $4.3 million and $1.5 million, respectively, in 2003, when compared to 2002, as a result of lower distributor purchases.

Lab*One*, our largest customer, accounted for approximately 17% and 26% of total revenues for 2003 and 2002, respectively. Medtech accounted for approximately 12% of total revenues for 2003, their first year of business with us.

Licensing and product development revenues increased 124% to approximately $711,000 in 2003, from approximately $318,000 in the comparable period in 2002. Licensing and product development revenues in 2003 were primarily related to our collaborative UP*link*® and oral fluid research project with the University of Pennsylvania, under a grant awarded by the National Institutes of Health.

The Company's gross margin was 60% in 2003, which was unchanged from 2002. Our gross margin was positively impacted by increased sales of Intercept® devices and related assays and more efficient utilization of our manufacturing capacity, which resulted in lower scrap and spoilage and better absorption of overhead. Offsetting these items were negative contributions realized through lower urine assay and reagent sales in the insurance risk assessment market and the lower sales of Histofreezer® in the U.S. professional market.

Research and development expenses decreased 3% to approximately $8.0 million in 2003, from approximately $8.3 million for the comparable period in 2002, primarily as a result of lower staffing costs, partially offset by higher outside consulting fees.

Sales and marketing expenses increased 33% to approximately $10.8 million in 2003 from approximately $8.1 million in 2002. This increase was primarily the result of higher expenditures for advertising and collateral marketing materials, travel costs, compensation expense, and market research and public relations fees. Included in the advertising expense for 2003 was $1.1 million paid to Medtech as reimbursement for marketing expenses incurred for the Compound W® Freeze Off™ product.

General and administrative expenses increased 9% to approximately $6.9 million in 2003 from approximately $6.3 million in 2002. This increase was primarily attributable to higher facility-related expenses, partially offset by the absence of a $500,000 severance charge related to the departure of the Company's former Chief Executive Officer in 2002.

Interest expense decreased to approximately $190,000 in 2003 from approximately $285,000 in 2002, as a result of lower effective interest rates. Interest income decreased to approximately $425,000 in 2003 from approximately $483,000 in 2002, as a result of lower interest rates on investments, partially offset by significantly higher investment balances in the fourth quarter of 2003 as a result of investing approximately $44.8 million in net proceeds from our October 2003 common stock offering.

During the year ended December 31, 2003, a $59,000 loss on foreign currency transactions was recorded.

During the year ended December 31, 2003, a provision for foreign income taxes of approximately $27,000 was recorded.

Liquidity and Capital Resources

	December 31 2004	December 31, 2003
	(In thousands)	
Cash and cash equivalents	$ 10,121	$ 30,695
Short-term investments	56,602	33,329
Working capital	68,910	67,171

Our cash, cash equivalents and short-term investments increased approximately $2.7 million during 2004 to approximately $66.7 million at December 31, 2004, primarily as a result of positive cash flow from operations of approximately $3.4 million and proceeds from the exercise of stock options of approximately $1.9 million, partially offset by debt repayments of $1.1 million, purchases of approximately $912,000 of property and equipment and our expenditure of $600,000 for patent license rights. At December 31, 2004, our working capital was approximately $68.9 million.

Net cash provided by operating activities was approximately $3.4 million in 2004. This resulted from a decrease of approximately $1.2 million in accounts receivable, primarily related to increased collection efforts, depreciation and amortization of approximately $2.5 million, non-cash charges of approximately $874,000 related to stock-based compensation expense, provisions for excess and obsolete inventories of $839,000 and an increase in account payables and accruals of $693,000, offset by inventory increases of $1.8 million, an increase in prepaid expenses of $272,000 and the approximate $560,000 loss for the period.

Net cash used in investing activities during 2004 was approximately $24.8 million. We purchased a net amount of $23.4 million of short-term investments, expended $600,000 for patent license rights and purchased approximately $912,000 of property and equipment.

We expect to incur approximately $3.2 million of capital expenditures in 2005.

Net cash provided by financing activities was approximately $778,000, reflecting the proceeds of approximately $1.9 million received from the sale of Common Stock pursuant to the exercise of stock options, offset by approximately $1.1 million of loan principal repayments.

In September 2002, we entered into a $10.9 million credit facility (the “Credit Facility”) with Comerica Bank. The Credit Facility, when originally executed, was 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.

In September 2003, we executed an amendment to the Credit Facility. Pursuant to this amendment, the $3.0 million non-revolving equipment line of credit (the “Original Non-Revolving Line”) was replaced with a new $4.0 million non-revolving line of credit for the purchase of both capital equipment and software (the “New Non-Revolving Line”). As a result, the Original Non-Revolving Line has expired and any new non-revolving borrowings for equipment or software will be made under the New Non-Revolving Line. Borrowings outstanding under the Original Non-Revolving Line at the time of the amendment will not be applied against the credit limit for the New Non-Revolving Line and will remain payable in accordance with their original terms. The amendment also extended the maturity date of the $4.0 million revolving working capital line of credit by one year, and provided for certain modifications to our financial covenants under the Credit Facility. The term loan and mortgage were not affected by the amendment. In September 2004, the Credit Facility was amended further to extend the maturity date of our revolving working capital line of credit to April 30, 2005.

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica’s prime rate (5.25% at December 31, 2004), 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, 2004 was $765,953.

The $3.0 million term loan matures in March 2006, bears interest at a fixed rate of 4.97% 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, 2004 was $1,071,429.

Under the New Non-Revolving Line, we could borrow up to $4.0 million to finance eligible equipment and software purchases through December 31, 2004. We had no outstanding borrowings under this facility, which expired at December 31, 2004 and was not renewed.

As of December 31, 2004, we had an outstanding balance of $331,286 under the Original Non-Revolving Line consisting of four individual loans of (i) $83,900 with a fixed annual interest rate of 5.07%, (ii) $121,935 with a floating annual interest rate equal to Comerica's prime rate of 5.25% at December 31, 2004, (iii) $64,317 with a floating annual interest rate equal to Comerica's prime rate of 5.25% at December 31, 2004, and (iv) $61,134 with a floating annual interest rate equal to Comerica's prime rate of 5.25% at December 31, 2004.

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 accrues 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 April 30, 2005, with interest payable monthly. We had no outstanding borrowings under this facility at December 31, 2004.

All borrowings under the 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 software non-revolving line and the revolving working capital line are limited to commercially standard percentages of equipment and software purchases and accounts receivable, respectively. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in full compliance with all covenants at December 31, 2004 and expect to remain in compliance with all covenants during 2005. The 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.

As of December 31, 2004, we also have a $288,023 note payable to the Pennsylvania Industrial Development Authority related to the purchase of one of our facilities in Bethlehem, Pennsylvania in 1998. This note is secured by a second lien on our building, bears interest at 2%, and requires monthly installments of principal and interest of $4,893 through March 2010.

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 former 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 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. We are evaluating whether to exercise our option under the lease to purchase the facility.

The combination of our current cash position, cash flow from operations and available borrowings under our Credit Facility is expected to be sufficient to fund our operating and capital needs for at least the next twelve months. However, our cash requirements may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of strategic acquisitions, 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 market launch of new products, market acceptance of new products, competing technological and market developments, the potential exercise of our options to purchase one, or both, of our leased facilities in Bethlehem, Pennsylvania, and other factors.

Contractual Obligations and Commercial Commitments. The following sets forth our approximate aggregate obligations at December 31, 2004 for future payments under contracts and other contingent commitments, for the years 2005 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2005**	**2006**	**2007**	**2008**	**2009**	**Thereafter**
Long-term debt[1]	$ 2,456,691	$ 1,122,455	$ 471,427	$ 130,915	$ 115,373	$ 119,672	$ 496,849
Operating leases[2]	6,418,430	874,510	780,000	783,062	798,810	814,262	2,367,786
Employment contracts[3]	3,138,397	1,937,636	995,761	205,000	—	—	—
Purchase obligations[4]	4,530,899	4,530,899	—	—	—	—	—
Minimum commitments under contracts[5]	8,641,667	425,000	625,000	725,000	725,000	650,000	5,491,667
Total contractual obligations	$ 25,186,084	$ 8,890,500	$ 2,872,188	$ 1,843,977	$ 1,639,183	$ 1,583,934	$ 8,356,302

(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 or retention bonus 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, capital expenditures and other goods or services. 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 303(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 Annual 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. 104, "Revenue Recognition" ("SAB No. 104"). This bulletin draws on existing accounting rules and provides specific guidance on revenue recognition for 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 No. 104, 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 there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are net of allowances for any discounts or rebates. 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 $345,257 at December 31, 2004. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period ($3,541, $88,659 and $213,188 in 2004, 2003 and 2002, 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, 2004, approximately $2.2 million, or 31% of our accounts receivable, was due from two major customers. Any significant changes in the liquidity or financial position of these customers, 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 2004, 2003 and 2002, we wrote-off inventory which had a cost of approximately $839,000, $540,000, and $1.4 million, respectively, as a result of scrap levels and product expiration issues. 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 $8.0 million or 9% of our total assets at December 31, 2004. 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 the 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, 2004. 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. At December 31, 2004, we have federal net operating loss ("NOL") carryforwards of approximately $74.9 million. The net deferred tax asset associated with these NOLs and other temporary differences is approximately $31.5 million at December 31, 2004. In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible or the NOLs and credit carryforwards can be utilized. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon our cumulative and recent history of losses and projections for future taxable income over the periods in which the deferred tax assets are deductible or the NOLs and credit carryforwards can be utilized, we believe that a full valuation allowance is necessary at December 31, 2004. Our level of future profitability could cause us to conclude that all or a portion of the deferred tax asset will be realizable. Upon reaching such a conclusion, we would immediately record the estimated net realizable value of the deferred tax asset and would begin to provide for income taxes at a rate equal to our combined federal and state effective rates at that time. 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 ("SFAS") No. 5, "Accounting for Contingencies." SFAS No. 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

In connection with the announcement in March 2004 that Mike Gausling, our former President and Chief Executive Officer, intended to retire from the Company by the end of 2004, we entered into a transition agreement with Mr. Gausling, which replaced and terminated his employment agreement. In June 2004, Mr. Gausling resigned from his position as President, Chief Executive Officer and a member of the Board, and his successor was named.

Pursuant to his transition agreement, Mr. Gausling remained an employee of our Company through December 31, 2004. During 2004, Mr. Gausling received an annual base salary of $333,864, received full executive benefits under our group health and other benefit arrangements and earned a cash bonus under our 2004 Self-Funding Annual Bonus Plan. Mr. Gausling was also granted a non-qualified option to purchase 100,000 shares of common stock, pursuant to our 2000 Stock Award Plan.

During 2005, Mr. Gausling will receive salary continuation payments in an aggregate amount of $333,864, payable in four equal installments at the end of each fiscal quarter during 2005. If Mr. Gausling elects to obtain continuing coverage under our health benefit plan pursuant to COBRA beginning January 1, 2005, we will reimburse Mr. Gausling for the cost of his COBRA premiums for the 12-month period ending December 31, 2005.

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 Mr. Gausling, the Company’s former President and Chief Executive Officer, and Dr. R. Sam Niedbala, the Company’s former Executive Vice President and Chief Science Officer. The facility houses manufacturing 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 received 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

In November 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 151, "Inventory Costs," which amends the guidance in Accounting Research Bulletin No. 43. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material and requires such costs to be recognized as current-period charges. Additionally, SFAS No. 151 requires that allocation of fixed production overhead costs be based on normal capacity. SFAS No. 151 is effective for years beginning after June 15, 2005, with early adoption permitted. The implementation of SFAS No. 151 is not expected to have a material effect on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123 Revised "Share-Based Payment" ("SFAS No. 123R"). SFAS No. 123R requires employee stock options to be accounted for in the statement of operations based on their fair values on the date of the grant, and eliminates the ability to account for these instruments under the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25. SFAS No. 123R requires the use of an option pricing model for estimating fair value, which is amortized to expense over the service period. The requirements of SFAS No. 123R are effective for fiscal periods beginning after June 15, 2005. SFAS No. 123R allows for either prospective recognition of compensation expense or retrospective recognition. The Company is considering the potential implementation of different valuation models to determine the fair value of stock-based compensation and, therefore, has not yet completed evaluating the impact of adopting SFAS No. 123R on its results of operations. If the Company had applied the provisions of SFAS No. 123R to the financial statements for the period ending December 31, 2004, net loss would have increased by approximately $5.0 million.

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

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

Our holdings of financial instruments are comprised of certificates of deposit, commercial paper, U.S. government and agency obligations, state and local government agency obligations, and U.S. corporate bonds. All such instruments are classified as available-for-sale securities. 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 revenues and expenses for these operations from euros to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency represented approximately $1.9 million or 4% of our total revenues for the year ended December 31, 2004. We do not expect the risk of foreign currency fluctuations to be material in the near future.

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.

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

Not applicable.

ITEM 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures as of December 31, 2004. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company that is required to be included in its periodic filings with the Securities and Exchange Commission.

Management's Report on Internal Control Over Financial Reporting.

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a(f) and 15d-15(f) under the Securities Exchange Act of 1934. Under the supervision and with the participation of the Company's management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework, our management concluded that our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles as of December 31, 2004.

Our management's assessment on the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report, which is included below.

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

Changes in Internal Control Over Financial Reporting.

No changes in the Company's internal control over financial reporting were identified as having occurred during the three months ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

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

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

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

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

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

In our opinion, management's assessment that OraSure Technologies, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commision (COSO). Also, in our opinion, OraSure Technologies, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commision (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of OraSure Technologies, Inc. as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity and comprehensive loss and cash flows for each of the years in the three-year period ended December 31, 2004, and our report dated March 14, 2005 expressed an unqualified opinion on those financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 14, 2005

ITEM 9B. Other Information.

Not applicable.

PART III

We have omitted from Part III the information that will appear in our Definitive Proxy Statement for our 2005 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.

Certain 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.

Our Board of Directors has adopted a Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer and principal accounting officer, as well as to the members of our Board of Directors and our other officers and employees. This Code of Business Conduct and Ethics is available on our web site, at www.orasure.com. We intend to satisfy the amendment and waiver disclosure requirements under applicable securities regulations by posting any amendments of, or waivers to, the Code of Business Conduct and Ethics on our web site.

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 and Transition Agreements," in the Proxy Statement.

ITEM 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated by reference to the information under the caption "Audit Fees; Audit-Related Fees; Tax Fees; All Other Fees," in the Proxy Statement.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules.

(a)(1) and (a)(2). *Financial Statements and Schedules*. For a list of the Financial Statements filed herewith, see the Index to Financial Statements following the signature page to this Annual 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 Annual Report.

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 15, 2005.

ORASURE TECHNOLOGIES, INC.

By: /S/ DOUGLAS A. MICHELS

Douglas A. Michels
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on March 15, 2005, by the following persons on behalf of the Registrant and in the capacities indicated.

SIGNATURE	TITLE
/S/ DOUGLAS A. MICHELS **Douglas A. Michels**	President, Chief Executive Officer and Director (Principal Executive Officer)
/S/ RONALD H. SPAIR **Ronald H. Spair**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)
/S/ MARK L. KUNA **Mark L. Kuna**	Vice President and Controller (Principal Accounting Officer)
*CARTER H. ECKERT **Carter H. Eckert**	Director
*FRANK G. HAUSMANN **Frank G. Hausmann**	Director
*RONNY B. LANCASTER **Ronny B. Lancaster**	Director
 Gregory B. Lawless	Director
*ROGER L. PRINGLE **Roger L. Pringle**	Director
*DOUGLAS G. WATSON **Douglas G. Watson**	Director

*By: /S/ RONALD H. SPAIR

Ronald H. Spair
(Attorney-in-Fact)

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

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

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of OraSure Technologies, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 14, 2005 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 14, 2005

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31, 2004	December 31, 2003
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 10,121,208	$ 30,695,177
Short-term investments	56,602,248	33,328,610
Accounts receivable, net of allowance for doubtful accounts of $345,257 and $359,158	7,073,988	8,233,869
Inventories	4,951,979	4,003,519
Prepaid expenses and other	1,195,085	922,820
Total current assets	79,944,508	77,183,995
PROPERTY AND EQUIPMENT, net	5,551,261	6,471,209
PATENTS AND PRODUCT RIGHTS, net	2,080,363	1,886,171
OTHER ASSETS	488,192	609,932
	$ 88,064,324	$ 86,151,307
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,122,455	$ 1,126,423
Accounts payable	2,360,214	3,511,148
Accrued expenses	7,552,279	5,375,851
Total current liabilities	11,034,948	10,013,422
LONG-TERM DEBT	1,334,236	2,456,454
OTHER LIABILITIES	118,135	172,142
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, 44,631,731 and 44,260,931 shares issued and outstanding	45	44
Additional paid-in capital	209,948,075	204,867,765
Deferred compensation	(2,916,503)	(614,515)
Accumulated other comprehensive loss	(324,669)	(173,704)
Accumulated deficit	(131,129,943)	(130,570,301)
Total stockholders' equity	75,577,005	73,509,289
	$ 88,064,324	$ 86,151,307

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

	For the year ended December 31,		
	2004	2003	2002
REVENUES:			
Product	$ 53,604,124	$ 39,740,406	$ 31,691,495
Licensing and product development	404,140	710,879	318,272
	54,008,264	40,451,285	32,009,767
COST OF PRODUCTS SOLD	22,143,190	16,061,457	12,888,556
Gross profit	31,865,074	24,389,828	19,121,211
OPERATING EXPENSES:			
Research and development	6,062,275	7,999,687	8,274,351
Sales and marketing	15,154,174	10,764,642	8,068,879
General and administrative	12,005,309	6,911,242	6,318,513
	33,221,758	25,675,571	22,661,743
Operating loss	(1,356,684)	(1,285,743)	(3,540,532)
INTEREST EXPENSE	(133,652)	(189,511)	(284,678)
INTEREST INCOME	983,841	425,344	483,431
FOREIGN CURRENCY LOSS	(53,147)	(59,037)	(694)
Loss before income taxes	(559,642)	(1,108,947)	(3,342,473)
INCOME TAXES	—	26,590	—
NET LOSS	$ (559,642)	$ (1,135,537)	$ (3,342,473)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.01)	$ (0.03)	$ (0.09)
WEIGHTED AVERAGE NUMBER OF BASIC AND DILUTED SHARES OUTSTANDING	44,463,861	39,793,919	37,582,780

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

For the years ended December 31, 2004, 2003 and 2002

	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount					
Balance at January 1, 2002	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
Common stock issued upon exercise of options	849,374	1	3,716,890	—	—	—	3,716,891
Common stock issued via public offering, net of expenses	5,311,000	5	44,827,998	—	—	—	44,828,003
Compensation expense for stock option grants	—	—	33,900	—	—	—	33,900
Restricted stock grants to employees	—	—	650,663	(650,663)	—	—	—
Amortization of deferred compensation expense	—	—	—	36,148	—	—	36,148
Comprehensive loss:							
Net loss	—	—	—	—	—	(1,135,537)	(1,135,537)
Currency translation adjustment	—	—	—	—	16,560	—	16,560
Net unrealized loss on marketable securities	—	—	—	—	(5,588)	—	(5,588)
Total comprehensive loss							(1,124,565)
Balance at December 31, 2003	44,260,931	44	204,867,765	(614,515)	(173,704)	(130,570,301)	73,509,289
Common stock issued upon exercise of options	370,800	1	1,904,160	—	—	—	1,904,161
Restricted stock grants to employees	—	—	3,176,150	(3,176,150)	—	—	—
Amortization of deferred compensation expense	—	—	—	874,162	—	—	874,162
Comprehensive loss:							
Net loss	—	—	—	—	—	(559,642)	(559,642)
Currency translation adjustment	—	—	—	—	(12,983)	—	(12,983)
Net unrealized loss on marketable securities	—	—	—	—	(137,982)	—	(137,982)
Total comprehensive loss							(710,607)
Balance at December 31, 2004	44,631,731	$ 45	$ 209,948,075	$ (2,916,503)	$ (324,669)	$ (131,129,943)	$ 75,577,005

The accompanying notes are an integral part of these statements

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

	For the year ended December 31,		
	2004	2003	2002
OPERATING ACTIVITIES:			
Net loss	$ (559,642)	$ (1,135,537)	$ (3,342,473)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Stock-based compensation expense	874,162	70,048	50,939
Amortization of deferred revenue	—	—	(107,500)
Depreciation and amortization	2,487,121	2,576,797	2,286,682
Loss on disposition of property and equipment, net	4,339	43,500	2,553
Provision for excess and obsolete inventories	839,130	539,647	1,373,614
Changes in assets and liabilities-			
Accounts receivable	1,159,881	(3,036,082)	860,140
Notes receivable	—	—	75,000
Inventories	(1,787,590)	(454,692)	(1,017,316)
Prepaid expenses and other	(272,265)	2,996	112,804
Accounts payable	(1,066,064)	1,738,171	(884,594)
Accrued expenses and other	1,759,144	2,356,948	72,644
Net cash provided by (used in) operating activities	3,438,216	2,701,796	(517,507)
INVESTING ACTIVITIES:			
Purchases of property and equipment	(912,144)	(993,722)	(1,649,129)
Proceeds from the sale of property and equipment	66,427	—	2,393
Purchase of patents, licenses and product rights	(600,000)	(250,000)	(700,000)
Purchases of short-term investments	(65,638,600)	(37,280,182)	(9,306,439)
Proceeds from maturities and redemptions of short-term investments	42,226,980	14,489,860	11,474,935
(Increase) decrease in other assets	80,160	(5,886)	(52,660)
Net cash used in investing activities	(24,777,177)	(24,039,930)	(230,900)
FINANCING ACTIVITIES:			
Borrowings of long-term debt	—	211,590	4,322,854
Repayment of long-term debt	(1,126,186)	(1,104,041)	(4,491,556)
Proceeds from issuances of common stock	1,904,161	3,716,891	2,828,785
Proceeds from common stock offering, net of expenses	—	44,828,003	—
Net cash provided by financing activities	777,975	47,652,443	2,660,083
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(12,983)	16,560	26,286
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(20,573,969)	26,330,869	1,937,962
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	30,695,177	4,364,308	2,426,346
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 10,121,208	$ 30,695,177	$ 4,364,308

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 internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. One of our products is also sold in the United States over-the-counter or consumer retail market.

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 with a purchased maturity of ninety days or less to be cash equivalents. As of December 31, 2004 and 2003, cash equivalents consisted of commercial paper, U.S. government agency obligations, state and local government agency obligations, and corporate bonds.

Short-term Investments

We consider all short-term investments to be 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, state and local government agency obligations, corporate bonds, and asset-backed obligations, all with purchased maturities greater than ninety days. 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. There were no securities as of December 31, 2004 in an unrealized loss position for twelve or more months.

The following is a summary of our available-for-sale securities at December 31, 2004 and 2003:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2004				
Certificates of deposit	$ 18,702,211	$ 56	$ (29,411)	$ 18,672,856
Commercial paper	4,281,910	185	—	4,282,095
Government and agency bonds	21,112,676	113	(61,631)	21,051,158
State and local government agency obligations	629,322	162	(1,059)	628,425
Asset-backed obligations	1,002,116	—	(866)	1,001,250
Corporate bonds	10,999,750	431	(33,717)	10,966,464
Total available-for-sale securities	$ 56,727,985	$ 947	$ (126,684)	$ 56,602,248
December 31, 2003				
Certificates of deposit	$ 14,047,127	$ 1,167	$ (5,586)	$ 14,042,708
Commercial paper	1,296,941	121	—	1,297,062
Government and agency bonds	14,483,893	7,667	—	14,491,560
State and local government agency obligations	629,999	1,118	(3)	631,114
Corporate bonds	2,867,261	1,641	(2,736)	2,866,166
Total available-for-sale securities	$ 33,325,221	$ 11,714	$ (8,325)	$ 33,328,610
At December 31, 2004, maturities of investments were as follows:				
Less than one year	$ 53,900,919	$ 516	$ (102,342)	$ 53,799,093
1 – 2 years	2,827,066	431	(24,342)	2,803,155
Total available-for-sale securities	$ 56,727,985	$ 947	$ (126,684)	$ 56,602,248

Supplemental Cash Flow Information

For 2004, 2003 and 2002, we paid interest of $137,112, $184,906 and $268,340, respectively.

For 2004, 2003 and 2002, we recorded provisions for bad debts of $(10,360), $155,671 and $295,842, respectively. We had deductions of $3,541, $88,659 and $213,188 against the allowance for doubtful accounts in 2004, 2003 and 2002, respectively.

For 2004, 2003 and 2002, we recorded accruals for purchases of property and equipment of $72,394, $93,987, and $122,962, respectively.

In 2004, we recorded a $300,000 non-cash accrual related to a new license agreement.

Accounts Receivable

Accounts receivable have been reduced by an allowance for amounts that may become uncollectible in the future. This estimated allowance is based primarily on management's evaluation of specific balances as the balances become past due, the financial condition of our customers and our historical experience of write-offs. If not reserved through these specific examination procedures, our policy is to reserve for uncollectible accounts by applying fixed percentages to the aging categories of accounts receivable.

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. In addition to reserving for these items identified through specific identification procedures, we also reserve for unidentified scrap or spoilage under a fixed-formula methodology. We currently buy our entire cryosurgical 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 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, licenses and product distribution rights. Patents and product rights are amortized using the straight-line method over estimated useful lives of three to ten years. Accumulated amortization was $2,868,294 and $2,162,486 at December 31, 2004 and 2003, respectively. Amortization expense for 2004, 2003 and 2002 was $705,808, $657,348 and $416,247, respectively. Amortization expense for each of the five succeeding fiscal years is estimated at $637,885 for 2005, $387,051 for 2006, $367,052 for 2007, $197,105 for 2008, and $90,000 for 2009.

Other Assets

Included in other assets is a $337,253 investment, representing a 7.7% 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 and 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, which is 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, 2004.

Revenue Recognition

We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are net of allowances for any discounts or rebates. 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.

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. 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 2004, 2003 and 2002, one customer accounted for approximately 12 percent, 17 percent and 26 percent, respectively, of our total revenues. This customer accounted for approximately 8 percent of accounts receivable as of both December 31, 2004 and 2003.

In 2004 and 2003, another customer accounted for 25 percent and 12 percent, respectively, of our total revenues. We had no sales to this customer in 2002. This customer accounted for approximately 23 percent of accounts receivable as of both December 31, 2004 and 2003.

Research and Development

Research and development costs are charged to expense as incurred.

Advertising Expenses

Advertising costs are charged to expense as incurred. During 2004, 2003 and 2002, we incurred $3,512,037, $1,774,093 and $53,452, respectively, in advertising expenses. Included in advertising expenses for 2004 and 2003 were $2,883,145 and $1,130,045, respectively, paid as reimbursement for marketing expenses incurred for the Compound W® Freeze Off™ product.

Stock-Based Compensation

We account for stock-based compensation to employees and directors using the intrinsic value method in accordance with Accounting Principles Board ("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" and Emerging Issues Task Force ("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 No. 123, as amended by SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure." Under SFAS No. 123, compensation expense related to stock awards granted to employees and directors is computed based on the fair value of the award at the date of grant using a valuation methodology, typically the Black-Scholes option pricing model. Pursuant to the disclosure requirements of SFAS No. 123, had compensation expense for our common stock awards been determined based upon the fair value of the awards at the date of grant, our net loss for 2004, 2003 and 2002 would have increased as follows:

	Year ended December 31,		
	2004	2003	2002
Net loss:			
As reported	$ (559,642)	$ (1,135,537)	$ (3,342,473)
Add: stock-based employee compensation expense included in net loss	874,162	70,048	—
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards	(5,921,957)	(4,306,587)	(3,359,281)
Pro forma	$ (5,607,437)	$ (5,372,076)	$ (6,701,754)
Basic and diluted net loss per share:			
As reported	$ (0.01)	$ (0.03)	$ (0.09)
Pro forma	$ (0.13)	$ (0.13)	$ (0.18)

The weighted average fair value of the options granted during 2004, 2003 and 2002 is estimated at $4.60, $4.15 and $3.45 per share, respectively, using the Black-Scholes option pricing model, with the following assumptions: dividend yield of zero; volatility of 65 percent, 70 percent and 71 percent, respectively; weighted average risk-free interest rate of 3.21 percent, 2.93 percent and 2.89 percent, respectively; and an expected life of 5.0 years for each year's grants.

Income Taxes

We follow the asset and liability method for accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax basis of assets and liabilities, and operating loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

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 in accumulated other comprehensive loss, which is a separate component of stockholders' equity.

Net Loss Per Common Share

We have presented basic and diluted net loss per common share pursuant to SFAS No. 128, "Earnings per Share." In accordance with SFAS No. 128, basic and diluted net loss per share has been computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is generally computed in a similar manner, except that the weighted average number of shares outstanding is increased to include incremental shares from the assumed conversion or exercise of all dilutive securities, such as common stock options, warrants and unvested restricted stock. As a result of our losses in 2004, 2003 and 2002, outstanding common stock options, warrants and unvested restricted stock representing 5,479,504, 4,130,463 and 3,999,608 shares were excluded from the computation of diluted net loss per common share for 2004, 2003 and 2002, respectively, as their inclusion would have been anti-dilutive.

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 stockholders' equity section of our balance sheet.

Fair Value of Financial Instruments

As of December 31, 2004, the carrying values of cash and cash equivalents, short-term investments, accounts receivable and accounts payable 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 values, approximates their fair values, given that the interest rates on outstanding borrowings approximate market rates.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 151, "Inventory Costs." SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material and requires such costs to be recognized as current-period charges. Additionally, SFAS No. 151 requires that allocation of fixed production overhead costs be based on normal capacity. SFAS No. 151 is effective for years beginning after June 15, 2005, with early adoption permitted. The implementation of SFAS No. 151 is not expected to have a material effect on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123 Revised, "Share-Based Payment" ("SFAS No. 123R"). SFAS No. 123R requires employee stock options to be accounted for in the statement of operations based on their fair values on the date of grant, and eliminates the ability to account for these instruments under the intrinsic value method prescribed by APB Opinion No. 25. SFAS No. 123R requires the use of an option pricing model for estimating fair value, which is amortized to expense over the service period. The requirements of SFAS No. 123R are effective for fiscal periods beginning after June 15, 2005. SFAS No. 123R allows for either prospective recognition of compensation expense or retrospective recognition. The Company is considering the potential implementation of different valuation models to determine the fair value of stock-based compensation and, therefore, has not yet completed evaluating the impact of adopting SFAS No. 123R on its results of operations. If the Company had applied the provisions of SFAS No. 123R to the financial statements for the period ending December 31, 2004, net loss would have been increased by $5,048,000.

3. INVENTORIES:

	December 31,	
	2004	2003
Raw materials	$ 3,405,578	$ 2,862,169
Work in process	659,304	486,284
Finished goods	887,097	655,066
	$ 4,951,979	$ 4,003,519

4. PROPERTY AND EQUIPMENT:

	December 31,	
	2004	2003
Building and leasehold improvements	$ 4,780,874	$ 5,989,170
Machinery and equipment	7,859,207	10,361,701
Computer equipment	1,809,582	2,446,736
Furniture and fixtures	804,061	1,545,562
Construction in progress	526,030	990,115
	15,779,754	21,333,284
Less—Accumulated depreciation and amortization	(10,228,493)	(14,862,075)
	$ 5,551,261	$ 6,471,209

Depreciation expense was $1,739,733, $1,879,092 and $1,828,855 for 2004, 2003 and 2002, respectively. In addition, in connection with the transfer of all operations to our Bethlehem facilities in 2004, we retired or disposed of $6,298,345 in fully depreciated assets that were previously utilized in our Oregon facility. No gain or loss was recognized on these disposals. Included in construction in progress in both 2004 and 2003 is approximately $448,000 related to a piece of equipment which is not yet completed and, therefore, is not yet being used to produce saleable product.

5. PATENTS AND PRODUCT RIGHTS:

In June 1998, we acquired the patents and exclusive worldwide distribution rights to our cryosurgical product line. 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 cryosurgical product line, 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 paid BMX $750,000, which we recorded as patent and product rights on our balance sheet.

In June 2004, we entered into a sublicense agreement with a third party, pursuant to which we have been granted a limited, worldwide, non-exclusive sublicense to certain HIV-2 patents held by such party. The agreement requires us to pay the third party a one-time non-refundable license fee of $900,000, $600,000 of

which was paid in August 2004. The remaining $300,000 obligation is payable by June 30, 2005 and is included in accrued expenses in the accompanying balance sheet at December 31, 2004. The $900,000 was recorded as patent and product rights on our balance sheet and is being amortized through June 30, 2014.

6. ACCRUED EXPENSES:

	December 31,	
	2004	2003
Payroll and related benefits	$ 2,069,309	$ 1,449,151
Deferred revenue	1,353,711	705,817
Professional fees	1,227,087	222,710
Royalties	1,069,932	1,428,816
Advertising	603,009	474,817
License fees	300,000	—
Laboratory testing fees	249,041	305,647
Other	680,190	788,893
	$ 7,552,279	$ 5,375,851

At December 31, 2004, accrued payroll and related benefits increased primarily as a result of the accrual for salary continuation payments to the former Chief Executive Officer and an increase in annual bonuses. Deferred revenue at December 31, 2004 increased as a result of additional customer prepayments, totaling $1,041,711 in 2004 versus $304,962 in 2003. Professional fees at December 31, 2004 are primarily comprised of legal and accounting fees related to current litigation and Sarbanes-Oxley Act compliance. Accrued royalties and advertising expenses at December 31, 2004 and 2003 are primarily related to our OraQuick® and Freeze Off™ products, respectively. License fees at December 31, 2004 are related to the new sublicense agreement, which we entered into in June 2004, as discussed in Note 5.

7. CREDIT FACILITIES:

In September 2002, we entered into a $10,887,000 credit facility (“Credit Facility”) with Comerica Bank, comprised of an $887,000 mortgage loan, a $3,000,000 term loan, a $3,000,000 non-revolving equipment line of credit, and a $4,000,000 revolving working capital line of credit. In September 2003, we executed an amendment to this Credit Facility, pursuant to which the $3,000,000 non-revolving equipment line of credit (the “Original Non-Revolving Line”) was replaced with a new $4,000,000 non-revolving line of credit (the “New Non-Revolving Line”). The Original Non-Revolving Line expired and borrowings under that facility at the time of the amendment were not applied against the credit limit for the New Non-Revolving Line, but rather, remained payable in accordance with their original terms. This amendment also extended the maturity date of the $4,000,000 revolving working capital line of credit (the “Revolving Line”) until September 10, 2004, modified certain covenants related to liquidity and tangible net worth, and eliminated the covenant requiring us to achieve positive net income for the year ended December 31, 2003 and for each year thereafter. The term loan and mortgage loan were not affected by this amendment (see Note 8). On September 27, 2004, we executed a letter agreement with Comerica Bank extending the maturity date of the Revolving Line until April 30, 2005. All other terms of the Revolving Line, as amended, remain in effect.

Under the New Non-Revolving Line, we could borrow up to $4,000,000 to finance eligible equipment or software purchases through December 31, 2004. 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 either 36 or 48 consecutive, equal monthly principal installments, depending upon the type of purchase financed, plus interest. We had no borrowings under this facility and, on December 31, 2004, it expired and was not renewed.

Under the Revolving Line, we can borrow up to $4,000,000 to finance working capital and other needs. Interest on outstanding borrowings accrues 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 April 30, 2005, with interest payable monthly. We had no outstanding borrowings under this facility at December 31, 2004.

All borrowings under the Credit Facility, as amended, 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 Revolving Line are limited to commercially standard percentages of accounts receivable. The Credit Facility, as amended, contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth and 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,	
	2004	**2003**
Term loan payable to bank, interest at 4.97%, monthly principal installments of $71,429, plus interest, through March 2006, secured by a first priority security interest in all of our assets	$ 1,071,429	$ 1,928,571
Mortgage loan payable to bank, interest at an annual floating rate equal to the bank's prime rate (5.25% at December 31, 2004), 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	765,953	820,796
Note payable to bank, interest at an annual floating rate equal to the bank's prime rate (5.25% at December 31, 2004), monthly principal installments of $5,081, plus interest, through December 2006, secured by certain equipment	121,935	182,904
Note payable to bank, interest at 5.07%, monthly principal installments of $3,995, plus interest, through September 2006, secured by certain equipment	83,900	131,843
Note payable to bank, interest at an annual floating rate equal to the bank's prime rate (5.25% at December 31, 2004), monthly principal installments of $2,144, plus interest, through June 2007, secured by certain equipment	64,317	90,044
Note payable to bank, interest at an annual floating rate equal to the bank's prime rate (5.25% at December 31, 2004), monthly principal installments of $2,264, plus interest, through March 2007, secured by certain equipment	61,134	88,304
Note payable to Pennsylvania Industrial Development Authority, interest at 2%, monthly installments of principal and interest of $4,893 through March 2010, secured by a second lien on our building	288,023	340,415
	2,456,691	3,582,877
Less—Current portion	(1,122,455)	(1,126,423)
	$ 1,334,236	$ 2,456,454

Long-term debt maturities as of December 31, 2004 are as follows:

2005	$ 1,122,455
2006	471,427
2007	130,915
2008	115,373
2009	119,672
Thereafter	496,849
	$ 2,456,691

Certain of these notes payable require, among other items, the maintenance of certain financial covenants (see Note 7). We were in compliance with these covenants as of December 31, 2004.

9. INCOME TAXES:

At December 31, 2004, we have federal net operating loss ("NOL") carryforwards of approximately $74,900,000. These federal NOL carryforwards will expire through 2024. The Tax Reform Act of 1986 contains provisions that may limit the annual amount of NOL carryforwards available to be used in any given year in the event of a significant change in ownership. On September 29, 2000, two separate companies, STC Technologies, Inc. and Epitope, Inc. ("Epitope"), merged to form our company. Accordingly, we believe there was a change in ownership in connection with that merger. As such, we are in the process of determining the effect of the limitation as to the utilization of NOL carryforwards related to any changes in ownership.

The tax effect of temporary differences that give rise to significant portions of deferred income taxes at December 31, 2004 and 2003 are as follows:

	December 31,	
	2004	2003
Deferred tax asset:		
Net operating loss carryforwards	$ 26,056,923	$ 26,597,884
Research and development credit carryforwards	2,011,653	2,138,080
Accruals and reserves currently not deductible	787,029	568,456
Capitalized research and development costs	782,557	895,085
Inventory	605,743	626,501
Patent costs	551,480	517,827
Deferred compensation	339,224	13,481
Depreciation and amortization	322,334	389,344
Valuation allowance on deferred tax asset	(31,456,943)	(31,746,658)
Net deferred tax asset	$ —	$ —

Of the total NOL deferred tax asset carryforwards as of December 31, 2004 and 2003, approximately $10,000,000 and $9,600,000, respectively, are related to stock option exercises. Upon recognition of the tax benefit associated with our NOL carryforwards, the amount attributable to stock option exercises and not limited by the change in ownership will be recorded as additional paid-in capital in stockholders' equity.

In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible or the NOLs and credit carryforwards can be utilized. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment.

Based upon our cumulative and recent history of losses and projections for future taxable income over the periods in which the deferred tax assets are deductible or the NOLs and credit carryforwards can be utilized, we believe that a full valuation allowance is necessary at December 31, 2004.

10. STOCKHOLDERS' EQUITY:

Common stock

On October 7, 2003, we successfully completed a public offering in which we sold 5,000,000 shares of our common stock. Upon the exercise of the underwriters' over-allotment option on November 5, 2003, we sold an additional 311,000 shares of common stock. The price to the public of the 5,311,000 shares of common stock was $9.00 per share. We received proceeds of $44,828,003, net of expenses, from this offering.

Stock-based Awards

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 related interpretations in accounting for stock awards granted to employees and directors. Accordingly, compensation cost, 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 cost, if any, is deferred and charged to expense over the respective vesting period.

We account for stock-based compensation to non-employees using the fair value method, in accordance with SFAS No. 123 and EITF Issue No. 96-18. In 2002, we recorded compensation expense of $50,939 related to options to purchase 20,000 shares of our common stock granted to outside consultants. This 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. No such awards were made in 2004 or 2003.

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, 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
Granted	1,129,885	5.51–10.47	6.97
Exercised	(849,374)	0.80– 7.88	4.38
Canceled	(224,656)	0.80–13.66	6.61
Balance, December 31, 2003	3,935,463	0.80–15.03	6.42
Granted	1,629,891	6.63–10.29	8.07
Exercised	(370,800)	0.80– 9.92	5.14
Canceled	(320,050)	3.83–13.19	7.89
Balance, December 31, 2004	4,874,504	$ 0.80–15.03	$ 6.98

The following table summarizes information about stock options outstanding at December 31, 2004:

	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–$4.06	377,378	9.23	$ 2.74	322,691	$ 2.51
$4.17–$5.04	345,066	24.77	4.58	341,732	4.58
$5.75–$5.76	30,000	4.10	5.75	27,395	5.75
$5.87	608,104	7.08	5.87	466,206	5.87
$6.10–$6.87	166,271	7.27	6.67	137,249	6.70
$6.96	792,086	8.08	6.96	461,680	6.96
$6.98–$7.09	549,737	6.11	7.09	544,737	7.09
$7.13–$8.03	547,583	8.43	7.74	140,708	7.68
$8.09–$8.20	1,061,341	9.04	8.20	114,165	8.20
$8.25–$15.03	396,938	6.53	10.55	325,935	10.56
	4,874,504	9.07	$ 6.98	2,882,498	$ 6.50

The 2000 Plan also permits us to grant restricted shares of our common stock to eligible employees, including officers. Generally, these shares are nontransferable and are subject to vesting requirements or forfeiture, as determined by the Compensation Committee of our Board of Directors. Upon granting of these restricted shares, deferred compensation cost equivalent to the market value at the date of grant is charged to stockholders' equity and subsequently amortized over the periods during which the restrictions lapse, generally three years. During 2004 and 2003, we granted 410,000 and 75,000 restricted shares, respectively, to certain officers and recorded $3,176,150 and $650,663 of deferred compensation, respectively. Amortization of deferred compensation related to these grants was $874,162 and $36,148 in 2004 and 2003, respectively. We did not grant any restricted shares in 2002.

As of December 31, 2004, 2,509,135 shares were available for future grants under the 2000 Plan.

Employee Stock Purchase Plan

In 1993, the stockholders of Epitope approved the adoption of the 1993 Employee Stock Purchase Plan (the "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. In September 2000 when Epitope merged to form OraSure Technologies, Inc., 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, 2004, 2003 and 2002, there were no subscriptions for common shares outstanding, and no shares were issued under the 1993 ESPP during the years ended December 31, 2004 and 2003. In 2002, 8,834 shares were issued at $3.96 per share under the 1993 ESPP.

Common Stock Warrants

As of December 31, 2004, 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 and royalty payments. These sponsored research funds were $87,500 in 2004 and decrease to $50,000 per year through 2008. Related royalty payments are $25,000 per year until 2008. All of these amounts are expensed as incurred. Future minimum payments under these agreements are as follows:

2005	$ 225,000
2006	225,000
2007	225,000
2008	225,000
2009	150,000
Thereafter	1,200,000
	$ 2,250,000

Sublicense Agreement

In June 2004, we entered into a sublicense agreement with a third party, pursuant to which we have been granted a limited, worldwide, non-exclusive sublicense to certain HIV-2 patents held by such party. Under the terms of this sublicense agreement, we are obligated to pay royalties based on a percentage of our net sales of certain products, which incorporate the technology covered by the licensed patents. Future minimum payments under this agreement are as follows:

2005	$ 200,000
2006	400,000
2007	500,000
2008	500,000
2009	500,000
Thereafter	4,291,667
	$ 6,391,667

Royalties from our commercial sale of products covered by the sublicense can be credited against these minimum royalty obligations.

Leases

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

2005	$ 874,510
2006	780,000
2007	783,062
2008	798,810
2009	814,262
Thereafter	2,367,786
	$ 6,418,430

Rent expense for 2004, 2003 and 2002 was $1,690,858, $1,594,240 and $1,070,510, respectively.

Purchase Commitments

As of December 31, 2004, we had outstanding noncancelable purchase commitments in the amount of $4,530,899, of which $3,268,031, $665,827 and $597,041 are related to inventory, capital expenditures, and other goods or services, respectively.

Employment Agreements

Under terms of employment agreements with certain executive officers and other employees, extending through 2007, we are required to pay each individual a base salary for continuing employment with our Company. The agreements require payments of $1,937,636, $995,761 and $205,000 in 2005, 2006 and 2007, respectively.

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:

In 2002, we entered into a ten-year facility lease with Tech III Partners, LLC ("Tech Partners"), an entity owned and controlled by two of our former 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. Neither of these executives were employed by the Company subsequent to December 31, 2004.

13. RETIREMENT PLANS:

Substantially all employees of the Company are eligible to participate in the OraSure Technologies, Inc. 401(k) Plan (the "401(k) Plan"). The 401(k) 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 401(k) Plan also provides for us to match employee contributions up to the lesser of $4,000 or ten percent of the employee's salary. Contributions to the 401(k) Plan, net of forfeitures, were $330,552, $330,275 and $394,714 in 2004, 2003 and 2002, respectively.

14. GEOGRAPHIC INFORMATION:

Under the disclosure requirements of SFAS No.131, "Disclosures about Segments of an Enterprise and Related Information," we operate within one segment. Our products are sold principally in the United States and Europe. Segmentation of operating income and identifiable assets is not applicable since our revenues outside the United States are export sales, and we do not have significant operating assets outside the United States.

The following table represents total revenues by geographic area, based on the location of the customer (amounts in thousands):

	For the year ended December 31,		
	2004	2003	2002
United States	$47,843	$35,896	$28,124
Europe	4,318	3,062	2,726
Other regions	1,847	1,493	1,160
	$54,008	$40,451	$32,010

15. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2004 and 2003. 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).

	2004 Results				
	Three months ended				
	March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004	Year ended December 31, 2004
Revenues	$12,409	$13,214	$ 14,176	$ 14,209	$ 54,008
Costs and expenses	12,734	13,265	14,657	14,709	55,365
Operating loss	(325)	(51)	(481)	(500)	(1,357)
Other income (expense), net	168	198	192	239	797
Income (loss) before income taxes	(157)	147	(289)	(261)	(560)
Income taxes (benefit)	5	5	5	(15)	—
Net income (loss)	$ (162)	$ 142	$ (294)	$ (246)	$ (560)
Basic and diluted net income (loss) per share(1)	$ (0.00)	$ 0.00	$ (0.01)	$ (0.01)	$ (0.01)
Weighted average number of shares outstanding:					
Basic	44,271	44,465	44,539	44,578	44,464
Diluted	44,271	45,334	44,539	44,578	44,464

	2003 Results				
	Three months ended				
	March 31, 2003	June 30, 2003	September 30, 2003	December 31, 2003	Year ended December 31, 2003
Revenues	$ 8,611	$ 9,629	$ 10,331	$ 11,880	$ 40,451
Costs and expenses	9,736	10,181	10,319	11,501	41,737
Operating income (loss)	(1,125)	(552)	12	379	(1,286)
Other income (expense), net	37	32	43	65	177
Income (loss) before income taxes	(1,088)	(520)	55	444	(1,109)
Income taxes	5	10	2	9	26
Net income (loss)	$ (1,093)	$ (530)	$ 53	$ 435	$ (1,135)
Basic and diluted net income (loss) per share	$ (0.03)	$ (0.01)	$ 0.00	$ 0.01	$ (0.03)
Weighted average number of shares outstanding:					
Basic	38,249	38,412	38,666	43,799	39,794
Diluted	38,249	38,412	39,777	44,795	39,794

(1) The summation of the quarterly amounts does not equal the year-end basic and diluted net loss per share due to rounding.

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INDEX TO EXHIBITS

Exhibit Number	Exhibit
3.1.1	Certificate of Incorporation of OraSure Technologies, Inc. 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.
3.1.2	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.
3.1.3	Certificate of Designation of Series A Preferred Stock of OraSure Technologies (filed as Exhibit A to the Rights Agreement referred to in Exhibit 4.1).
3.2	Amended and Restated Bylaws of OraSure Technologies, effective as of February 4, 2003, are incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002.
4.1	Rights Agreement, dated as of May 6, 2000, between OraSure Technologies, Inc. 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.
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	Employment Agreement, dated as of June 22, 2004, between OraSure Technologies, Inc. and Douglas A. Michels, is incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.3	Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and Ronald H. Spair, is incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.4	Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and P. Michael Formica, is incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.5	Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and Joseph E. Zack, is incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.6	Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and Jack E. Jerrett, is incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.7	Description of Nonemployee Director Compensation Policy is incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2003.*
10.8	Amended and Restated Epitope, Inc. 1991 Stock Award Plan is incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002.*
10.9	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.*
10.10	OraSure Technologies, Inc. 2000 Stock Award Plan, as amended effective as of May 18, 2004, is incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*

Exhibit Number	Exhibit
10.11	Form of Restricted Share Grant Agreement is incorporated by reference to Exhibit 10.2.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.12	Incentive Stock Option General Terms and Conditions (Officers and Employees).*
10.13	Nonqualified Stock Option Award General Terms and Conditions (Officers and Employees).*
10.14	Nonqualified Stock Option Award General Terms and Conditions (Non-Employee Directors).*
10.15	Description of OraSure Technologies, Inc. 2004 Self-Funding Annual Incentive Plan is incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the year ended December 31, 2003.*
10.16	Description of OraSure Technologies, Inc. Management Stock Award Guidelines dated January 26, 2005.*
10.17	Transition Agreement and Release, dated as of March 8, 2004, between Michael J. Gausling and OraSure Technologies, Inc., is incorporated by reference to Exhibit 10 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004.*
10.18	Distribution Agreement, dated as of April 24, 2003, between OraSure Technologies, Inc. and Medtech Holdings, Inc., is incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.
10.19	Production Agreement between STC Technologies, Inc. and 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.
10.20	Amendment No. 1 to Production Agreement, dated as of December 11, 2001, between OraSure Technologies, Inc. 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.
10.21	Amendment No. 2 to Production Agreement, dated as of April 28, 2003, between OraSure Technologies, Inc. and Koninklijke Utermöhlen N.V., is incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K for the year ended December 31, 2003.
10.22	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.
10.23	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.
10.24	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.
10.25	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.
10.26	Fourth Amendment to Commercial Lease dated as of March 4, 2005, between OraSure Technologies, Inc. and Northampton County New Jobs Corp., is incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed March 11, 2005.

Exhibit Number	Exhibit
10.27	Commercial Lease between Tech III Partners, LLC and OraSure Technologies, Inc., 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.
10.28	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.
10.29	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.
10.30	First Amendment to Loan and Security Agreement, dated as of May 23, 2003, between OraSure Technologies, Inc. and Comerica Bank – California, is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2003.
10.31	Second Amendment to Loan and Security Agreement, dated as of September 12, 2003, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, dated September 17, 2003.
10.32	Letter Agreement, dated September 8, 2004, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K, dated September 10, 2004.
10.33	Letter Agreement, executed September 27, 2004, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K, dated September 28, 2004.
10.34	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.
10.35	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, Independent Registered Public Accounting Firm.
24	Powers of Attorney.
31.1	Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management contract or compensatory plan or arrangement.

Incentive Stock Option Award
General Terms and Conditions

The OraSure Technologies, Inc. 2000 Stock Award Plan ("Plan") is administered by the executive compensation committee (the "Committee") of the board of directors of Corporation. Capitalized terms not otherwise defined have the definitions assigned in Section 11 of these Incentive Stock Option Award General Terms and Conditions ("Agreement Terms").

1. Option Type and Term.

1.1 Type of Option. The Option is intended to be an incentive stock option as described in Internal Revenue Code Section 422. **However, the Option will automatically become a nonqualified option after expiration of the "ISO Employment Period" described in the Note in Section 2.3 below.**

1.2 Term. The Option term will expire on the expiration date shown on the cover page unless earlier terminated pursuant to this Agreement, but in no event later than ten years from the Grant Date.

1.3 Vesting. Except as otherwise provided in this Agreement, the Option will be vested as to, and accordingly may be exercised from time to time to purchase, Shares up to the number shown on the cover page as vested as of the date of exercise.

2. Employment Requirement.

2.1 General. Except as provided in Section 3 of this Agreement, the Option may not be exercised and will not be deemed vested unless the recipient of the Option (the "Participant") is employed by Corporation and/or one or more of its Subsidiaries (an "Employer") continuously for at least one year after the Grant Date, unless employment is terminated by death, Disability or Retirement. "Employment" for purposes of the Option will include periods of illness or other leaves of absence authorized by an Employer or by law.

2.2 No Employment Contract. Neither the Plan nor the Option constitutes a contract of employment of Participant by any Employer.

2.3 **Expiration After Termination of Employment**. If Participant ceases to be an active employee of the Employer, the right to exercise the Option will expire at the end of the following periods:

After Termination On Account Of	Period
Death	1 year
Retirement	5 years
Disability	1 year
Any other reason	1 year

NOTE: Notwithstanding the continued exercisability of the Option pursuant to the table above, exercise of the Option will qualify for the favorable income tax treatment given to incentive stock options only if or to the extent the Option is exercised within the "**ISO Employment Period**" that consists of the period that Participant is an employee of an Employer and (subject to the exceptions related to death and disability noted below) the period ending three months after Participant ceases to be an employee of any Employer. **After the expiration of the ISO Employment Period, the Option, to the extent it still remains exercisable, will automatically become a nonqualified option**. If Participant terminates employment by reason of disability, the three-month ISO Employment Period is extended to one year after the date of such termination. The ISO Employment Period limitation does not apply to the heirs or estate of a Participant who dies while an employee of an Employer or within three months (or one year if termination is by reason of disability) after termination of such employment.

2.4 **Effect of Termination on Vesting**. Subject to Section 2.1, the Option will continue vesting in accordance with Section 1.3 for 90 days following termination of employment for any reason other than for cause (as defined in Section 9.1) and will then cease vesting. The Shares as to which the Option is exercisable under Section 2.3 will be those as to which the Option is vested as of the date of exercise.

3. **Acceleration of Exercisability**. If a Change in Control Date occurs while Participant is employed by Employer or if a Change in Control Date occurs within 90 days after termination of employment, the Option will become immediately and fully vested and exercisable as to all Shares covered by the Option. A Change in Control Date that occurs more than 90 days after termination of employment will not cause the Option to become vested as to additional Shares.

4. **Method of Exercise**.

4.1 **Exercise of Option**. All or any portion of the Option may be exercised, to the extent it has become exercisable pursuant to this Agreement, by delivery of written notice to Corporation in the

attached form stating the number of Shares, form of payment, and proposed date of closing.

4.2 **Other Documents**. Participant must furnish Corporation, before closing of any exercise of the Option, such other documents or representations as Corporation may require to assure compliance with applicable laws and regulations.

4.3 **Payment**. The exercise price for the Shares purchased upon exercise of the Option must be paid in full at or before closing by one or a combination of the following:

(a) Payment in cash;

(b) 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 exercise 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 exercise price and withholding taxes due; or

(c) Delivery of previously acquired Shares having a Fair Market Value at least equal to the exercise price.

4.4 **Previously Acquired Shares**. Delivery of previously acquired Shares surrendered in full or partial payment of the exercise price of all or any portion of the Option, will be subject to the following conditions:

(a) The Shares tendered must be in good delivery form;

(b) The Fair Market Value of the Shares, together with the amount of cash, if any, tendered must equal or exceed the exercise price of the Option;

(c) Any Shares remaining after satisfying payment of the exercise price will be reissued in the same manner as the Shares tendered; and

(d) No fractional Shares will be issued and cash will not be paid to Participant for any fractional Share value not used to satisfy payment of the exercise price.

5. **Transferability**.

5.1 **Restriction**.

(a) The Option is not transferable by Participant other than by testamentary will or the laws of descent and distribution and, during Participant's lifetime, may be exercised only by Participant or Participant's guardian or legal representative;

(b) No assignment or transfer of the Option, whether voluntary, involuntary, or by operation of law or otherwise, except by testamentary will or the laws of descent and distribution, will vest in the assignee or transferee any interest or right; and

(c) Immediately upon any attempt to assign or transfer the Option, the Option will terminate and be of no force or effect.

5.2 **Exercise in the Event of Death or Disability**. Whenever the word "Participant" is used in any provision of this Agreement under circumstances when the provision should logically be construed to apply to Participant's guardian, legal representative, executor, administrator, or the person or persons to whom the Option may be transferred by testamentary will or by the laws of descent and distribution, the word "Participant" will be deemed to include such person or persons.

6. **Securities Laws**. Corporation will not be required to issue any Shares upon exercise of the Option, or any portion thereof, until Corporation has taken any action required to comply with the provisions of the Securities Act of 1933 or any other then applicable federal or state securities laws.

7. **Tax Reimbursement**. In the event any withholding or similar tax liability is imposed on Corporation in connection with or with respect to the exercise of the Option or the disposition by Participant of the Shares acquired upon exercise of the Option, Participant will pay to Corporation an amount sufficient to satisfy such tax liability.

8. **Conditions Precedent**. Corporation will use its best efforts to obtain any required approvals of the Plan and the Option by any state or federal agency or authority that Corporation determines has jurisdiction. If Corporation determines that any required approval cannot be obtained, all Awards to Participant will terminate on notice to Participant to that effect.

9. **Termination for Cause; Competition**.

9.1 **Annulment of Awards**. The grant of the Option is provisional until Participant becomes entitled to a certificate for Shares in settlement of the Option. In the event the employment of Participant is terminated for cause (as defined below), any portion of the Option that is provisional will be annulled as of the date of such termination for cause. For the purpose of this Section 9.1, the term "for cause" has the meaning set forth in 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 that is materially detrimental to the best interests of Corporation, as determined by the Committee.

9.2 **Engaging in Competition With Corporation**. If Participant terminates employment with an Employer for any reason whatsoever, and within 18 months after the date of termination accepts employment with any competitor of (or otherwise engages in competition with) Corporation, the Committee, in its sole discretion, may require Participant to return to Corporation the economic value of any Award that is realized or obtained (measured at the date of exercise) by Participant at any time during the period beginning on the date that is six months prior to the date of Participant's termination of employment with the Employer through the date of the Committee's action.

10. **Successorship**. Subject to the restrictions on transferability of the Option set forth in this Agreement and in the Plan, this Agreement will be binding upon and benefit the parties, their successors, and assigns.

11. **Defined Terms**. When used in this Agreement, the following terms have the meanings specified below:

11.1 "**Acquiring Person**" means any person or related person or related persons which constitute a "group" for purposes of Section 13(d) and Rule 13d-5 under the Securities Exchange Act of 1934 (the "Exchange Act"), as such Section and Rule are in effect as of the date of the Agreement; provided, however, that the term Acquiring Person does not include:

(a) Corporation or any of its Subsidiaries;

(b) Any employee benefit plan of Corporation or any of its Subsidiaries;

(c) Any entity holding voting capital stock of Corporation for or pursuant to the terms of any such employee benefit plan; or

(d) Any person or group solely because such person or group has voting power with respect to capital stock of Corporation arising from a revocable proxy or consent given in response to a public proxy or consent solicitation made pursuant to the Exchange Act.

11.2 "**Agreement**" means the agreement evidencing an Option governed by these Agreement Terms.

11.3 "**Change in Control**" means:

(a) A change in control of Corporation of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A as in effect on the date of the Agreement pursuant to the Exchange Act; provided that, without limitation, such a change in control will be deemed to have occurred at such time as any Acquiring Person hereafter becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 30 percent or more of the combined voting power of Voting Securities; or

(b) During any period of 12 consecutive calendar months, individuals who at the beginning of such period constitute the board of directors cease for any reason to constitute at least a majority of the board unless the election, or the nomination for election, by Corporation's shareholders of each new director was approved by a vote of at least a majority of the directors then in office who were directors at the beginning of the period; or

(c) There is consummated (i) any consolidation or merger of Corporation in which Corporation is not the continuing or surviving corporation or pursuant to which Voting Securities would be converted into cash, securities, or other property, other than a merger of Corporation in which the holders of Voting Securities immediately prior to the merger have the same, or substantially the same, proportionate ownership of common stock of the surviving corporation immediately after the merger, or (ii) any sale, lease, exchange, or other transfer (in one transaction or a series of related transactions) of all, or substantially all, of the assets of Corporation; or

(d) Approval by the shareholders of Corporation of any plan or proposal for the liquidation or dissolution of Corporation.

11.4 "**Change in Control Date**" means the first date following the date of the Agreement on which a Change in Control has occurred.

11.5 "**Grant Date**" means the date of the Agreement, which is the date the Option is granted to Participant.

11.6 "**Option**" means the Incentive Stock Option granted to Participant evidenced by this Agreement.

11.7 "**Voting Securities**" means Corporation's issued and outstanding securities ordinarily having the right to vote at elections for Corporation's board of directors.

11.8 Capitalized terms not otherwise defined in this Agreement have the meanings given them in the Plan.

12. **Notices**. Any notices regarding the Option must be in writing and will be effective when actually delivered personally or, if mailed, when deposited as certified mail directed to the address maintained in Corporation's records or to such other address as a party may certify by notice to the other party.

Attachment: Exercise Form

Exhibit 10.13

Nonqualified Stock Option Award
General Terms and Conditions

The OraSure Technologies, Inc. 2000 Stock Award Plan ("Plan") is administered by the executive compensation committee (the "Committee") of the board of directors of Corporation. Capitalized terms not otherwise defined have the definitions assigned in Section 11 of these Nonqualified Stock Option Award General Terms and Conditions ("Agreement Terms").

1. Option Type and Term.

1.1 Type of Option. The Option is not intended to be an incentive stock option as described in Internal Revenue Code Section 422.

1.2 Term. The Option term will expire on the expiration date shown on the cover sheet unless earlier terminated pursuant to this Agreement.

1.3 Vesting. Except as otherwise provided in this Agreement, the Option will be vested as to, and accordingly may be exercised from time to time during the term to purchase, Shares up to the number shown on the cover page as vested as of the date of exercise.

2. Employment Requirement.

2.1 General. Except as provided in Section 3 of this Agreement, the Option may not be exercised and will not be deemed vested unless the recipient of the Option (the "Participant") is employed by Corporation and/or one or more of its Subsidiaries (an "Employer") continuously for at least one year after the Grant Date, unless employment is terminated by death, Disability or Retirement. "Employment" for purposes of the Option will include periods of illness or other leaves of absence authorized by an Employer or by law.

2.2 No Employment Contract. Neither the Plan nor the Option constitutes a contract of employment of Participant by any Employer.

2.3 Expiration After Termination of Employment. If Participant ceases to be an active employee of the Employer, the right to exercise the Option will expire at the end of the following periods:

After Termination On Account Of	Period
Death	1 year
Retirement	5 years
Disability	1 year
Any other reason	1 year

2.4 **Effect of Termination on Vesting**. Subject to Section 2.1, the Option will continue vesting in accordance with Section 1.3 for 90 days following termination of employment for any reason other than for cause (as defined in Section 9.1) and will then cease vesting. The Shares as to which the Option is exercisable under Section 2.3 will be those as to which the Option is vested at the time of exercise.

3. **Acceleration of Exercisability**. If a Change in Control Date occurs while Participant is employed by Employer or if a Change in Control Date occurs within 90 days after termination of employment, the Option will become immediately and fully vested and exercisable as to all Shares covered by the Option. A Change in Control Date that occurs more than 90 days after termination of employment will not cause the Option to become vested as to additional Shares.

4. **Method of Exercise**.

4.1 **Exercise of Option**. All or any portion of the Option may be exercised, to the extent it has become exercisable pursuant to this Agreement, by delivery of written notice to Corporation in the attached form stating the number of Shares, form of payment, and proposed date of closing.

4.2 **Other Documents**. Participant must furnish Corporation, before closing of any exercise of the Option, such other documents or representations as Corporation may require to assure compliance with applicable laws and regulations.

4.3 **Payment**. The exercise price for the Shares purchased upon exercise of the Option must be paid in full at or before closing by one or a combination of the following:

(a) Payment in cash;

(b) 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 exercise 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 exercise price and withholding taxes due; or

(c) Delivery of previously acquired Shares having a Fair Market Value at least equal to the exercise price.

4.4 **Previously Acquired Shares**. Delivery of previously acquired Shares surrendered in full or partial payment of the exercise price of all or any portion of the Option, will be subject to the following conditions:

(a) The Shares tendered must be in good delivery form;

(b) The Fair Market Value of the Shares, together with the amount of cash, if any, tendered must equal or exceed the exercise price of the Option;

(c) Any Shares remaining after satisfying payment of the exercise price will be reissued in the same manner as the Shares tendered; and

(d) No fractional Shares will be issued and cash will not be paid to Participant for any fractional Share value not used to satisfy payment of the exercise price.

5. **Transferability**.

5.1 **Restriction**.

(a) The Option is not transferable by Participant other than by testamentary will or the laws of descent and distribution and, during Participant's lifetime, may be exercised only by Participant or Participant's guardian or legal representative;

(b) No assignment or transfer of the Option, whether voluntary, involuntary, or by operation of law or otherwise, except by testamentary will or the laws of descent and distribution, will vest in the assignee or transferee any interest or right; and

(c) Immediately upon any attempt to assign or transfer the Option, the Option will terminate and be of no force or effect.

5.2 **Exercise in the Event of Death or Disability**. Whenever the word "Participant" is used in any provision of this Agreement under circumstances when the provision should logically be construed to apply to Participant's guardian, legal representative, executor, administrator, or the person or persons to whom the Option may be transferred by testamentary will or by the laws of descent and distribution, the word "Participant" will be deemed to include such person or persons.

6. **Securities Laws**. Corporation will not be required to issue any Shares upon exercise of the Option, or any portion thereof, until Corporation has taken any action required to comply with the provisions of the Securities Act of 1933 or any other then applicable federal or state securities laws.

7. **Tax Reimbursement**. In the event any withholding or similar tax liability is imposed on Corporation in connection with or with respect to the exercise of the Option or the disposition by Participant of the Shares acquired upon exercise of the Option, Participant will pay to Corporation an amount sufficient to satisfy such tax liability.

8. **Conditions Precedent**. Corporation will use its best efforts to obtain any required approvals of the Plan and the Option by any state or federal agency or authority that Corporation determines has jurisdiction. If Corporation determines that any required approval cannot be obtained, all Awards to Participant will terminate on notice to Participant to that effect.

9. **Termination for Cause; Competition**.

9.1 **Annulment of Awards**. The grant of the Option is provisional until Participant becomes entitled to a certificate for Shares in settlement of the Option. In the event the employment of Participant is terminated for cause (as defined below), any portion of the Option that is provisional will be annulled as of the date of such termination for cause. For the purpose of this Section 9.1, the term "for cause" has the meaning set forth in 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 that is materially detrimental to the best interests of Corporation, as determined by the Committee.

9.2 **Engaging in Competition With Corporation**. If Participant terminates employment with an Employer for any reason whatsoever, and within 18 months after the date of termination accepts employment with any competitor of (or otherwise engages in competition with) Corporation, the Committee, in its sole discretion, may require Participant to return to Corporation the economic value of any Award that is realized or obtained (measured at the date of exercise) by Participant at any time during the period beginning on the date that is six months prior to the date of Participant's termination of employment with the Employer through the date of the Committee's action.

10. **Successorship**. Subject to the restrictions on transferability of the Option set forth in this Agreement and in the Plan, this Agreement will be binding upon and benefit the parties, their successors, and assigns.

11. **Defined Terms**. When used in this Agreement, the following terms have the meanings specified below:

11.1 "**Acquiring Person**" means any person or related person or related persons which constitute a "group" for purposes of Section 13(d) and Rule 13d-5 under the Securities Exchange Act of 1934 (the "Exchange Act"), as such Section and Rule are in effect as of the date of

the Agreement; provided, however, that the term Acquiring Person does not include:

(a) Corporation or any of its Subsidiaries;

(b) Any employee benefit plan of Corporation or any of its Subsidiaries;

(c) Any entity holding voting capital stock of Corporation for or pursuant to the terms of any such employee benefit plan; or

(d) Any person or group solely because such person or group has voting power with respect to capital stock of Corporation arising from a revocable proxy or consent given in response to a public proxy or consent solicitation made pursuant to the Exchange Act.

11.2 "**Agreement**" means the agreement evidencing an Option governed by these Agreement Terms.

11.3 "**Change in Control**" means:

(a) A change in control of Corporation of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A as in effect on the date of the Agreement pursuant to the Exchange Act; provided that, without limitation, such a change in control will be deemed to have occurred at such time as any Acquiring Person hereafter becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 30 percent or more of the combined voting power of Voting Securities; or

(b) During any period of 12 consecutive calendar months, individuals who at the beginning of such period constitute the board of directors cease for any reason to constitute at least a majority of the board unless the election, or the nomination for election, by Corporation's shareholders of each new director was approved by a vote of at least a majority of the directors then in office who were directors at the beginning of the period; or

(c) There is consummated (i) any consolidation or merger of Corporation in which Corporation is not the continuing or surviving corporation or pursuant to which Voting Securities would be converted into cash, securities, or other property, other than a merger of Corporation in which the holders of Voting Securities immediately prior to the merger have the same, or substantially the same, proportionate ownership of common stock of the surviving corporation immediately after the merger, or (ii) any sale, lease, exchange, or other transfer (in one transaction or a series of related

transactions) of all, or substantially all, of the assets of Corporation; or

(d) Approval by the shareholders of Corporation of any plan or proposal for the liquidation or dissolution of Corporation.

11.4 "**Change in Control Date**" means the first date following the date of the Agreement on which a Change in Control has occurred.

11.5 "**Grant Date**" means the date of the Agreement, which is the date the Option is granted to Participant.

11.6 "**Option**" means the Nonqualified Stock Option granted to Participant evidenced by this Agreement.

11.7 "**Voting Securities**" means Corporation's issued and outstanding securities ordinarily having the right to vote at elections for Corporation's board of directors.

11.8 Capitalized terms not otherwise defined in this Agreement have the meanings given them in the Plan.

12. **Notices**. Any notices regarding the Option must be in writing and will be effective when actually delivered personally or, if mailed, when deposited as certified mail directed to the address maintained in Corporation's records or to such other address as a party may certify by notice to the other party.

Attachment: Exercise Form

Exhibit 10.14

Nonqualified Stock Option Award
General Terms and Conditions
(Non-Employee Directors)

OraSure Technologies, Inc. (the "Company") maintains the 2000 Stock Award Plan (the "Plan"). These Non-Qualified Stock Option Award General Terms and Conditions (the "Award Terms") govern the Award of an Option to Participant as a Non-Employee Director pursuant to the Plan. Capitalized terms not otherwise defined shall have the meanings set forth in Section 10 of these Award Terms.

1. Option Type and Term.

1.1 Type of Option. The Option is not intended to be an incentive stock option as described in Internal Revenue Code Section 422.

1.2 Term. The Option term will expire on the expiration date shown on the cover sheet unless earlier terminated pursuant to the Agreement.

1.3 Vesting. Except as otherwise provided in the Agreement, the Option will be vested as to, and accordingly may be exercised from time to time during the term to purchase, Shares up to the number shown on the cover page as vested as of the date of exercise.

2. Service As Director.

2.1 Expiration After Termination of Service. If the recipient of the Option ("Participant") ceases to be a member of the Board of Directors of the Company (the "Board") for any reason, to the extent the option is then exercisable (or becomes exercisable at that time or within 90 days thereafter pursuant to Subsection 2.2) the right to exercise the Option will expire at the end of the following periods:

After Termination On Account Of	Period
Death	1 year
Retirement	5 years
Disability	1 year
Any other reason	1 year

2.2 Effect of Termination on Vesting. The Option will continue vesting in accordance with Section 1.3 for 90 days following the date on which Participant ceases to serve on the Board for any reason and will then cease vesting. The Shares as to which the Option is exercisable will be those as to which the Option is vested at the time of exercise.

3. **Acceleration of Exercisability**. If a Change in Control Date occurs while Participant serves on the Board or if a Change in Control Date occurs within 90 days after Participant's termination of service on the Board, the Option will become immediately and fully vested and exercisable as to all Shares covered by the Option.

4. **Method of Exercise**.

4.1 **Exercise of Option**. All or any portion of the Option may be exercised, to the extent it has become exercisable pursuant to the Agreement, by delivery of written notice to the Company in the attached form stating the number of Shares, form of payment, and proposed date of closing.

4.2 **Other Documents**. Participant must furnish the Company, before closing of any exercise of the Option, such other documents or representations as the Company may require to assure compliance with applicable laws and regulations.

4.3 **Price and Payment**. The exercise price for the Shares purchased upon exercise of the Option shall be as set forth on the cover sheet and must be paid in full at or before closing by one or a combination of the following:

(a) Payment in cash;

(b) 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 the Company in payment of all or a part of the exercise 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 the Company in payment of all or a part of the exercise price and withholding taxes due; or

(c) Delivery of previously acquired Shares having a Fair Market Value at least equal to the exercise price.

4.4 **Previously Acquired Shares**. Delivery of previously acquired Shares surrendered in full or partial payment of the exercise price of all or any portion of the Option, will be subject to the following conditions:

(a) The Shares tendered must be in good delivery form;

(b) The Fair Market Value of the Shares, together with the amount of cash, if any, tendered must equal or exceed the exercise price of the Option;

(c) Any Shares remaining after satisfying payment of the exercise price will be reissued in the same manner as the Shares tendered; and

(d) No fractional Shares will be issued and cash will not be paid to Participant for any fractional Share value not used to satisfy payment of the exercise price.

5. **Transferability**.

5.1 **Restriction**. Except for Permitted Transfers, as defined in Section 5.2:

(a) The Option is not transferable by Participant other than by testamentary will or the laws of descent and distribution and, during Participant's lifetime, may be exercised only by Participant or Participant's guardian or legal representative;

(b) No assignment or transfer of the Option, whether voluntary, involuntary, or by operation of law or otherwise, except by testamentary will or the laws of descent and distribution, will vest in the assignee or transferee any interest or right; and

(c) Immediately upon any attempt to assign or transfer the Option, the Option will terminate and be of no force or effect.

5.2 **Permitted Transfers**. Participant may transfer all or any portion of the Option, without payment of consideration, to Participant's family members, trusts for such family members, or a partnership or limited liability company in which Participant and members of Participant's family own more than 50% of the voting interests.

5.3 **Exercise in the Event of Death or Disability**. Whenever the word "Participant" is used in any provision of the Agreement under circumstances when the provision should logically be construed to apply to Participant's guardian, legal representative, executor, administrator, or the person or persons to whom the Option may be transferred by testamentary will or by the laws of descent and distribution, the word "Participant" will be deemed to include such person or persons.

6. **Securities Laws**. The Company will not be required to issue any Shares upon exercise of the Option, or any portion thereof, until the Company has taken any action required to comply with the provisions of the Securities Act of 1933 or any other then applicable federal or state securities laws.

7. **Tax Reimbursement**. In the event any withholding or similar tax liability is imposed on the Company in connection with or with respect to the exercise of the Option or the disposition by Participant of the Shares acquired upon exercise of the Option, Participant will pay to the Company an amount sufficient to satisfy such tax liability.

8. **Conditions Precedent**. The Company will use its best efforts to obtain any required approvals of the Plan and the Option by any state or federal agency or authority that the Company determines has jurisdiction. If the Company determines that any required approval cannot be obtained, all Awards to Participant will terminate on notice to Participant to that effect.

9. **Successorship**. Subject to the restrictions on transferability of the Option set forth in the Agreement and in the Plan, the Agreement will be binding upon and benefit the parties, their successors, and assigns.

10. **Defined Terms**. When used in the Agreement, the following terms have the meanings specified below:

10.1 "**Acquiring Person**" means any person or related person or related persons which constitute a "group" for purposes of Section 13(d) and Rule 13d-5 under the Securities Exchange Act of 1934 (the "Exchange Act"), as such Section and Rule are in effect as of the date of the Agreement; provided, however, that the term Acquiring Person does not include:

(a) The Company or any of its Subsidiaries;

(b) Any employee benefit plan of the Company or any of its Subsidiaries;

(c) Any entity holding voting capital stock of the Company for or pursuant to the terms of any such employee benefit plan; or

(d) Any person or group solely because such person or group has voting power with respect to capital stock of the Company arising from a revocable proxy or consent given in response to a public proxy or consent solicitation made pursuant to the Exchange Act.

10.2 "**Agreement**" means the agreement evidencing an Option governed by these Award Terms.

10.3 "**Change in Control**" means:

(a) A change in control of the Company of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A as in effect on the date of the Agreement pursuant to the Exchange Act; provided that, without limitation, such a change in control will be deemed to have occurred at such time as any Acquiring Person hereafter becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 30 percent or more of the combined voting power of Voting Securities; or

(b) During any period of 12 consecutive calendar months, individuals who at the beginning of such period constitute the Board cease for

any reason to constitute at least a majority of the Board unless the election, or the nomination for election, by the Company's stockholders of each new director was approved by a vote of at least a majority of the directors then in office who were directors at the beginning of the period; or

(c) There is consummated (i) any consolidation or merger of the Company in which the Company is not the continuing or surviving corporation or pursuant to which Voting Securities would be converted into cash, securities, or other property, other than a merger of the Company in which the holders of Voting Securities immediately prior to the merger have the same, or substantially the same, proportionate ownership of common stock of the surviving corporation immediately after the merger, or (ii) any sale, lease, exchange, or other transfer (in one transaction or a series of related transactions) of all, or substantially all, of the assets of the Company; or

(d) Approval by the stockholders of the Company of any plan or proposal for the liquidation or dissolution of the Company.

10.4 "**Change in Control Date**" means the first date following the date of the Agreement on which a Change in Control has occurred.

10.5 "**Committee**" means the Compensation Committee of the Board or any successor thereto.

10.6 "**Grant Date**" means the date of the Agreement, which is the date the Option is granted to Participant.

10.7 "**Option**" means the Nonqualified Stock Option granted to Participant evidenced by the Agreement.

10.8 "**Voting Securities**" means the Company's issued and outstanding securities ordinarily having the right to vote at elections for the Company's Board.

10.9 Capitalized terms not otherwise defined in this Agreement have the meanings given them in the Plan.

11. **Notices**. Any notices regarding the Option must be in writing and will be effective when actually delivered personally or, if mailed, when deposited as certified mail directed to the address maintained in the Company's records or to such other address as a party may certify by notice to the other party.

Attachment: Exercise Form

ELECTION TO EXERCISE NONQUALIFIED STOCK OPTION

To: OraSure Technologies, Inc.
150 Webster Street
Bethlehem, PA 18015

The undersigned hereby exercises the NonQualified Stock Option _____ evidenced
(option number)
by the NonQualified Stock Option Award Agreement dated _____ (the "NonQualified
(date options were granted)
Agreement"), for _____ shares (the "Shares") of common stock of OraSure
(# of shares you wish to purchase)
Technologies, Inc. (the "Company") at the price of $_____ per share and agrees to tender payment
(option price)
therefor in the amount of $_____ (the "Exercise Price") **and required withholding taxes** in
(# of shares purchased X option price)
accordance with the terms of the NonQualified Stock Option Award Agreement for closing on
_____.
(approximately 10 days after exercise)

Mark the appropriate responses below:

1. Payment

☐ Payment in the amount of the Exercise Price and required withholding taxes is enclosed.

☐ Payment in the amount of the Exercise Price and required withholding taxes will be made to the Company within ten business days by _____ ("Broker"), to which I have given irrevocable instructions to sell enough of the Shares for such purpose and to deliver proceeds in the amount of the Exercise Price and withholding taxes to the Company. If the Broker does not make such payment within such time, I agree to pay the Exercise Price and withholding taxes to the Company within an additional five business days.

☐ Payment shall be made as described on the page attached hereto.

2. Delivery of Shares.

☐ The shares have been sold. Please deliver the stock certificate to, and made out in the name of the following:

_____
_____
_____
_____
_____
_____

(e.g., Broker, Address, Account Number)

☐ The Shares have not been sold. Please deliver the stock certificate to, and made out in the name of:

_____
_____
_____
_____
_____
_____

(e.g., your name)

DATED: _____ _____
(Printed Name)

_____
(Signature of Participant)

EXERCISE OF NONQUALIFIED STOCK OPTIONS

OraSure Technologies, Inc.
150 Webster Street
Bethlehem, PA 18015

For Federal Income Tax purposes, ORASURE TECHNOLOGIES, INC. is required to include on each Participant's year-end tax Form W-2 or 1099-MISC and on the Company's tax return, an amount equal to the difference between the fair market value of stock purchased upon exercise of a NonQualified Stock Option on the exercise date and the option exercise price (the "Option Spread").

If you sold any of these option shares ***on the same day that you exercised them***, please provide the following information and return a copy of this form to the Accounting department. This information will assist in the determination of the fair market value of the shares at the time of exercise to be used to calculate the Option Spread and proper withholding amounts.

Option Number _____ **Date** _____ **Sale price per share** _____

Option Number _____ **Date** _____ **Sale price per share** _____

Option Number _____ **Date** _____ **Sale price per share** _____

Option Number _____ **Date** _____ **Sale price per share** _____

_____ _____

Printed Name *Signature of Participant*

Exhibit 10.16

Description of OraSure Technologies, Inc.
Management Stock Award Guidelines

January 26, 2005

On January 26, 2005, the Compensation Committee (the "Committee") of the Board of Directors (the "Board") of OraSure Technologies, Inc. (the "Company") amended the Company's Stock Option Award Guidelines for the Company's management (the "Award Guidelines"). The purpose of the Award Guidelines was to establish a framework for granting stock awards in order to reward individual performance by the Company's management team against stated objectives. Employees covered by the Award Guidelines are at the director level and above, and include all Company officers.

The Award Guidelines were amended to provide for target stock awards containing a mix of restricted shares and stock awards. This amendment was approved by the Committee in response to the change in accounting rules that will require the expensing of stock awards for financial reporting purposes. The Committee also concluded that a mixed award would provide an appropriate long-term incentive for the Company's management.

Awards under the Award Guidelines, as amended, in any fiscal year will continue to 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 fiscal year in question:

	Award Targets (No. of Shares)	
	Restricted Shares	**Stock Options**
Chief Executive Officer	52,500	45,000
Executive Vice President	21,000	18,000
Senior Vice President	14,000	12,000
Vice President	8,750	7,500
Director	Up to 2,625	Up to 2,250

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 awards.

Performance objectives for individual employees will be derived from the Company's corporate objectives for the applicable fiscal 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. 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 at the end of the fiscal year in question and at the time of grant in order to receive a stock award, and awards may 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 Committee based on an assessment of each individual's performance against his or her applicable performance objectives. The Committee may approve or disapprove any recommended award in whole or in part in its sole discretion. The Committee will evaluate the performance of the Chief Executive Officer and recommend for Board approval an appropriate award in accordance with the Award Guidelines, as amended, and such evaluation.

Exhibit 23

Consent of Independent Registered Public Accounting Firm

The Board of Directors
OraSure Technologies, Inc.:

We consent to the incorporation by reference in the registration statements on Form S-8 (No. 333-118385, No. 333-102235, No. 333-50340 and No. 333-48662) and the registration statements on Form S-3 (No. 333-106786 and No. 333-73498) of OraSure Technologies, Inc. of our reports dated March 14, 2005, with respect to the balance sheets of OraSure Technologies, Inc. as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity and comprehensive loss and cash flows for each of the years in the three-year period ended December 31, 2004, management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2004 and the effectiveness of internal control over financial reporting as of December 31, 2004, which reports appear in the December 31, 2004 annual report on Form 10-K of OraSure Technologies, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 14, 2005

Exhibit 24

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Douglas A. Michels, 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, 2004, 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 28, 2005.

/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 **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, 2004, 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 28, 2005.

/s/ *Douglas A. Michels*
Signature

Douglas A. Michels
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Douglas A. Michels, 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, 2004, 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 28, 2005.

/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 **Douglas A. Michels, 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, 2004, 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 28, 2005.

/s/ *Ronny B. Lancaster*
Signature

Ronny B. Lancaster
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Douglas A. Michels, 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, 2004, 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, 2005.

/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 **Douglas A. Michels, 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, 2004, 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, 2005.

/s/ *Douglas G. Watson*
Signature

Douglas G. Watson
Print Name

Exhibit 31.1

Certification

I, Douglas A. Michels, 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 – 15(e) and 15d –15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a – 15(f) and 15d – 15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2005

/s/ DOUGLAS A. MICHELS
Douglas A. Michels
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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 – 15(e) and 15d –15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a – 15(f) and 15d – 15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors:
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2005

/s/ RONALD H. SPAIR
Ronald H. Spair
Executive Vice President and
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §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, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas A. Michels, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §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/ Douglas A. Michels

Douglas A. Michels
President and Chief Executive Officer

March 15, 2005

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §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, 2004 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. §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 15, 2005