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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

for the fiscal year ended December 31, 2003.

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, 2003)**:** $266,719,016

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of March 1, 2004: 44,260,931 shares.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement for the 2004 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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

PART I

ITEM 1. Business.

Our 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.

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 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®	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.	Finger-stick whole blood—Pre-market application ("PMA") approved by FDA in November 2002. CLIA (Clinical Laboratory Improvement Amendments of 1988) waived in January 2003.	Marketed
		Venipuncture whole blood—PMA supplement approved by FDA in September 2003.	Marketed
		HIV-2—PMA supplement initially filed with FDA in June 2003; resubmitted with additional data in December 2003.	Pending
		Oral fluid—PMA supplement filed with FDA in September 2003.	Pending
		Plasma—PMA supplement filed with FDA in September 2003.	Pending
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.	Marketed
		Also have FDA 510(k) clearance for use of this device in detecting cocaine and cotinine (an indicator of nicotine) in oral fluid.	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
Histofreezer®-OTC (Freeze Off™)	Sold under the Freeze Off™ and Compound W® tradenames in the over-the-counter market in the U.S. for the cryosurgical removal of common and plantar warts.	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.	Pending

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 venipuncture) 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 is the OraQuick® rapid HIV-1 antibody test, a rapid test for the presence of antibodies against HIV-1. On November 7, 2002, we received premarket approval of this test from the FDA for detecting HIV-1 in finger-stick whole blood samples. This FDA approval is based on data from clinical studies we performed using finger-stick whole blood specimens, which indicate 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 is 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.

On September 5, 2003, we received FDA approval for use of the OraQuick® test in detecting HIV-1 antibodies in venipuncture whole blood samples. We believe this claim will help us further penetrate the hospital market where venipuncture whole blood samples are routinely taken from patients.

We are seeking FDA approval for certain other claims for OraQuick®. We have completed the necessary clinical trials and filed for FDA approval for use of the OraQuick® device to detect antibodies to the Human Immunodeficiency Virus, Type 2 ("HIV-2"), a second type of the HIV virus. We have taken this action in anticipation of obtaining access to an HIV-2 patent license, either through an arrangement with a third party or directly with the holder of the HIV-2 patents. Although we believe the addition of an FDA-approved HIV-2 claim would enhance the versatility of our OraQuick® test and allow us to more fully implement a strategy to sell OraQuick® internationally, there is no assurance that we will receive FDA approval of an HIV-2 claim or be able to obtain access to an HIV-2 patent license.

We have also completed the required clinical trials and submitted an application for FDA approval of oral fluid and plasma claims in September 2003. Although there is no assurance that we will receive approval of these claims, we believe that an OraQuick® device approved for detecting antibodies to both HIV-1 and 2 in fingerstick and venipuncture whole blood, oral fluid and plasma samples, will provide a significant competitive advantage in the market for rapid HIV testing in the United States.

In April 2003, the Centers for Disease Control and Prevention ("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 and placed a second order for an additional 250,000 devices for delivery in 2004.

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-1 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-1 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 nylon handle that is placed in a person's mouth for two to five minutes. The device collects oral mucosal transudate ("OMT"), a serum-derived fluid that contains higher concentrations of certain antibodies and analytes than saliva. As a result, OMT testing is a highly accurate method for detecting HIV-1 infection and other analytes.

We believe that oral fluid testing has several significant advantages over blood or urine-based 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").

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 exclusively 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 the Histofreezer® product 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 an on-site, cost-effective test device that is an alternative to breath or blood alcohol testing. The test is a quantitative, saliva-based method for the detection of ethanol, and has been cleared for sale by the FDA and the U.S. Department of Transportation ("DOT"). In 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.

Products Under Development

UPT™ and UP*link*® *Development*

During 2003 and several prior years, much of our research and development efforts were focused on our Up-Converting Phosphor Technology ("UPT™") and the first UPT™ application expected to be commercialized, our UP*link*® rapid, point-of-care system for detecting drugs of abuse in oral fluid.

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

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

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

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

- Ability to multiplex or detect biological markers for several substances simultaneously through the use of phosphor particles having various colors;

- Applicability to a variety of instrument platforms; and
- Compatibility with alternative testing matrices such as oral fluid, blood or others.

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

Although we believe that UPT™ may have several potential applications for *in vitro* diagnostics, we have not yet completed development of UPT™ or fully explored these potential UPT™ applications. We also have not determined which applications to pursue or the manner in which these opportunities will be pursued, if at all. Additional research and development will be required to determine the full potential of the UPT™ label technology, including with respect to the potential limits on the level of detection of this technology. In addition, we believe we may need to enter into partnering arrangements with other entities and devote substantial funds and other resources to exploit fully the potential of UPT™.

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

In April 2002, we received FDA 510(k) clearance for the UP*link*® system to detect opiates in oral fluid. This is the only point-of-care oral fluid drug test system to receive FDA clearance. The UP*link*® analyzer has also been certified by Underwriters Laboratories, Inc. (i.e., UL approval) as meeting certain standards required for the sale of electrical and light-emitting equipment internationally. Although an opiates-only UP*link*® detection system has no commercial potential, we have developed an UP*link*® detection system for the full NIDA-5 panel of tests – cocaine, methamphetamines/amphetamines, PCP, opiates and marijuana – which we believe can be commercialized. In September 2003, we submitted an application for FDA 510(k) clearance of an UP*link*® system for the full NIDA-5 panel of tests. We plan initially to distribute this product through Dräger Safety AG & Co. KGaA (as discussed below) in the roadside testing market in Europe and other countries. Subject to receipt of FDA clearance and the completion of additional market research, we eventually intend to market this system directly in the workplace and criminal justice markets in the United States.

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

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. After completion of all research and development activities, Dräger has the option to become our exclusive distributor of this product in Europe and certain other countries to law enforcement officials for rapidly assessing whether an operator or passenger in a motor vehicle is under the influence of one or more drugs of abuse (the “roadside market”) and ultimately to certain military, criminal justice, and workplace testing markets. We received a non-refundable fee from Dräger under the agreement and will receive additional fees upon achievement of certain technical milestones. We expect Dräger to exercise its option and to commercially launch the UP*link*® system in the roadside market in Europe by April 2004.

In September 2000, we signed a research and development agreement with Meridian Bioscience, Inc. (“Meridian”), a medical diagnostics company. Under this agreement, we intended to develop a range of UP*link*®

point-of-care tests for the rapid detection of parasites, and gastrointestinal and upper respiratory diseases. Development of one test, for detection of the respiratory syncytial virus ("RSV"), has been substantially completed. However, due to development delays and certain other events, we terminated our agreement with Meridian in 2003.

We are participating in the second 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 and is expected to be approximately $350,000 in the second year, and if the grant is renewed by the NIH as we expect, approximately $350,000 to $400,000 each year thereafter. Payments under the grant are subject to availability of funding from the NIH and satisfactory progress of the research and development project.

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.

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. We also believe these devices may be useful for the collection of DNA in oral fluid.

Business Strategy

We have adopted a three-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 through the strategic acquisition of other technologies and products. We intend to follow a disciplined approach to maximize the value of our business for the benefit of our stockholders. Specifically, our business strategy includes the following key elements:

- We intend to maximize the sales potential of our existing product lines in the markets where they are currently sold. This would principally involve fully capitalizing 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 intend to expand the use of our existing products and technology platforms into new applications and new markets. For example, we believe that both the OraQuick® and OraSure® product technologies are very flexible and could be used potentially for the detection of diseases or conditions other than HIV. We also expect to explore other potential applications for both the UP*link*® and UPT™ technology platforms in the future, and to selectively expand the distribution of our established products into certain international markets.
- We will evaluate potential acquisitions that may provide new products and technology platforms to supplement our existing product pipeline.

Research and Development

In 2003, 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, DNA feasibility studies, clinical trials related to claims for venipuncture whole blood, HIV-2, oral fluid and plasma for our OraQuick® test, and improvements to certain of our existing products.

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

Research and development expenses totaled approximately $8.0 million in 2003, $8.3 million in 2002 and $9.4 million in 2001. 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 of our products through a mix of trade shows, print advertising, and distributor promotions to support sales in each target market.

We market our products in the United States and internationally. Revenues attributable to customers in the United States amounted to $35.9 million, $28.1 million and $27.3 million in 2003, 2002 and 2001, respectively. Revenues attributable to international customers amounted to $4.6 million, $3.9 million and $5.3 million, or 11%, 12% and 16% of our total revenues, in 2003, 2002 and 2001, 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 Laboratories. These laboratories in turn provide the devices to insurance companies, usually in combination with testing services.

We also maintain a direct sales force that promotes use of the OraSure® device directly to insurance companies 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 the OraQuick® rapid HIV-1 antibody test directly to customers in the public health market for HIV-1 testing. This market consists of a broad range of clinics and laboratories and includes states, counties, and other governmental agencies, The Centers for Disease Control and Prevention, 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. We intended to primarily target our direct sales to the public health and criminal justice markets, the military, the CDC and other agencies. Because Abbott failed to meet its minimum purchase commitments under the Agreement, we asserted that the agreement terminated in 2003. Abbott disputed our right to terminate, and this dispute was submitted to binding arbitration for resolution. The arbitrator found that the agreement did not terminate and will continue. In addition, consistent with the arbitrator's rulings we notified Abbott that its distribution rights were converted from co-exclusive to non-exclusive. For a further discussion of this dispute with Abbott Laboratories, see the Section of this Annual Report entitled, "Legal Proceedings."

We are in the process of recruiting and intend to deploy a small sales force that will provide direct access to and marketing support for the hospital market for our OraQuick® test and possibly other products. We also intend to seek one or more distributors to help penetrate the physicians' office market with our OraQuick® test.

Substance Abuse Testing

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

We have entered into agreements for the distribution of Intercept® collection 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, Clinical Reference Laboratory and NWT, Inc., and internationally for workplace and forensic toxicology testing through Bio-Rad Laboratories, Altrix HealthCare, plc, and other distributors. We assist our laboratory customers in customizing their testing services by selling them equipment required to test oral fluid specimens collected with the Intercept® device.

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

Cryosurgical Systems

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. We have also commenced sales of Freeze Off™, a product similar to Histofreezer®, in the over-the-counter market in the U.S. pursuant to a distribution agreement with MedTech Holdings, Inc., the owner of the Compound W® line of wart removal products.

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-1 antibody test accounted for total revenues of approximately $14.5 million, $10.8 million, $6.6 million and $6.3 million in 2003, $14.3 million, $7.2 million, $7.6 million and $400,000 in 2002, and $12.7 million, $6.7 million, $7.9 million and $0.7 million in 2001, respectively. As new products are developed and commercialized, we expect to reduce our dependence on these products.

We currently have two customers, Lab*One* and MedTech Holdings, Inc., that accounted for 17% and 12% of our total revenues, respectively, during 2003.

As of June 30, 2003, Lab*One* stopped purchasing our AUTO-LYTE® urine assays. As a result, our revenues in 2003 were reduced by approximately $1.2 million and are expected to be reduced by as much as $1.7 million in 2004, when compared to 2002 revenues in the insurance risk assessment market.

In the fourth quarter of 2003, Lab*One* acquired the Insurance Testing Laboratory of the Metropolitan Life Insurance Company ("Metlife"). Metlife had been a long time purchaser of our urine assays for life insurance risk assessment testing. In light of Lab*One's* decision to stop purchasing our AUTO-LYTE® urine assays, this acquisition is expected to result in further revenue loss for those products above the levels set forth above.

There can be no assurance that sales to Lab*One* will not decrease in an amount greater than our current expectations, or that this customer will not choose to replace our MICRO-PLATE oral fluid assays or other products with internally-developed products or products manufactured by our competitors. The loss of Lab*One* or a significant decrease in the volume of products purchased by it could have a material adverse effect on our results.

Supply and Manufacturing

We have entered into an agreement with a contractor in the United States for the assembly and supply of our OraSure® and Intercept® oral fluid collection devices. This agreement renews annually each calendar year unless either party provides timely notice of termination prior to the end of an annual period. A change in the manufacturer of the OraSure® device would require FDA review and approval, which could require significant time to complete and disrupt our ability to manufacture this product. We intend to terminate the agreement with this contractor and transfer manufacturing of both the OraSure® and Intercept® collection devices to our Bethlehem, Pennsylvania facility. The transfer of the OraSure® device requires 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 transfer. The transfer of our Intercept® device requires only that we notify the FDA of the transfer. We expect to complete the transfer of both products during the first half of 2004, which is expected to 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 facilities. In addition, we have entered into a supply agreement for the assembly of the OraQuick® device in Thailand, in order to supply certain international markets. This 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 strips required for the OraQuick® test only from a limited number of sources. The antigen is currently purchased from a single contract supplier under a long-term agreement with an initial term ending in January 2010 and one-year automatic renewal terms thereafter. The nitrocellulose used in the test is also provided by a single contract supplier, and we are presently negotiating a long-term supply agreement with this party. If for any reason these suppliers are no longer able to supply our antigen or nitrocellulose needs, we believe that alternative supplies could be obtained at a competitive cost. However, a change in the antigen or nitrocellulose would require FDA approval and some additional development work. 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 Beaverton, Oregon facility. In December 2003, the FDA approved the transfer of manufacturing of this product to our Bethlehem, Pennsylvania facility. This transfer is now complete, and we are currently ramping up manufacturing of this product in Pennsylvania.

The HIV antigen needed to manufacture the Western Blot test is available from only a limited number of sources. For many years, we have purchased the antigen for this product from BMX on an exclusive basis. BMX is also the exclusive distributor of the Western Blot test kits.

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

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

Employees

As of December 31, 2003, we had 171 full-time employees, including 45 in sales, marketing, and client services; 48 in research and development; 51 in operations, manufacturing, quality control, quality assurance, regulatory affairs, clinical trials, information systems, purchasing and shipping; and 27 in administration and finance. This compares to 187 employees as of December 31, 2002. As of December 31, 2003, 15 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 HIV-1 antibody test, such as the Ortho Diagnostics division of Johnson & Johnson and Bio-Rad Laboratories, sell laboratory-based HIV-1 EIAs, and Calypte, Inc. sells an HIV-1 screening test for urine, in the United States. Abbott Laboratories sold 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. Under our OraQuick® distribution agreement with Abbott, we compete with Abbott in selling our OraQuick® test in many markets. In addition, MedMira and Trinity Biotech each recently received FDA approval to sell competing rapid HIV-1 blood tests in the United States, and we believe these tests, under their current FDA approvals, will compete with our OraQuick® test in the hospital or other laboratory settings. We believe other companies may 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 thiazide 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 in order, we believe, to use internally-developed assays. As a result, revenues from these products were substantially lower in 2003, and we expect revenues from these products to continue to decrease and eventually be eliminated. Our MICRO-PLATE assays may also face competition from lower cost "home brew" oral fluid assays.

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® collection device, are expected to come under increasing competitive pressure from "home-brew" assays developed internally by our laboratory customers.

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 is expected to begin selling a competing cryosurgical wart removal product in 2004.

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

We have one patent for lateral flow diagnostic tests that covers our OraQuick® rapid HIV antibody test 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® test. We obtained these licenses through the payment of certain upfront fees and ongoing royalties. We believe these royalties are comparable to rates generally paid by other companies under similar arrangements.

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

In April 1995, we received exclusive worldwide rights under patents and know-how owned by SRI International to develop and market products that involve the use of UPT™. We also received non-exclusive worldwide rights under patents and know-how owned by the Sarnoff Corporation (a subsidiary of SRI International formerly called the David Sarnoff Research Center) to develop and market products that involve the use of UPT™. We have the right to sublicense these rights, subject to consent from SRI and Sarnoff.

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

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

We have 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 expect to continue to expand our UPT™ patent portfolio in 2004.

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®, Histofreezer®, Q.E.D.® and AUTO-LYTE® trademarks. We also own many of these marks and others in several foreign countries.

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

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

Government Regulation

General

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

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

Domestic Regulation

Most of our diagnostic products are regulated in the United States as medical devices.

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

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA's regulations to have an approved application), the FDA must approve a premarket 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.

In 2002, Congress enacted the Medical Device User Fee and Modernization Act, which authorizes the FDA to assess and collect user fees for premarket notifications and premarket approval applications filed on or after October 1, 2002. Fees for fiscal year 2004 range from $3,480 for 510(k) premarket notifications to $206,811 for PMA's, although fee reductions are available for companies qualifying as small businesses. We do not currently qualify as a small business.

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

Every company that manufactures medical devices distributed in the United States must comply with the FDA's Quality System Regulations ("QSRs"). These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation and purchasing. In complying with QSRs, manufacturers must continue to expend time, money, and effort in the area of production and quality 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 *in vitro* tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings, unless there is in effect for such laboratories a certificate issued by the U.S. Department of Health and Human Services applicable to the category of examination or procedure performed. We consider the applicability of the requirements of CLIA in the design and development of our products. We have obtained a waiver of the CLIA requirements for our OraQuick® rapid HIV-1 antibody test and Q.E.D.® alcohol saliva test and may seek similar waivers for certain other products. A CLIA waiver allows certain customers to use the waived products that may not have been able to use them without complying with certain quality control and other requirements.

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

International

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

The International Organization for Standardization (“ISO”) is a worldwide federation of national standards bodies from some 130 countries, established in 1947. The mission of 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 (98/79/EC) (“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 Beaverton facility. 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 must comply with the essential requirements of the IVDD in order to receive authorization to affix a CE mark to our 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.

Environmental Regulation

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

Forward-Looking Statements

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

Forward-looking statements are not guarantees of future performance or results. Known and unknown factors could cause actual performance or results to be materially different from those expressed or implied in these statements. Some of these factors are: ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to maintain new or existing product distribution channels (including our ability to implement a direct sales effort or alternate distribution method for OraQuick® in the hospital market); reliance on sole supply sources for critical product components; availability of related products produced by third parties; ability to obtain and timing of obtaining necessary regulatory approvals; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks, war and civil unrest; ability to complete consolidation or

restructuring activities; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in the Section entitled, “Risk Factors,” and elsewhere in this Report.

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

Risk Factors

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

Regulatory Risks

The Time Needed 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, we are seeking FDA approval for the use of the OraQuick® test for detecting antibodies to HIV-2 and for testing oral fluid and plasma samples. Approval of these claims required the submission of clinical data and could require significant time to obtain. The submission of an application to the FDA or other regulatory authority for these or other claims does not guarantee that an approval or clearance to market the product will be received. Each authority may impose its own requirements and delay or refuse to grant approval or clearance, even though a product has been approved in another country 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, the Substance Abuse and Mental Health Services Administration (“SAMHSA”), which is part of the U.S. Department of Health and Human Services, is expected to issue regulations for the use of oral fluid drug testing for federal workers. Although we believe the SAMHSA regulations, when issued in final form, will permit us to market and sell our oral fluid drug tests for use with federal workers, there is no guarantee that those regulations will do so, and our ability to sell those products in that market could be limited. 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 ("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 Which Could Result in a Loss of Revenues.

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

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 Regulations," 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 $1.1 million, $3.3 million, and $3.7 million, in 2003, 2002 and 2001, respectively. As of December 31, 2003, the Company had an accumulated deficit of approximately $130.6 million.

Our limited combined operating history makes it difficult to forecast our future operating results. In order to achieve sustainable profitability, our revenues will have to continue to grow at a significant rate. Our ability to achieve revenue growth, and therefore profitability, will be dependent upon a number of factors including, without limitation, the following:

- Creating market acceptance for and selling increasing volumes of the OraSure® collection device, the Intercept® and UP*link*® drug testing products, and the OraQuick® rapid HIV-1 antibody test;
- The degree to which certain of our new products 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® rapid HIV-1 antibody test and other products; and
- Commercially developing, and obtaining regulatory approval and creating market acceptance for UPT™, the UP*link*® drugs-of-abuse rapid detection system, and other new products in a time frame consistent with our objectives.

We have not yet fully achieved 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 scope and results of clinical testing;
- The magnitude of capital expenditures;
- Changes in existing and potential relationships with business partners;
- The time and cost of obtaining regulatory approvals;
- The costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses;
- The costs and timing of expansion of sales and marketing activities;
- The timing of the commercial launch of new products;
- The extent to which existing and new products gain market acceptance;
- Competing technological and market developments; and
- The scope and timing of strategic acquisitions.

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

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 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 public concern as to the safety of products that we or others have developed;
- The relatively low trading volume for our common stock;
- Period to period fluctuations in our operating results;
- Changes in estimates of our performance by securities analysts;
- General market and economic conditions; and
- Terrorist attacks, civil unrest and war.

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 ("FASB"), 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.

For example, while current accounting rules allow us to exclude the expense of stock options granted to our employees from our financial statements, influential legislators and business policy groups have suggested that the rules be changed to require those options to be expensed. We rely on stock options as an important component of our employee compensation packages.

If we are required to expense stock options, we may be less likely to achieve profitability, or we may have to decrease or eliminate option grants. Decreasing or eliminating option grants may adversely impact our ability to attract and retain qualified employees.

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. Our principal competitors often have considerably greater financial, technical and marketing resources. As new products enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold than ours. If we fail to maintain and enhance our competitive position, our customers may decide to use products developed by competitors which could result in a loss of revenues.

We also face competition from products which may be sold at a lower price. To the extent customers desire to purchase these lower cost products sold by other parties, our revenues could be lower. Additionally, under our OraQuick® distribution agreement with Abbott Laboratories, we compete against Abbott in selling our OraQuick® test in many markets. To the extent Abbott sells the OraQuick® test below the price that we offer, customers may choose to buy this product from Abbott or we may be forced to sell the OraQuick® test at a lower price, both of which could result in a loss of revenues and a lower gross margin contribution from the sale of our OraQuick® test.

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 2003, 2002 and 2001, we incurred $8.0 million, $8.3 million and $9.4 million, respectively, in research and development expenses. We expect to continue to incur significant costs from our research and development activities.

A primary focus of our efforts has been, and is expected to continue to be, our UPT™ technology and the related UP*link*® rapid detection system, which are still under development. However, there can be no assurance that we will succeed in our research and development efforts with respect to UPT™, UP*link*® or other technologies or products.

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 our Histofreezer® portable cryosurgical system 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 2001 we began a restructuring of our manufacturing operations which included the transfer of OraQuick® manufacturing from our Beaverton, Oregon facility to Bethlehem, Pennsylvania. In addition, we plan to close our Oregon facility and transfer all remaining manufacturing operations in that facility to our facilities in Pennsylvania. We must obtain FDA approval to transfer certain operations to another location. This 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 not being able to successfully assimilate differences in foreign business practices or overcome language 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.

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 recently consolidated, and such consolidation has had, and may continue to have, an adverse impact on the level of orders for our products. One of these laboratories, Lab*One*, Inc., acquired another large insurance laboratory customer, Osborne Group, Inc., in 2001. These customers together accounted for approximately 17%, 26% and 29% of our revenues for the years 2003, 2002 and 2001, respectively. As a result of efficiencies gained following this acquisition, Lab*One* purchased approximately $1 million less of our insurance assays in 2002 than both companies purchased in 2001.

In addition, some distributors have experienced, and may continue to experience, pressure from their customers to reduce the price of their products and testing services. For example, Lab*One* and our other insurance testing laboratories are facing this pressure and are using lower cost “home brew” insurance testing assays that they have developed internally or purchased from our competitors. As a result, Lab*One* stopped purchasing our urine assays on June 30, 2003. This has reduced our sales of urine assays and is expected to lower sales of these products in 2004 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. Given Lab*One*’s recent decision to stop purchasing these products, this acquisition is expected to further reduce sales of our urine assays.

More recently, Lab*One* has announced that it has agreed to acquire the assets of the drug testing division of NWT, Inc., with an expected closing of that acquisition in March 2004. NWT is a laboratory that distributes the Company’s Intercept® drug test into the workplace testing market. Although it is unclear what, if any, impact this consolidation may have, it is possible that revenues from Intercept® sales could be reduced.

Finally, some of our distributors may not perform their contractual obligations. For example, during 2003 Abbott Laboratories did not meet its minimum purchase obligations under a co-exclusive distribution agreement for our OraQuick® test. We asserted the agreement had terminated as a result of this failure, and an arbitrator recently ruled that the agreement did not terminate and our remedy was limited to converting Abbott’s distribution rights from co-exclusive to non-exclusive. Consequently, and although we have notified Abbott regarding the conversion of its rights to non-exclusive, Abbott was not required to compensate us for the shortfall in its purchases.

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. These events could either disrupt our ability to manufacture and sell certain of our products or completely prevent us from doing so. Either event would have a material adverse effect on our results of operations, cash flows and business.

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

In testing an oral fluid sample collected with an OraSure® device for HIV-1 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 $12.2 million and $12.7 million, or 30% and 40% of our total revenues, in 2003 and 2002, 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. In particular, our strategy for development and commercialization of UPT™, including the UP*link*® rapid detection system, and certain other products may entail entering into additional arrangements with distributors or other corporate partners, universities, research laboratories, licensees and others. We may be required to transfer material rights to such strategic partners, licensees and others. While we expect that our current and future partners, licensees and others have and will have an economic motivation to succeed in performing their contractual responsibilities, 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.

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

There are several factors that will affect the specific countries in which we will be able to sell our OraQuick® rapid HIV antibody test and therefore the overall sales potential of the test. One factor is whether we can arrange a sublicense or distribution agreement related to patents for detection of the HIV-2 virus. HIV-2 is a type of the HIV virus estimated to represent a small fraction of the known HIV cases worldwide. Nevertheless, HIV-2 is considered to be an important component in the testing regimen for HIV in many markets. HIV-2 patents are in force in the United States, Canada and Mexico, in most of the countries of Western Europe, and in Japan, Korea, South Africa, and Australia. Access to a license for one or more HIV-2 patents may be necessary to sell HIV-2 tests in countries where such patents are in force, or to manufacture in countries where such patents are in force and then sell into non-patent markets.

The importance of HIV-2 differs by country, and can be affected by both regulatory requirements and by competitive pressures. Because the competitive situation in each country will be affected by the availability of other testing products as well as the country’s regulatory environment, we may be at a competitive disadvantage

in some markets without an HIV-2 product. In particular, our ability to sell a product that does not include an HIV-2 test may be limited, or a competitor's product that includes an HIV-2 test may be preferred and have a competitive advantage over an HIV-1 only test that we sell.

We have approached Bio-Rad Laboratories, the holder of patents concerning the HIV-2 virus, about securing a world-wide non-exclusive license for HIV-2 and have completed negotiation of a license agreement that we believe is complete and satisfactory to both parties. Bio-Rad is now in the process of securing the necessary signatures and approval from several other licensees and other relevant parties.

Another factor that may affect the specific countries in which we will be able to sell an OraQuick® rapid HIV-1 or HIV-2 test, and therefore the overall sales potential, concerns whether we can arrange a sublicense or distribution agreement related to any patents which claim lateral flow assay methods and devices covering the OraQuick® rapid HIV antibody tests or their use. OraQuick® is a lateral flow assay device that tests for specific antibodies or other substances. The term "lateral flow" generally refers to a test strip through which a sample flows and which provides a test result on a portion of the strip downstream from where the sample is applied. There are numerous patents in the United States and other countries which claim lateral flow assay methods and devices. Some of these patents may broadly cover the technology used in the OraQuick® test and are in force in the United States and other countries. We may not be able to make 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.

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

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

We have licensed the worldwide rights to UPT™ compositions, methods and apparatuses for use in diagnostic applications, which are the subject of numerous United States patents and several pending United States applications. Corresponding patents and patent applications have been granted, issued or filed in numerous foreign countries, including, for example, European countries, Japan and Canada. We cooperate with the licensor to prosecute such patent applications and protect such patent rights. If the licensors do not meet their obligations under the license agreements or do not reasonably consent to sublicenses by us, or if the license agreement is terminated, we could lose the opportunity to develop UPT™.

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® rapid HIV-1 antibody test, the UP*link*® oral fluid drugs of abuse rapid detection system, 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 in the Market Does Not Continue, Our Future Results May Suffer.

We have made significant progress in gaining acceptance of oral fluid testing for HIV in the insurance and public health markets. We have also made significant progress in gaining acceptance of oral fluid testing for drugs of abuse in the workplace and criminal justice testing markets. 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 $4.6 million or 11% of total revenues for 2003, approximately $3.9 million or 12% of total revenues for 2002, and approximately $5.3 million or 16% of total revenues for 2001.

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 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.

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

ITEM 2. Properties.

In October 2002, we leased an approximate 48,000 square foot facility, which is our new primary corporate office and manufacturing facility, on property in Bethlehem, Pennsylvania. The lease has a ten-year initial term ending in October 2012 and base rental rate starting at 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 own a 33,500 square foot building in Bethlehem, Pennsylvania, which is used for manufacturing, engineering and information systems activities.

We lease approximately 30,500 square feet of office, manufacturing, and laboratory space in Beaverton, Oregon, under a lease that expires in January, 2005. We have annual base lease obligations under the lease starting at $351,000 and increasing to $395,000 during the term of the lease. We expect to consolidate the manufacturing operations that remain in Oregon with our Bethlehem operations in 2004 and do not expect to renew the lease for our Oregon facilities.

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.

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 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 that our remedy is limited to revoking Abbott's status as a co-exclusive distributor. We have notified Abbott that, based on the magnitude of its purchases, we have decided to convert Abbott's distribution rights to non-exclusive. As a further result of the arbitrator's rulings, we will be required to fulfill Abbott's purchase orders at the agreed upon price contained in the original agreement.

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, 2003.

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,			
	2003		2002	
	High	Low	High	Low
First Quarter	$ 8.620	$5.050	$12.280	$4.750
Second Quarter	8.290	5.470	8.350	5.500
Third Quarter	10.920	7.363	6.820	3.330
Fourth Quarter	10.300	7.550	8.150	3.700

On March 1, 2004, there were 598 holders of record and approximately 13,000 holders in street name of the Common Stock, and the closing price of the Common Stock was $8.75 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. On September 29, 2000, STC and Epitope were merged into the Company (the "Merger"). The Merger was accounted for as a pooling of interests and, accordingly, all prior period financial statements of Epitope have been restated to include the results of operations, financial position and cash flows of STC. The selected financial data as of September 30, 1999 and for the year then ended, includes Epitope's previous September 30 fiscal year amount and STC's December 31 calendar year amount. On September 20, 2000, the Company changed its fiscal year-end from September 30 to December 31, effective with the calendar year beginning January 1, 2000. A three-month transition period from October 1, 1999 through December 31, 1999 (the "Transition Period") precedes the start of the 2000 fiscal year. As a result of the Merger, financial statements for the Transition Period include amounts for Epitope and STC for the three months ended December 31, 1999. Accordingly, STC's results of operations for the three months ended December 31, 1999 are included in both the financial statements for the year ended September 30, 1999 and for the Transition Period.

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

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

	Year ended December 31,				Three months ended December 31,		Year ended September 30,
	2003	2002	2001	2000	1999	1998	1999
Operating Results:						(Unaudited)	
Revenues	$ 40,451	$ 32,010	$ 32,573	$ 28,788	$ 6,822	$ 5,138	$ 24,046
Costs and expenses	41,737	35,550	36,906	42,917	7,105	5,857	28,138
Other income (expense), net	177	198	634	1,407	(138)	(159)	(91)
Net loss	(1,136)	(3,342)	(3,728)	(12,747)	(471)	(878)	(4,233)
Basic and diluted net loss per share	$ (0.03)	$ (0.09)	$ (0.10)	$ (0.36)	$ (0.02)	$ (0.03)	$ (0.14)
Weighted average number of shares outstanding	39,794	37,583	36,868	35,002	30,887	26,246	30,597

	December 31,						September 30,
	2003	2002	2001	2000	1999	1998	1999
Financial position:							
Working capital	$ 67,171	$ 18,931	$ 19,764	$ 21,440	$ 16,314	$ 8,255	$ 16,773
Total assets	86,151	35,737	37,285	37,736	29,626	20,075	30,251
Long-term debt, excluding current portion	2,456	3,409	3,586	4,644	5,820	6,001	5,820
Accumulated deficit	(130,570)	(129,435)	(126,092)	(122,365)	(109,618)	(105,603)	(109,104)
Stockholders' equity	73,509	26,019	26,541	26,172	18,238	10,264	18,592

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

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

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

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 a medical device 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-1 antibody test and UP*link*® oral fluid rapid drug detection system are designed for use at the point-of-care. Our cryosurgical product, which is sold under the names Histofreezer® and Freeze Off™, is 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 2003. Our total revenues were $40.5 million, or an increase of 26% over 2002, and our net loss for the year was $1.1 million, representing an improvement of more than $2.2 million over 2002. Additionally, both the third and fourth quarters of 2003 were profitable. Our liquidity also improved, as we reported $2.7 million in cash flow from operations in 2003 and we had $64.0 million in cash, cash equivalents and short-term investments as of December 31, 2003.

Sales into the infectious disease testing market segment increased significantly in 2003 due to the 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.

In 2003, the CDC placed purchase orders totaling $4 million for 500,000 OraQuick® devices, with equal amounts to be shipped in 2003 and 2004. We expect that the CDC, and perhaps other federal governmental agencies, will make future bulk purchases of OraQuick® devices for further distribution to the public health and other markets throughout the United States.

In October 2003, we announced the termination of our agreement with Abbott for distribution of OraQuick®. Abbott disputed our termination, and this dispute was recently resolved by an arbitrator who ruled that the agreement was not terminated and will continue in effect. In addition, consistent with the arbitrator's rulings we recently notified Abbott that the agreement was converted from co-exclusive to non-exclusive.

We also announced our intent to establish an internal sales force for selling OraQuick® directly into the hospital market. We have made progress in establishing this sales force with the recent hiring of a new Director, Hospital Sales to lead it. The success of this effort will impact the future sales of OraQuick®. We also intend to address the market potential of physicians' offices by engaging one or more distribution partners, as we believe it would be impractical to build and sustain an internal sales force large enough to adequately service that market. We believe that the combined efforts of our Company, Abbott and our other distribution partners will help us gain significant market penetration with OraQuick® in the hospital, physicians' office and other markets for rapid HIV testing.

During 2003, two competitors received U.S. Food and Drug Administration ("FDA") approval for rapid HIV tests. Based on their current FDA approvals, we expect that these tests will be sold, and will compete with our OraQuick® test, primarily in the hospital market in the United States. We are still waiting for FDA action on three pending PMA submissions for OraQuick®. If we receive these approvals, as we expect, the additional claims will allow OraQuick® to be used for detecting antibodies to both HIV-1 and HIV-2 and for testing oral fluid and plasma, in addition to finger-stick and venipuncture whole blood samples. We believe these approvals will give us the most versatile rapid HIV test in the world and provide a significant advantage over our competitors.

Sales to the substance abuse testing market also increased in 2003, reflecting the growing acceptance of our Intercept® collection device and related oral fluid drug assays, as companies and criminal justice customers are increasingly shifting to oral fluid and away from traditional urine-based drug testing. We expect continuing growth in the utilization of our Intercept® product line, primarily in the United States and United Kingdom.

We also expect to launch our UP*link*® oral fluid rapid drugs of abuse detection system in Germany and other European countries with our partner, Dräger, beginning in April 2004. An application for 510(k) clearance of this system is currently pending with the FDA. Assuming this clearance is received, and subject to completion of additional market research, we also intend to market the UP*link*® system to the workplace and criminal justice markets in the United States beginning in 2005.

Sales to the cryosurgical systems market grew substantially in 2003, largely because we entered the consumer or over-the-counter ("OTC") market for the first time. The cryosurgical systems market represents sales of Histofreezer® into both the domestic and international physicians' office markets and sales of the OTC formulation of this product, called Freeze Off™, to our partner, MedTech Holdings, Inc. ("MedTech"). MedTech distributes Freeze Off™ to consumers under its Compound W® trademark.

Sales to MedTech accounted for all of the growth in this market during 2003 and more than offset a decline of Histofreezer® revenues in the U.S. professional market. While we are pleased with the level of Freeze Off™ sales and hope that they continue at the same or higher levels, these sales were largely initial stocking orders and may not be indicative of the ongoing sales levels we can expect for this channel. We believe that sales of Histofreezer® in the U.S. professional market in 2004 should return to levels seen in 2002.

We experienced a significant decline in sales to the insurance risk assessment market during 2003, primarily as a result of the loss of urine assay sales to our largest customer, Lab*One*. These products 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 and we may continue to experience declines in this market until we are successful in developing new oral fluid based diagnostic tests for additional predictive health markers desired by the insurance industry.

We currently are in the process of transferring 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. While this transfer has gone well to date, we are still waiting for FDA approval for the transfer of our OraSure® device. Any disruption of this transfer could adversely affect our ability to sell these products.

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® test 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.

Finally, we generated approximately 89% of our 2003 revenues in the U.S. marketplace. Consequently, we are evaluating strategies to increase our sales penetration in markets outside the U.S.

Results of Operations

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. 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 reduced, and are expected to continue to reduce, their purchases of these products and instead use lower cost, internally-developed (i.e., "home-brew") assays or testing products purchased from our competitors. For example, as of June 30, 2003, Lab*One*, Inc., our largest customer, stopped purchasing our urine assays. Our revenues have been negatively impacted by the loss of this business in 2003 and will likely suffer a further decline of approximately $0.5 million in 2004, when compared to 2003 revenues in the insurance risk assessment

market. Overall, we expect revenues from this market in 2004 to be equal to or less than the level of revenues generated in 2003.

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.

In June 2002, Abbott 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. Because Abbott's purchases were below these levels, we declared the agreement terminated. However, Abbott disputed the termination, and this dispute was recently resolved through binding arbitration, which held that the agreement was not terminated and will continue in effect. In addition, consistent with the arbitrator's rulings, we recently notified Abbott that our agreement was converted from co-exclusive to non-exclusive. As a result of the arbitration, we will be required to fulfill Abbott's purchase orders at the agreed upon price contained in the original agreement. During the quarter ending March 31, 2004, we expect to incur legal fees and expenses of approximately $110,000 associated with this arbitration.

In order to improve penetration of the hospital market, we have decided to expand our internal sales force so that we can sell directly to hospitals, which was a primary market targeted by Abbott. We believe that expanding our direct sales efforts will provide us with greater control over distribution, a higher margin contribution from this product and a channel for distributing other high value-added products to these customers, and allow us to provide marketing support for hospital customers.

We currently intend to establish a small, but highly effective sales force focusing on the top metropolitan areas in the country, possibly supplemented with selective telemarketing and outside sales forces, and we may develop, purchase or license additional products to be sold by this sales force to hospitals in the future. We may also engage one or more distributors to help us penetrate the physicians' office market, which is another market targeted by Abbott.

Abbott purchased approximately 400,000 OraQuick® devices in 2003, representing approximately 40% of the total OraQuick® sales in that year. We expect Abbott to purchase substantially more devices in 2004, largely because the OraQuick® test is now approved by the FDA for use with venipuncture whole blood samples (as discussed below). In addition, we believe that our direct sales efforts, combined with the efforts of Abbott and other distribution partners, will help us gain significant market penetration in the hospital, physicians' office and other markets for rapid HIV testing.

As previously announced, we have 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 CDC's first purchase order, we sold 250,000 devices to the CDC in 2003. The second purchase order for an additional $2.0 million, which was received in late 2003, requires us to supply the remaining 250,000 devices to the CDC by no later than September 1, 2004.

Although sales of our OraQuick® test 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® test. 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® test, if it occurs at all.

In September 2003, we received approval from the FDA for use of the OraQuick® device to detect HIV-1 antibodies in venipuncture whole blood samples. The device had previously received FDA approval for use with finger-stick whole blood samples, and has received a waiver under CLIA (Clinical Laboratory Improvement

Amendments of 1988). We believe the venipuncture whole blood claim will assist us in penetrating the hospital market with our OraQuick® device.

We have also filed for FDA approval for use of the OraQuick® device to detect antibodies to HIV-2. We have taken this action in anticipation of obtaining access to an HIV-2 patent license, either directly with Bio-Rad Laboratories ("Bio-Rad"), the holder of the HIV-2 patents, or through a distribution arrangement with a third party. During September 2003, we also completed the remaining clinical trials and filed an application with the FDA for approval of the OraQuick® device for use with both oral fluid and plasma samples.

We believe that an OraQuick® device which is approved for detecting antibodies to both HIV-1 and 2 on multiple sample types would enhance the versatility of our OraQuick® test, provide a significant competitive advantage, and allow us to more fully implement a strategy to sell OraQuick® internationally. However, there is no assurance that we will receive FDA approval of an HIV-2 claim or claims for oral fluid and plasma.

We have approached Bio-Rad about securing a world-wide non-exclusive license for HIV-2 and have completed negotiation of a license agreement that we believe is complete and satisfactory to both parties. Bio-Rad is now in the process of securing the necessary signatures and approval from several other licensees and other relevant parties.

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, which 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 $1,150,000 over the comparable period in 2002. We expect continued growth in Intercept® sales in 2004 as customers shift from urine-based to oral-fluid based testing methods.

In September 2003, we filed an application with the FDA for 510(k) clearance of our UP*link*® rapid point-of-care 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. We do not expect to generate revenues from the sale of this product until mid-2004, when our partner, Dräger Safety, is expected to begin distributing this product primarily in the roadside testing market in Europe.

Sales of our products in the cryosurgical systems market (which includes 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 Holdings, Inc. ("MedTech"), the owner of the Compound W® line of wart removal products, offset by lower sales of Histofreezer® in the professional markets in both the U.S. and international markets. We entered into an agreement with MedTech following receipt of FDA 510(k) clearance in February 2003 for the sale of Histofreezer® in the OTC market in the U.S.

The product, which was launched by MedTech in the third quarter of 2003, is called Freeze Off™ and is being sold under MedTech's Compound W® trademark. The 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 $5.0 million during the first half of 2004.

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. We anticipate that U.S. sales of Histofreezer® in the professional market will decrease further in the first quarter of 2004 compared to the fourth quarter of 2003, as a result of a

preannounced price increase which became effective in December 2003. This type of price increase normally causes distributors to purchase additional product in advance of the increase. We are investing in promotional programs to raise the brand awareness of Histofreezer® in the U.S. marketplace and expect our 2004 full-year revenues to increase over 2003 and approximate the revenue levels generated in 2002 as a result of a focused sales and marketing effort. Sales in the international market are expected to remain at approximately the 2003 levels until we are able to secure additional distributors in countries where the product is currently not sold.

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.

Lab*One*, our largest customer, accounted for approximately 19% 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 current phase of this grant expires in June 2004 and we expect to receive approximately $350,000 in additional revenues through that date. Further revenues beyond June 2004 will depend on progress achieved in the research and future funding 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 resulting in lower scrap and spoilage and better absorption of overhead. Offsetting these 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. Research and development costs are expected to decrease as a result of lower clinical trial and product transfer costs in 2004.

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, compensation expense, 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. We expect sales and marketing expenses to increase significantly during 2004 as a result of our recruitment and deployment of a sales force focused on selling our OraQuick® test in the hospital market. Sales and marketing expenses are also expected to increase as we attempt to increase market awareness 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 first four 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 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. General and administrative expenses are expected to increase in 2004 as a result

of the additional costs to comply with the requirements of the Sarbanes-Oxley Act of 2002 and higher professional fees.

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.

Twelve Months Ended December 31, 2002 Compared to December 31, 2001

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

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

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

Sales to the insurance risk assessment market increased by 3% to approximately $12.0 million in 2002 from approximately $11.7 million in 2001, as a result of increased sales of our OraSure® laboratory-based HIV-1 test, partially offset by lower sales of our urine assays and reagents. Sales of our urine assays and reagents faced increased competition as the laboratories that purchase these products were facing pressure from their insurance customers to reduce the cost of testing services. As a result, these laboratories reduced their purchases of our products and instead used lower cost internally developed assays or reagents (i.e., home-brews) or testing products purchased from our competitors.

Sales to the infectious disease testing market increased 5% to approximately $6.1 million in 2002 from approximately $5.8 million in 2001, as a result of a $0.6 million increase in sales of our OraSure® laboratory-based HIV-1 test into the public health market, offset by a $324,000 decrease in international sales of the OraQuick® rapid HIV antibody test. In June 2002, we entered into an agreement with Abbott Laboratories for the co-exclusive distribution of the OraQuick® test in the United States. We received FDA approval of the OraQuick® test for detecting HIV-1 in finger-stick whole blood samples in November 2002 and received a CLIA waiver for this product in January 2003. We shipped an initial order for approximately $218,000 of OraQuick®

devices to Abbott in the fourth quarter of 2002, representing our first domestic sale of this product following FDA approval.

Sales to the substance abuse testing market decreased 7% to approximately $6.4 million in 2002 from approximately $7.0 million in 2001, primarily as a result of a decrease of approximately $500,000 in sales of laboratory equipment manufactured by third party vendors and the absence of approximately $500,000 in sales of UP*link*® analyzers, which occurred in 2001, coupled with a $50,000 decrease in sales of domestic substance abuse products. Offsetting this aggregate decrease was an approximate $500,000 increase in international sales of our Intercept® collection device and related assays.

Sales to the cryosurgical systems market, which consisted solely of our Histofreezer® wart removal system to physicians' offices, increased 7% to approximately $7.2 million in 2002 from approximately $6.7 million in 2001, as a result of increased product sales in the United States partially offset by lower international sales. The increase in domestic sales of Histofreezer® was partially attributable to distributors increasing their inventory levels in the fourth quarter of 2002 as a result of an announced price increase in the U.S. market, which became effective in December 2002.

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

Lab*One*, our largest customer, and Osborne Group, which was acquired by Lab*One* in 2001, together accounted for approximately 26% and 29% of total revenues in 2002 and 2001, respectively.

Licensing and product development revenues decreased 78% to approximately $318,000 in 2002 from approximately $1.5 million in 2001, reflecting a significant drop in funded research and development. During 2001, licensing and product development revenues were primarily derived from the continued development of the UP*link*® drugs-of-abuse rapid detection system under our agreement with Dräger, development of infectious disease applications for UP*link*® under our agreement with Meridian Bioscience, and the second phase of a grant from the National Institutes of Health ("NIH") for the development of an oral fluid syphilis test. The decrease in 2002 resulted from the absence of research and development funding from both Dräger and Meridian, as our projects with these companies advanced to a stage where we became responsible for funding, and the termination of work under the NIH grant for the development of the syphilis test.

Our gross margin decreased to approximately 60% in 2002 from 62% in 2001. This decrease was primarily the result of lower licensing and product development revenues, partially offset by a more favorable product mix and our ongoing cost savings efforts. Additionally, as we prepared for FDA approval and the commercial launch of OraQuick® in the United States during 2002, we incurred substantial expenses related to staffing, materials and overhead. These expenses were included in our cost of goods throughout 2002, however, we did not begin to generate revenues from OraQuick® until the initial sales of this product in the United States in December 2002. We also recognized approximately $1.4 million of inventory scrap in 2002.

Research and development expenses declined 12% to approximately $8.3 million in 2002 from approximately $9.4 million in 2001. Decreased expenditures for staffing, consulting and travel were partially offset by increased clinical trial costs related to our efforts to obtain FDA approval of the OraQuick® rapid HIV-1 antibody test.

Sales and marketing expenses increased 1% to approximately $8.1 million in 2002 from approximately $8.0 million in 2001. This increase was primarily the result of additional consulting fees for the development of our strategic marketing plans and increased staffing costs, offset by lower travel expenses, sales commissions and freight costs.

General and administrative expenses declined 6% to approximately $6.3 million in 2002 from approximately $6.8 million in 2001. This decrease was primarily the result of lower legal, recruiting, and staffing costs offset by an approximate $500,000 severance charge related to the departure of our former Chief Executive Officer in the first quarter of 2002.

Restructuring-related expenses were $450,000 in 2001. These costs included expenses for employee severance and travel and transport resulting from relocating and consolidating manufacturing operations. There were no such costs in 2002.

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

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

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

Liquidity and Capital Resources

	December 31, 2003	December 31, 2002
	(In thousands)	
Cash and cash equivalents	$ 30,695	$ 4,364
Short-term investments	33,329	10,544
Working capital	67,171	18,931

The Company's cash, cash equivalents and short-term investments increased approximately $49.1 million during 2003 to approximately $64.0 million at December 31, 2003, primarily as a result of the Company's common stock offering that raised $44.8 million, proceeds of $3.7 million from stock option exercises and $2.7 million in cash flow from operations offset by net debt reduction of $0.9 million and purchases of capital equipment and licenses of $1.2 million. At December 31, 2003, the Company's working capital was approximately $67.2 million.

Net cash provided by operating activities was approximately $2.7 million in 2003, an increase of approximately $3.2 million from the $500,000 used in operations in 2002. The $2.7 million of cash provided by operating activities resulted primarily from an increase in accounts payable and accruals, together with depreciation and amortization offset by the Company's net loss for the year of $1.1 million and a $3.0 million increase in accounts receivable. Accounts receivable are expected to grow as our sales increase and the proportion of sales increase to parties such as the CDC and MedTech, which have 60-day payment terms.

Net cash used in investing activities during 2003 was $24.0 million. We purchased approximately $1.0 million of property and equipment and expended $250,000 on licenses, product supply and distribution agreements. Additionally, we purchased a net of $22.8 million of short-term investments.

Capital expenditures are anticipated to increase during 2004 to approximately $3.0 million as a result of additional commitments we have made for the purchase and installation of manufacturing and research and development equipment. We also expect to purchase additional information systems equipment and to upgrade certain older equipment in 2004.

Net cash provided by financing activities was approximately $47.7 million, reflecting the proceeds of $44.8 million received from the sale of common stock and approximately $3.7 million from the exercise of stock options, offset by approximately $0.9 million of net 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 for 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.

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica’s prime rate, and is repayable in fixed monthly principal and interest installments of $7,426 through September 2007, at which time the interest rate and fixed monthly repayment amount will be reset for the remaining 60 monthly installments. The outstanding balance of the loan at December 31, 2003 was $820,796.

The $3.0 million term loan matures in March 2006, bears interest at a fixed rate of 4.99% and is repayable in forty-two consecutive equal monthly principal payments of $71,429, plus interest. The outstanding balance of the loan at December 31, 2003 was $1,928,571.

Under the New Non-Revolving Line, we can borrow up to $4.0 million to finance eligible equipment and software purchases through December 31, 2004. Interest on outstanding borrowings accrues at a rate, selected at our option, equal to Comerica’s prime rate, 180-day or 360-day LIBOR plus 2.625%, or the 4-year Treasury Note Rate plus 2.30%, determined at the time of each borrowing. Borrowings are repayable in 48 (for equipment purchases) or 36 (for software purchases) consecutive, equal monthly principal installments, plus interest. We had no outstanding borrowings under this facility at December 31, 2003.

As of December 31, 2003, we had an outstanding balance of $493,095 under the Original Non-Revolving Line consisting of four individual loans of (i) $131,843 with a fixed annual interest rate of 5.07%, (ii) $182,904 with a floating annual interest rate equal to Comerica’s prime rate of 4.0% at December 31, 2003, (iii) $88,304 with a floating annual interest rate equal to Comerica’s prime rate of 4.0% at December 31, 2003, and (iv) $90,044 with a floating annual interest rate equal to Comerica’s prime rate of 4.0% at December 31, 2003.

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 September 10, 2004, with interest payable monthly. We had no outstanding borrowings under this facility at December 31, 2003.

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 during 2003 and expect to remain in compliance with all covenants during 2004. 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.

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

We have entered into a ten-year facility lease with Tech III Partners, LLC ("Tech Partners"), an entity owned and controlled by two of our executive officers (See "Certain Relationships and Related Transactions," included herein). Under the terms of this operating lease, we began leasing a 48,000 square-foot facility in October 2002 at a base rent of $780,000 per year, increasing to $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.

The combination of our current cash position and available borrowings under our Credit Facility is expected to be sufficient to fund our foreseeable operating and capital needs. However, our cash requirements may vary materially from those now planned due to many factors, including, but not limited to, the 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 commercial 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, 2003 for future payments under contracts and other contingent commitments, for the years 2004 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2004**	**2005**	**2006**	**2007**	**2008**	**Thereafter**
Long-term debt(1)	$ 3,582,877	$ 1,126,423	$ 1,130,071	$ 478,806	$ 138,062	$ 122,249	$ 587,266
Operating leases(2)	7,912,520	1,481,881	888,984	780,000	783,108	798,854	3,179,693
Employment contracts(3)	817,127	817,127	—	—	—	—	—
Purchase obligations(4)	3,121,469	3,121,469	—	—	—	—	—
Minimum commitments under contracts(5)	1,650,000	300,000	225,000	225,000	225,000	225,000	450,000
Total contractual obligations	$ 17,083,993	$ 6,846,900	$ 2,244,055	$ 1,483,806	$ 1,146,170	$ 1,146,103	$ 4,216,959

(1) Represents principal repayments required under notes payable to our lenders. See Note 8 to the financial statements included herein.
(2) Represents payments required under our operating leases. See Notes 11 and 12 to the financial statements included herein.

(3) Represents salary, retention bonus or severance payments payable under the terms of employment agreements executed by us with certain officers and employees. See Note 11 to the financial statements included herein.
(4) Represents payments required by non-cancelable purchase orders related to inventory, 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 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 of up-front non-refundable licensing and development fees. We license certain products or technology to outside third parties, in return for which we receive up-front licensing fees. Some of these fees can be significant. In accordance with SAB 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 $359,158 at December 31, 2003. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period ($88,659, $213,188 and $5,193 in 2003, 2002 and 2001, 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, 2003, approximately $2.5 million or 31% of our accounts receivable were 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 2003, 2002 and 2001, we wrote-off inventory which had a cost of approximately $500,000, $1.4 million and $0.6 million, respectively, as a result of scrap levels and product expiration issues. Forecasting product demand can be a complex process, especially for a new product such as our OraQuick® rapid HIV-1 antibody test, which was launched in the United States in November 2002. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of our inventories and reported operating results.

Long-lived and Intangible Assets. Our long-lived assets are comprised of property and equipment and an investment in a nonaffiliated entity, and our intangible assets primarily consist of patents and product rights. Together, these assets have a net book value of approximately $9.0 million or 10% of our total assets at December 31, 2003. Our investment in a privately-held nonaffiliated company is recorded under the cost method of accounting because we do not have a controlling interest in this company nor do we have the ability to exert significant influence over the operating and financial policies of this investee company. Property and equipment, patents and product rights are amortized on a straight-line basis over their useful lives, which we determine based upon our estimate of the period of time over which each asset will generate revenues. An impairment of long-lived or intangible assets could occur whenever events or changes in circumstances indicate that the net book value of these assets may not be recoverable. Events which could trigger an asset impairment include significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of our use of an asset or in our strategy for our overall business, significant negative industry or economic trends, shortening of product life-cycles or changes in technology, and negative financial performance of our nonaffiliated investee company. If we believe impairment of an asset has occurred, we measure the amount of such impairment by comparing the net book value of the affected assets to the fair value of these assets, which is generally determined based upon the present value of the expected cash flows associated with the

use of these assets. If the net book value exceeds the fair value of the impaired assets, we would incur an impairment expense equal to this difference. We currently believe the future cash flows to be received from our long-lived and intangible assets will exceed their book value and, as such, we have not recognized any impairment losses through December 31, 2003. 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, 2003, we have federal net operating loss ("NOL") carryforwards of approximately $76.6 million. The deferred tax asset associated with these NOLs and other temporary differences is approximately $31.7 million at December 31, 2003. 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. 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, we believe that a full valuation allowance is necessary at December 31, 2003. 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, which we believe would approximate 40%. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

Contingencies. In the ordinary course of business, we have entered into various contractual relationships with strategic corporate partners, customers, distributors, research laboratories and universities, licensors, licensees, suppliers, vendors and other parties. As such, we could be subject to litigation, claims or assessments arising from any or all of these relationships. We account for contingencies such as these in accordance with Statement of Financial Accounting Standards ("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

We have entered into a commercial lease (the "Lease") with Tech III Partners, LLC ("Tech Partners"), which provided for the construction of a 48,000 square foot facility on land adjacent to our Bethlehem, Pennsylvania headquarters, and the lease of that facility to us. Tech Partners is owned and controlled by Michael J. Gausling, the Company's President and Chief Executive Officer, and Dr. R. Sam Niedbala, the Company's Executive Vice President and Chief Science Officer. The facility 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 December 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46 (Revised), "Consolidation of Variable Interest Entities" ("FIN No. 46R"), which addresses how a business enterprise should evaluate whether it has a controlling financial interest in an entity through means other than voting rights, and accordingly should consolidate the entity. FIN No. 46R replaces FASB Interpretation No. 46, "Consolidation of Variable Interest Entities," which was issued in January 2003. We will be required to apply FIN No. 46R to variable interests in variable interest entities created after December 31, 2003. For variable interests in variable interest entities created before January 1, 2004, FIN No. 46R will be applied beginning on January 1, 2005. We do not currently have any variable interests in variable interest entities. As such, the application of FIN No. 46R is not expected to have a material effect on our financial position, results of operations or cash flows.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." SFAS No. 149 amends SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" and SFAS No. 138 "Accounting for Certain Derivative Instruments and Certain Hedging Activities" and is related to certain derivatives embedded in other contracts and for hedging activities under SFAS No. 133. SFAS No. 149 was effective for contracts entered into or modified after June 30, 2003. We do not employ derivative instruments or engage in hedging activities. Accordingly, SFAS No. 149 currently has not had an impact on our financial position, results of operations or cash flows.

In May 2003, the FASB issued SFAS No. 150 "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 establishes standards for how companies classify and measure, in their statement of financial position, certain financial instruments with characteristics of both liabilities and equities. SFAS No. 150 was effective for financial instruments entered into or modified after May 31, 2003, and otherwise was effective at the beginning of the first interim period beginning after June 15, 2003. We do not have any financial instruments which embody the characteristics of SFAS No. 150. As such, SFAS No. 150 currently has not had any impact on our financial position, results of operations or cash flows.

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 $1.6 million or 4.0% of our total revenues for the year ended December 31, 2003. We do not expect the risk of foreign currency fluctuations to be material.

ITEM 8. Financial Statements and Supplementary Data.

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

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

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

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

Not applicable.

ITEM 9A. Controls and Procedures

(a) *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, 2003. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company, which is required to be included in its periodic filings with the Securities and Exchange Commission.

(b) *Changes in Internal Control Over Financial Reporting*. The evaluation referred to in paragraph (a) of this Item did not identify any change in the Company's internal control over financial reporting that occurred during the twelve months ended December 31, 2003 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART III

We have omitted from Part III the information that will appear in our Definitive Proxy Statement for our 2004 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 and Related Stockholder Matters.

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

ITEM 13. Certain Relationships and Related Transactions.

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

ITEM 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated by reference to the information under the caption, "Independent Accountants," in the Proxy Statement.

PART IV

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

(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 Report. No schedules are included with the Financial Statements because the required information is inapplicable or is presented in the Financial Statements or related notes thereto.

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

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

1. Current Report on Form 8-K dated October 2, 2003 (i) announcing that the Company had entered into an underwriting agreement with certain underwriters for the sale of 5,000,000 shares of its common stock and (ii) including as exhibits certain documents required to be filed in connection with the sale of such stock.

2. Current Report on Form 8-K dated October 28, 2003, in which the Company announced its financial results for the quarter and nine months ended September 30, 2003, provided an update on its strategy for distributing OraQuick® into the hospital market, and reaffirmed its financial guidance for 2003 and 2004.

3. Current Report on Form 8-K dated November 3, 2003, announcing the exercise of the underwriters' overallotment option in connection with a recent public offering of the Company's common stock.

4. Current Report on Form 8-K dated November 17, 2003, announcing that the Company will be submitting additional data to the FDA in support of an HIV-2 claim for its OraQuick® Rapid HIV-1 Antibody Test.

5. Current Report on Form 8-K dated December 18, 2003, announcing that (i) the Company has submitted the additional data requested by the FDA in support of an HIV-2 claim for its OraQuick® Rapid HIV-1 Antibody Test and (ii) the FDA has successfully completed a facility inspection in connection with the transfer of the Company's Oregon manufacturing operations to Bethlehem, Pennsylvania.

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 4, 2004.

ORASURE TECHNOLOGIES, INC.

By: /s/ MICHAEL J. GAUSLING

Michael J. Gausling
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on March 4, 2004, by the following persons on behalf of the Registrant and in the capacities indicated.

SIGNATURE	TITLE
/s/ MICHAEL J. GAUSLING **Michael J. Gausling**	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 **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

INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying balance sheets of OraSure Technologies, Inc. as of December 31, 2003 and 2002, and the related statements of operations, stockholders' equity and comprehensive loss, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements of OraSure Technologies, Inc. for the year ended December 31, 2001 were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated January 31, 2002, except for the facility lease discussed in Note 12, as to which the date was March 21, 2002.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of OraSure Technologies, Inc. as of December 31, 2003 and 2002, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

Philadelphia, Pennsylvania
January 29, 2004, except
as to the second paragraph
of Note 15, which is as of
February 18, 2004

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

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To OraSure Technologies, Inc.:

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

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

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

ARTHUR ANDERSEN LLP

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

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31, 2003	December 31, 2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 30,695,177	$ 4,364,308
Short-term investments	33,328,610	10,543,876
Accounts receivable, net of allowance for doubtful accounts of $359,158 and $292,146	8,233,869	5,197,787
Inventories	4,003,519	4,088,474
Prepaid expenses and other	922,820	925,707
Total current assets	77,183,995	25,120,152
PROPERTY AND EQUIPMENT, net	6,471,209	7,427,950
PATENTS AND PRODUCT RIGHTS, net	1,886,171	2,543,519
OTHER ASSETS	609,932	645,626
	$ 86,151,307	$ 35,737,247
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,126,423	$ 1,065,966
Accounts payable	3,511,148	1,801,952
Accrued expenses	5,375,851	3,321,509
Total current liabilities	10,013,422	6,189,427
LONG-TERM DEBT	2,456,454	3,409,362
OTHER LIABILITIES	172,142	119,546
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, 44,260,931 and 38,100,557 shares issued and outstanding	44	38
Additional paid-in capital	204,867,765	155,638,314
Deferred compensation	(614,515)	—
Accumulated other comprehensive loss	(173,704)	(184,676)
Accumulated deficit	(130,570,301)	(129,434,764)
Total stockholders' equity	73,509,289	26,018,912
	$ 86,151,307	$ 35,737,247

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

	For the year ended December 31,		
	2003	2002	2001
REVENUES:			
Product	$ 39,740,406	$ 31,691,495	$ 31,095,850
Licensing and product development	710,879	318,272	1,477,494
	40,451,285	32,009,767	32,573,344
COST OF PRODUCTS SOLD	16,061,457	12,888,556	12,333,695
Gross profit	24,389,828	19,121,211	20,239,649
OPERATING EXPENSES:			
Research and development	7,999,687	8,274,351	9,389,313
Sales and marketing	10,764,642	8,068,879	7,980,496
General and administrative	6,911,242	6,318,513	6,752,326
Restructuring-related	—	—	450,000
	25,675,571	22,661,743	24,572,135
Operating loss	(1,285,743)	(3,540,532)	(4,332,486)
INTEREST EXPENSE	(189,511)	(284,678)	(402,686)
INTEREST INCOME	425,344	483,431	933,050
FOREIGN CURRENCY GAIN (LOSS)	(59,037)	(694)	3,122
GAIN ON SALE OF SECURITIES	—	—	100,000
Loss before income taxes	(1,108,947)	(3,342,473)	(3,699,000)
INCOME TAXES	26,590	—	28,789
NET LOSS	$ (1,135,537)	$ (3,342,473)	$ (3,727,789)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.03)	$ (0.09)	$ (0.10)
WEIGHTED AVERAGE NUMBER OF BASIC AND DILUTED SHARES OUTSTANDING	39,793,919	37,582,780	36,868,101

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

	Common Stock						
	Shares	Amount	Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
Balance at December 31, 2000	36,434,004	$ 36	$ 148,767,789	$ —	$ (231,247)	$ (122,364,502)	$ 26,172,076
Common stock issued upon exercise of options	968,729	1	3,851,805	—	—	—	3,851,806
Common stock issued under Employee Stock Purchase Plan	536	—	2,123	—	—	—	2,123
Compensation expense for stock option grants	—	—	136,874	—	—	—	136,874
Comprehensive loss:							
Net loss	—	—	—	—	—	(3,727,789)	(3,727,789)
Currency translation adjustment	—	—	—	—	(75,670)	—	(75,670)
Net unrealized gain on marketable securities	—	—	—	—	181,253	—	181,253
Total comprehensive loss							(3,622,206)
Balance at December 31, 2001	37,403,269	37	152,758,591	—	(125,664)	(126,092,291)	26,540,673
Common stock issued upon exercise of options	688,454	1	2,793,742	—	—	—	2,793,743
Common stock issued under Employee Stock Purchase Plan	8,834	—	35,042	—	—	—	35,042
Compensation expense for stock option grants	—	—	50,939	—	—	—	50,939
Comprehensive loss:							
Net loss	—	—	—	—	—	(3,342,473)	(3,342,473)
Currency translation adjustment	—	—	—	—	(6,481)	—	(6,481)
Net unrealized loss on marketable securities	—	—	—	—	(52,531)	—	(52,531)
Total comprehensive loss							(3,401,485)
Balance at December 31, 2002	38,100,557	38	155,638,314	—	(184,676)	(129,434,764)	26,018,912
Common stock issued upon exercise of options	849,374	1	3,716,890	—	—	—	3,716,891
Common stock issued via public offering	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

The accompanying notes are an integral part of these statements

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

	For the year ended December 31,		
	2003	**2002**	**2001**
OPERATING ACTIVITIES:			
Net loss	$ (1,135,537)	$ (3,342,473)	$ (3,727,789)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Stock based compensation expense	70,048	50,939	136,874
Amortization of deferred revenue	—	(107,500)	(179,167)
Depreciation and amortization	2,576,797	2,286,682	2,175,055
Gain on sale of securities and disposition of investment in affiliated company	—	—	(116,853)
Loss on disposition of property and equipment	43,500	2,553	173,975
Provision for excess and obsolete inventories	539,647	1,373,614	600,000
Changes in assets and liabilities-			
Accounts receivable	(3,036,082)	860,140	(1,118,408)
Notes receivable	—	75,000	100,649
Inventories	(454,692)	(1,017,316)	(3,549,168)
Prepaid expenses and other	2,996	112,804	75,180
Accounts payable	1,738,171	(884,594)	443,050
Accrued expenses and other	2,356,948	72,644	(269,248)
Net cash provided by (used in) operating activities	2,701,796	(517,507)	(5,255,850)
INVESTING ACTIVITIES:			
Purchases of property and equipment	(993,722)	(1,649,129)	(2,763,639)
Proceeds from the sale of property and equipment	—	2,393	33,231
Purchase of patents, licenses and product rights	(250,000)	(700,000)	—
Purchases of short-term investments	(37,280,182)	(9,306,439)	(21,297,303)
Proceeds from sales or maturities of short-term investments	14,489,860	11,474,935	23,420,432
Proceeds from sale of securities	—	—	637,500
Proceeds from disposition of investment in affiliated company	—	—	106,102
Increase in other assets	(5,886)	(52,660)	(202,819)
Net cash used in investing activities	(24,039,930)	(230,900)	(66,496)
FINANCING ACTIVITIES:			
Borrowings of term debt	211,590	4,322,854	—
Repayment of term debt	(1,104,041)	(4,491,556)	(1,125,206)
Proceeds from stock option exercises	3,716,891	2,828,785	3,853,929
Proceeds from common stock offering, net	44,828,003	—	—
Net cash provided by financing activities	47,652,443	2,660,083	2,728,723
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	16,560	26,286	(75,670)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	26,330,869	1,937,962	(2,669,293)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	4,364,308	2,426,346	5,095,639
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 30,695,177	$ 4,364,308	$ 2,426,346

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.

Merger

On September 29, 2000, STC Technologies, Inc. ("STC") and Epitope, Inc. ("Epitope") were merged (the "Merger") into OraSure Technologies, Inc., a newly formed company, incorporated under Delaware law solely for the purposes of combining the two companies and changing the state of incorporation of Epitope from Oregon to Delaware. The Merger was accounted for as a pooling of interests. There were no material adjustments required to conform the accounting policies of the two companies.

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, 2003 and 2002, cash equivalents consisted of certificates of deposit, commercial paper, U.S. government and agency obligations, state and local government agency obligations and corporate bonds.

Short-term Investments

We consider all short-term investments as available-for-sale securities, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are comprised of certificates of deposits, commercial paper, U.S. government and agency obligations, state and local government agency obligations and corporate bonds 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.

The following is a summary of our available-for-sale securities at December 31, 2003 and 2002:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
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
December 31, 2002				
Certificates of deposit	$ 3,581,734	$ —	$ —	$ 3,581,734
Commercial paper	399,017	88	—	399,105
Government and agency bonds	1,974,734	—	(3,321)	1,971,413
Corporate bonds	4,570,558	22,041	(975)	4,591,624
Total available-for-sale securities	$ 10,526,043	$ 22,129	$ (4,296)	$ 10,543,876
At December 31, 2003, maturities of investments were as follows:				
Less than one year	$ 27,590,483	$ 6,668	$ (383)	$ 27,596,768
1 – 2 years	5,734,738	5,046	(7,942)	5,731,842
Total available-for-sale securities	$ 33,325,221	$ 11,714	$ (8,325)	$ 33,328,610

Supplemental Cash Flow Information

For 2003, 2002 and 2001, we paid interest of $184,906, $268,340 and $402,686, respectively.

For 2003, 2002 and 2001, we recorded provisions for bad debts of $155,671, $295,842, and $100,000, respectively. We had deductions of $88,659, $213,188, and $5,193 against the allowance for doubtful accounts in 2003, 2002 and 2001, respectively.

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

Inventories

Inventories are stated at the lower of cost or market determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate quantities on hand and the carrying value of our inventories to determine the need for reserves for excess and obsolete inventories, based primarily on the estimated forecast of product sales. When factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off, as in the case of lapsing expiration dates. We currently buy our entire 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 generally amortized over the shorter of the estimated useful lives or the terms of the related leases. When assets are sold or otherwise disposed of, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the statement of operations.

Patents and Product Rights

Patents and product rights consist of costs associated with the acquisition of patents and product distribution rights. Patents and product rights are amortized using the straight-line method over estimated useful lives of three to ten years. Amortization expense for 2003, 2002 and 2001 was $657,348, $416,247, and $359,853, respectively.

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, patents and product rights, by determining whether the carrying value of such assets can be recovered through the sum of the undiscounted future operating cash flows and eventual disposition of the asset. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the assets to the fair value of these assets, generally determined based on the present value of the expected future cash flows associated with the use of the asset. We believe the future cash flows to be received from our long-lived assets will exceed the assets’ carrying value, and accordingly we have not recognized any impairment losses through December 31, 2003.

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 2003, 2002 and 2001, one customer accounted for approximately 17 percent, 26 percent and 29 percent, respectively, of our total revenues. The same customer accounted for approximately 8 percent and 19 percent of accounts receivable as of December 31, 2003 and 2002, respectively.

In 2003, another customer accounted for 12 percent of total revenues. We had no sales to this customer in 2002 and 2001. This customer also accounted for approximately 23 percent of accounts receivable as of December 31, 2003.

Advertising Expenses

Advertising costs are charged to expense as incurred. During 2003, we incurred $1,774,093 in advertising expenses, primarily attributed to launching two new products in 2003. During 2002 and 2001, advertising expense was $53,452 and $88,591 respectively.

Research and Development

Research and development costs are charged to expense as incurred.

Restructuring-related Expenses

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

Stock-Based Compensation

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

We have elected to adopt the disclosure provisions of SFAS 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 2003, 2002 and 2001 would have increased as follows:

	Year ended December 31,		
	2003	2002	2001
Net loss:			
As reported	$ (1,135,537)	$ (3,342,473)	$ (3,727,789)
Add: stock-based employee compensation expense included in net loss	33,900	—	—
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards	(4,270,439)	(3,359,281)	(2,913,149)
Pro forma	$ (5,372,076)	$ (6,701,754)	$ (6,640,938)
Basic and diluted net loss per share:			
As reported	$ (0.03)	$ (0.09)	$ (0.10)
Pro forma	$ (0.13)	$ (0.18)	$ (0.18)

The weighted average fair value of the options granted during 2003, 2002 and 2001 is estimated at $4.15, $3.45 and $7.10 per share, respectively, using the Black-Scholes option pricing model, with the following assumptions: dividend yield of zero; volatility of 70 percent, 71 percent and 65 percent, respectively; weighted average risk-free interest rate of 2.93 percent, 2.89 percent and 4.86 percent, respectively; and an expected life of 5.0, 5.0 and 7.0 years, respectively.

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

The assets and liabilities of our foreign operations are translated from euros into U.S. dollars at current exchange rates as of the balance sheet date, and revenues and expenses are translated at average exchange rates for the period. Resulting translation adjustments are reflected as a separate component of stockholders' equity.

Gain on Sale of Securities

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

Net Loss Per Common Share

We have presented basic and diluted net loss per 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 using the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is generally computed assuming the conversion or exercise of all dilutive securities such as common stock options, warrants and unvested restricted stock. As a result of our losses in 2003, 2002 and 2001, outstanding common stock options, warrants and unvested restricted stock representing 4,130,463, 3,999,608 and 3,915,233 shares were excluded from the computation of diluted net loss per common share for 2003, 2002 and 2001, 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, 2003, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, accounts payable, and accrued expenses approximate their respective fair values based on their short-term nature. In addition, we believe the carrying value of our debt instruments, which do not have readily ascertainable market values, approximates their fair values, given that the interest rates on outstanding borrowings approximate market rates.

Recent Accounting Pronouncements

In December 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46 (Revised), "Consolidation of Variable Interest Entities" ("FIN No. 46R"), which addresses how a business enterprise should evaluate whether it has a controlling financial interest in an entity through means other than voting rights, and accordingly should consolidate the entity. FIN No. 46R replaces FASB Interpretation No. 46, "Consolidation of Variable Interest Entities," which was issued in January 2003. We will be required to apply FIN No. 46R to variable interests in variable interest entities created after December 31, 2003. For variable interests in variable interest entities created before January 1, 2004, FIN No. 46R will be applied beginning on January 1, 2005. We do not currently have any variable interests in variable interest entities. As such, the application of FIN No. 46R is not expected to have a material effect on our financial position, results of operations or cash flows.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." SFAS No. 149 amends SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" and SFAS No. 138 "Accounting for Certain Derivative Instruments and Certain Hedging Activities" and is related to certain derivatives embedded in other contracts and for hedging activities under SFAS No. 133. SFAS No. 149 was effective for contracts entered into or modified after June 30, 2003. We do not employ derivative instruments or engage in hedging activities. Accordingly, SFAS No. 149 currently has not had an impact on our financial position, results of operations or cash flows.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 establishes standards for how companies classify and measure, in their statement of financial position, certain financial instruments with characteristics of both liabilities and equities. SFAS No. 150 was effective for financial instruments entered into or modified after May 31, 2003, and otherwise was effective at the beginning of the first interim period beginning after June 15, 2003. We do not have any financial instruments which embody the characteristics of SFAS No. 150. As such, SFAS No. 150 has not had any impact on our financial position, results of operations or cash flows.

3. INVENTORIES:

	December 31,	
	2003	**2002**
Raw materials	$ 2,862,169	$ 2,787,967
Work in process	486,284	430,977
Finished goods	655,066	869,530
	$ 4,003,519	$ 4,088,474

4. PROPERTY AND EQUIPMENT:

	December 31,	
	2003	**2002**
Building and leasehold improvements	$ 5,989,170	$ 5,893,702
Machinery and equipment	10,361,701	10,104,511
Computer equipment	2,446,736	2,314,015
Furniture and fixtures	1,545,562	1,442,644
Construction in progress	990,115	656,061
	21,333,284	20,410,933
Less—Accumulated depreciation and amortization	(14,862,075)	(12,982,983)
	$ 6,471,209	$ 7,427,950

Depreciation expense was $1,879,092, $1,828,855 and $1,815,202 for 2003, 2002 and 2001, respectively.

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. We are amortizing this amount through September 2005, the initial term of the agreements.

6. ACCRUED EXPENSES:

	December 31,	
	2003	2002
Payroll and related benefits	$ 1,449,151	$ 1,387,834
Royalties	1,428,816	137,509
Deferred revenue	705,817	316,139
Advertising	474,817	—
Laboratory testing fees	305,647	531,921
Professional fees	222,710	296,162
Other	788,893	651,944
	$ 5,375,851	$ 3,321,509

At December 31, 2003, accrued royalties and advertising expenses are primarily attributed to launching two new products during 2003.

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 will remain 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 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).

Under the New Non-Revolving Line, we can 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 outstanding borrowings under this facility at December 31, 2003.

Under the revolving working capital line of credit, 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 September 10, 2004, with interest payable monthly. We had no outstanding borrowings under this facility at December 31, 2003.

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 equipment and working capital lines of credit are limited to commercially standard percentages of equipment purchases and accounts receivable, respectively. 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,	
	2003	**2002**
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.	$ 1,928,571	$ 2,785,714
Mortgage loan payable to bank, interest at an annual floating rate equal to the bank's prime rate (4.0% at December 31, 2003), 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.	820,796	874,186
Note payable to bank, interest at an annual floating rate equal to the bank's prime rate (4.0% at December 31, 2003), monthly principal installments of $5,081, plus interest, through December 2006, secured by certain equipment.	182,904	243,872
Note payable to bank, interest at 5.07%, monthly principal installments of $3,995, plus interest, through September 2006, secured by certain equipment.	131,843	179,786
Note payable to bank, interest at an annual floating rate equal to the bank's prime rate (4.0% at December 31, 2003), monthly principal installments of $2,144, plus interest, through July 2007, secured by certain equipment	90,044	—
Note payable to bank, interest at an annual floating rate equal to the bank's prime rate (4.0% at December 31, 2003), monthly principal installments of $2,264, plus interest, through April 2007, secured by certain equipment.	88,304	—
Note payable to Pennsylvania Industrial Development Authority, interest at 2%, monthly installments of principal and interest of $4,895 through March 2010, secured by a second lien on our building.	340,415	391,770
	3,582,877	4,475,328
Less—Current portion	(1,126,423)	(1,065,966)
	$ 2,456,454	$ 3,409,362

Long-term debt maturities as of December 31, 2003 are as follows:

2004	$ 1,126,423
2005	1,130,071
2006	478,806
2007	138,062
2008	122,249
Thereafter	587,266
	$ 3,582,877

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

9. INCOME TAXES:

At December 31, 2003, we have federal net operating loss ("NOL") carryforwards of approximately $76,600,000. These federal NOL carryforwards will continue to expire through 2023. 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. We believe that there was a change in ownership in connection with the Merger. 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, and on a preliminary basis, do not expect that the limitation will have a material effect.

The tax effect of temporary differences that give rise to significant portions of deferred income taxes at December 31, 2003 and 2002 are as follows:

	December 31,	
	2003	2002
Deferred tax asset:		
Net operating loss carryforwards	$ 26,597,884	$ 26,583,157
Depreciation and amortization	389,344	636,332
Inventory	626,501	664,593
Accruals and reserves currently not deductible	581,937	313,497
Patent costs	517,827	558,270
Capitalized research and development costs	895,085	—
Research and development credit carryforwards	2,138,080	2,153,591
Valuation allowance on deferred tax asset	(31,746,658)	(30,909,440)
Net deferred tax asset	$ —	$ —

Of the total NOL carryforwards as of December 31, 2003 and 2002, approximately $9,600,000 and $8,500,000, 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. 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, we believe that a full valuation allowance is necessary at December 31, 2003.

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 expense, if any, is recognized for the intrinsic value (the difference between the exercise price and the fair value of our common stock) on the date of grant. Compensation, if any, is deferred and charged to expense over the respective vesting period.

We account for stock-based compensation to non-employees using the fair value method, in accordance with SFAS No. 123 and EITF No. 96-18. In 2002 and 2001, we recorded compensation expense of $50,939 and $136,874 related to options to purchase 20,000 shares and 19,000 shares, respectively, of our common stock granted to outside consultants or members of a non-employee advisory board. 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 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, 2000	4,507,357	$ 0.80–15.03	$ 4.85
Granted	357,000	7.88–12.95	10.51
Exercised	(968,729)	0.80– 9.47	3.98
Canceled	(150,395)	0.80–14.81	6.14
Balance, December 31, 2001	3,745,233	0.80–15.03	5.57
Granted	1,267,275	3.83– 7.42	5.74
Exercised	(688,454)	0.80– 7.09	4.06
Canceled	(444,446)	0.80–14.84	6.14
Balance, December 31, 2002	3,879,608	0.80–15.03	5.83
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

The following table summarizes information about stock options outstanding at December 31, 2003:

	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	485,471	8.83	$ 2.46	397,471	$ 2.10
$ 4.17–$5.04	389,504	23.07	4.61	382,232	4.61
$ 5.50–$5.76	33,313	5.45	5.73	25,313	5.75
$ 5.87	756,211	8.08	5.87	411,029	5.87
$ 6.10–$6.87	190,577	7.92	6.69	120,784	6.79
$ 6.96	936,262	9.08	6.96	131,665	6.96
$ 6.98	40,000	9.17	6.98	15,000	6.98
$ 7.09	560,665	6.95	7.09	439,014	7.09
$ 7.13–$10.71	439,960	7.59	9.79	291,755	9.65
$10.92–$15.03	103,500	7.03	12.65	67,873	12.62
	3,935,463	9.63	$ 6.42	2,282,136	$ 6.04

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 expense 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 2003, we granted 75,000 restricted shares to certain key executive officers and recorded $650,663 of deferred compensation. Amortization of deferred compensation related to these grants was $36,148 in 2003. We did not grant any restricted shares in 2002 or 2001.

As of December 31, 2003, 1,228,976 shares were available for future grants under the 2000 Plan.

Employee Stock Purchase Plan

In 1993, Epitope's stockholders approved the adoption of the 1993 Employee Stock Purchase Plan ("1993 ESPP"). The 1993 ESPP, as subsequently amended by Epitope's stockholders, covered a maximum of 500,000 shares of common stock for subscription over established offering periods. As a result of the Merger, the 1993 ESPP was adopted and renamed by us. The Compensation Committee of the Board of Directors determines the number of offering periods, the number of shares offered, and the length of each period, provided that no more than three offering periods may be set during any given fiscal year. The purchase price for stock purchased under the 1993 ESPP for each subscription period is the lesser of 85 percent of the fair market value of a share of common stock at the commencement of the subscription period and the fair market value at the close of the subscription period. An employee may also elect to withdraw at any time during the subscription period and receive the amounts paid plus interest at the rate of 6 percent.

As of December 31, 2003 and 2002, there were no subscriptions for common shares outstanding. As of December 31, 2001, 8,834 shares of common stock were subscribed for through one offering. These shares could be purchased over 24 months at an initial subscription price of $3.96. During the years ended December 31, 2003, 2002 and 2001, 0, 8,834, and 536 shares, respectively, were issued at $3.96 per share under the 1993 ESPP.

Common Stock Warrants

As of December 31, 2003, warrants to purchase 120,000 shares of common stock at $6.13 per share were outstanding. These warrants were issued on September 30, 1998 and expire on September 30, 2008.

11. COMMITMENTS AND CONTINGENCIES:

Phosphor Agreements

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

Leases

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

2004	$ 1,481,881
2005	888,984
2006	780,000
2007	783,108
2008	798,854
Thereafter	3,179,693
	$ 7,912,520

Rent expense for 2003, 2002 and 2001 was $1,594,240, $1,070,510 and $805,878, respectively.

Purchase Commitments

As of December 31, 2003, we had outstanding non-cancelable purchase commitments in the amount of $3,121,469, of which $2,830,497, $183,291 and $107,681 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 2004, we are required to pay each individual a base salary and for some individuals, a retention bonus, for continuing employment with our Company. The agreements require payments of $817,127 in 2004.

Litigation

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

12. RELATED-PARTY FACILITY LEASE:

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

13. RETIREMENT PLANS:

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

On May 1, 2001, we merged the two aforementioned plans into the OraSure Technologies, Inc. 401(k) Plan (the "New Plan"). The New Plan permits voluntary employee contributions to be excluded from an employee's current taxable income under provisions of Internal Revenue Code Section 401(k) and the regulations thereunder. The New Plan also provides for us to match employee contributions up to the lesser of $4,000 or ten percent of the employee's salary. Contributions to the New Plan were $376,541, $443,280 and $239,402 in 2003, 2002 and 2001, respectively.

14. GEOGRAPHIC INFORMATION:

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

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

	For the year ended December 31,		
	2003	2002	2001
United States	$35,896	$28,124	$27,321
Europe	3,062	2,726	3,510
Other regions	1,493	1,160	1,742
	$40,451	$32,010	$32,573

15. SUBSEQUENT EVENTS:

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 $4,000,000 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. On February 18, 2004, the arbitrator ruled that the agreement did not terminate, and that our remedy is limited to revoking Abbott's status as a co-exclusive distributor. We have notified Abbott that, based on the magnitude of its purchases, we have decided to convert Abbott's distribution rights to non-exclusive. As a further result of the arbitrator's rulings, we will be required to fulfill Abbott's purchase orders at the agreed-upon price contained in the original agreement. During the quarter ending March 31, 2004, we expect to incur legal fees and expenses of approximately $110,000 associated with this arbitration.

16. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2003 and 2002. 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).

	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 (loss), 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

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

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.
4.2	Stockholders' Agreement among STC Technologies, Inc. (a predecessor to the Company), HealthCare Ventures V, L.P., RHO Management Trust II, Hudson Trust and Pennsylvania Early Stage Partners, L.P., dated March 30, 1999, is incorporated by reference to Exhibit 4.3 to Amendment No. 3 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 30, 2000.
4.3	Amendment to Stockholders' Agreement filed as Exhibit 4.2 is incorporated by reference to Exhibit 4.4 to Amendment No. 3 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 30, 2000.
4.4	Second Amendment to Stockholders' Agreement filed as Exhibit 4.2 is incorporated by reference to Exhibit 4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
10.1	Form of Indemnification Agreement (and list of parties to such agreement) is incorporated by reference to Exhibit 10.1 to Amendment No. 3 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed August 30, 2000.*
10.2	Employment Agreement, dated as of September 29, 2000, between OraSure Technologies, Inc. and Michael J. Gausling is incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*
10.3	Employment Agreement, dated as of November 1, 2001, between OraSure Technologies, Inc. and Ronald H. Spair is incorporated by reference to Exhibit 10 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.*
10.4	Employment Agreement, dated as of September 29, 2000, between OraSure Technologies, Inc. and Dr. R. Sam Niedbala is incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*
10.5	Employment Agreement, dated as of September 29, 2000, between OraSure Technologies, Inc. and P. Michael Formica is incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001.*
10.6	Description of Nonemployee Director Compensation Policy.*
10.7	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.*
10.8	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.*

Exhibit Number	Exhibit
10.9	OraSure Technologies, Inc. 2000 Stock Award Plan, as amended effective as of May 20, 2002, is incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.*
10.10	Description of OraSure Technologies, Inc. 2003 Self-Funding Annual Incentive Plan is incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002.*
10.11	Description of OraSure Technologies, Inc. 2004 Self-Funding Annual Incentive Plan.*
10.12	Description of OraSure Technologies, Inc. Management Stock Option Award Guidelines.*
10.13	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.
10.14	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.
10.15	Amendment No. 2 to Production Agreement, dated as of April 28, 2003, between OraSure Technologies, Inc. and Koninklijke Utermöhlen N.V.**
10.16	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.
10.17	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.
10.18	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.
10.19	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.
10.20	Lease dated October 25, 1999 between PS Business Parks, L.P., a California Limited Partnership, and Epitope, Inc., is incorporated by reference to Exhibit 10.6 to the Epitope, Inc. Annual Report on Form 10-K for 1999.
10.21	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.
10.22	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.
10.23	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.
10.24	First Amendment to Loan and Security Agreement, dated as of May 23, 2003, between OraSure Technologies, Inc. and Comerica Bank – California.

Table of Contents

Exhibit Number	Exhibit
10.25	Second Amendment to Loan and Security Agreement, dated as of September 12, 2003, between OraSure Technologies, Inc. and Comerica Bank, is incorporated herein by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, dated September 17, 2003.
10.26	Distribution Agreement, dated as of October 11, 2002, between OraSure Technologies, Inc. and bioMérieux, Inc., is incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
10.27	Supply Agreement, dated as of October 11, 2002, between OraSure Technologies, Inc. and bioMérieux, Inc., is incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
23	Consent of KPMG LLP.
24	Powers of Attorney.
31.1	Certification of Michael J. Gausling 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 Michael J. Gausling 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.

** Portions of this exhibit were omitted and filed separately with the Securities and Exchange Commission pursuant to an application for confidential treatment.

Exhibit 10.6

Description of Nonemployee Director Compensation Policy

The following describes the Company's Compensation Policy for Nonemployee Directors (the "Policy").

Pursuant to the Policy, all nonemployee Directors receive an annual fee of $12,000. In addition, the Chairman of the Company's Board of Directors (the "Board") receives an additional annual fee of $13,000, the Chairman of the Audit Committee of the Board receives an additional annual fee of $5,000, and the Chairmen of the Compensation Committee and the Strategic Planning Committee of the Board each receive an additional annual fee of $4,000. Annual fees are payable quarterly in advance.

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

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

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

Exhibit 10.11

Description of OraSure Technologies, Inc.
2004 Self-Funding Annual Incentive Plan

On January 13, 2004, the Compensation Committee of the Company's Board of Directors (the "Board") adopted the 2004 Self-Funding Annual Incentive Plan (the "Bonus Plan"). The purpose of the Bonus Plan is to reward outstanding individual performance by management with cash bonuses. All employees, except for sales employees (who are covered by a separate commission plan) at the level of director and above, will be eligible to participate in the Bonus Plan.

Pursuant to the Bonus Plan, cash bonuses may be paid out of a cash bonus pool to be funded based on the Company's achievement of certain financial objectives regarding revenues, net income, cash flow from operations and gross margin for 2004. If the Company achieves 100% of these financial targets, the bonus pool would be funded in the amount of $900,000.

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

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

Performance criteria for individual employees will be derived from the Company's 2004 corporate objectives concerning financial performance, strategic planning, research and development, business development, regulatory affairs and quality control, manufacturing, engineering, information systems, sales and marketing, human resources, investor relations matters and/or such other objectives chosen by the Compensation Committee in its sole discretion. Awards are expected to reflect a weighted average measurement of an employee's achievement of his or her individual performance objectives.

Employees must be employed by the Company as of December 31, 2004 and at the time of the bonus award in order to participate in the Bonus Plan, and awards will be adjusted on a pro rata basis to the extent any employee is employed for only a portion of the year 2004. The Chief Executive Officer will recommend individual awards for all participating employees (except for the Chief Executive Officer) for approval by the Compensation Committee based on an assessment of each individual's performance against his or her applicable performance objectives. The Compensation Committee may approve or disapprove any recommended bonus award in whole or in part in its sole discretion. The Compensation Committee shall recommend for Board approval any bonus award for the Chief Executive Officer based on an assessment of his performance against his individual performance objectives. The Board may approve or disapprove any recommended bonus award for the Chief Executive Officer in whole or in part in its sole discretion.

The Compensation Committee and the Board shall have the right in their sole discretion to reject any or all of the recommended bonus awards, even if the bonus pool has been funded and any and all applicable performance criteria have been satisfied, based on the business conditions of the Company at or immediately after the end of 2004.

Exhibit 10.12

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

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

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

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

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

Performance criteria for individual employees will be derived from the Company's corporate objectives for the applicable 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 or the Compensation Committee of the Board in their sole discretion. Awards are expected to reflect a weighted average measurement of an employee's achievement of his or her individual performance objectives.

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

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

Exhibit 10.15

Execution Copy

AMENDMENT NO. 2 TO PRODUCTION AGREEMENT

This Amendment No. 2 to Production Agreement (this "Amendment") is made and entered into this 28th day of April, 2003 by and between OraSure Technologies, Inc., a Delaware corporation, with its registered offices at Bethlehem, Pennsylvania 18015 U.S.A. (the "Purchaser"), and Koninklijke Utermöhlen N.V., a limited liability company organized under the laws of the Netherlands, with its registered offices at Wolvega, the Netherlands (the "Seller"). Seller and Purchaser are each referred to herein as a "Party" and collectively as the "Parties."

BACKGROUND

Seller and Purchaser are parties to a Production Agreement, dated June 8, 1998, as amended by Amendment No. 1 to Production Agreement ("Amendment No. 1"), dated as of December 11, 2001 (collectively, the "Original Agreement"), pursuant to which Seller agreed to produce certain products related to the Histofreezer Business for the Purchaser. The Parties desire to amend further the Original Agreement in order to provide for the production of a New Product by Seller for Purchaser for ultimate sale into the over-the-counter or consumer market in certain territories.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, and of the mutual promises and covenants contained in this Amendment, Seller and Purchaser, intending to be legally bound, hereby agree as follows:

1. Definitions. Capitalized terms not otherwise defined in this Amendment shall have the meanings set forth in the Original Agreement.

2. New Product. Exhibit 1 to the Original Agreement is hereby amended to add the following New Product (referred to herein as the "OTC Product"):

Art. Nr.	Description
1001-0063	Compound W Freeze OFF

The OTC Product shall be deemed to be a "Product" under the Original Agreement.

3. OTC Product Specifications. The Specifications for the OTC Product (the "OTC Product Specifications") shall mean the technical file set forth in Exhibit 3 to this Amendment as the same shall be amended from time to time pursuant to Section 3.1 of the Original Agreement, together with current ISO 9002/46002 standards, CE standards, all relevant laws, all relevant regulations, all relevant directives, the Quality System Regulation (including then current Good Manufacturing Practices) as promulgated by the United States Food and Drug Administration, principles of good workmanship, acknowledged standards and specific (but reasonable) instructions of the Purchaser in the relevant order for any OTC Product(s). The OTC Product Specifications shall be deemed to be the "Specifications" for the OTC Product for all purposes of the Original Agreement.

4. Other Specifications. The Specifications for all other Products are hereby amended to include the Quality System Regulation (including then current Good Manufacturing Practices) as promulgated by the United States Food and Drug Administration.

5. Supply of Packaging Components. Purchaser shall be responsible for supplying or arranging for the supply of the packaging and labeling materials noted in Exhibit 4 to this Amendment (collectively, the "OTC Packaging Components"). Seller shall not be responsible for providing or paying for the OTC Packaging Components, but shall use such OTC Packaging Components in packaging and assembling the OTC Product purchased hereunder.

6. Purchase Price.

(a) The price for the purchase of OTC Product shall be as set forth in Exhibit 6 to this Amendment.

(b) The parties acknowledge a typographical error in Section 4.2 of Amendment No. 1. The change from "30%" to "10%" in such Section should have been, and is hereby deemed to have been, made to Section 4.3 of the Original Agreement.

7. No Other Changes. Except as set forth in this Amendment, the Original Agreement remains in full force and effect without any other changes. The Original Agreement, together with this Amendment, constitute the entire agreement between the Seller and the Purchaser with respect to the subject matter hereof and thereof and supersede and cancel all previous negotiations, agreements, and commitments, whether oral or in writing, with respect to such subject matter. All references to the Original Agreement shall be deemed to mean the Original Agreement as amended by this Amendment.

8. Counterparts. This Amendment may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. A facsimile transmission of a signed original shall be deemed to be the same as delivery of a signed original.

9. Governing Law. This Amendment and any controversy, claim or dispute arising under this Amendment shall be governed by, and construed in accordance with, the laws of the Netherlands.

IN WITNESS WHEREOF, the undersigned duly authorized officers of the Seller and the Purchaser have executed this Amendment as of the date first above written.

ORASURE TECHNOLOGIES, INC.

By: /s/ *Mike Gausling*

Name: Mike Gausling
Title: President and CEO

KONINKLIJKE UTERMÖHLEN N.V.

By: /s/ *D. T. van der Vat*

Name: D.T. van der Vat
Title: President

EXHIBIT 3

OTC Product Specifications

* * * * * * * * * * *

EXHIBIT 4

OTC Package Components

1. Boxes for each unit of OTC Product, with labeling approved by Purchaser;
2. Package inserts or instructions in form approved by Purchaser;
3. Shipping cases (standard corrugated);
4. Shipping case label in form approved by Purchaser; and
5. Transparent tamper resistant labels for the box (if required).

EXHIBIT 6

OTC Product Price
(Per Unit)

		Price
1.	Materials	
	- 110 ml. canister filled with 80 ml. of refrigerant	* * * *
	- Foam Bud Applicators (12 in a bag)	* * * *
2.	Labor	* * * *
3.	Overhead	* * * *
4.	Profit	* * * *
	Total Price Per Unit	* * * *

A unit of OTC Product shall consist of an 110 ml canister filled with 80 ml. of refrigerant and a 12-count set of 5 mm. foam tip applicators, manufactured, assembled and packaged in accordance with the OTC Product Specifications.

Exhibit 10.24

FIRST AMENDMENT TO

LOAN AND SECURITY AGREEMENT

This **FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT** ("First Amendment") is made and entered into this 23rd day of May, 2003, by and between **ORASURE TECHNOLOGIES, INC.**, a Delaware corporation ("Borrower"), and **COMERICA BANK—CALIFORNIA**, a California banking corporation ("Bank").

WHEREAS, Borrower and Bank are parties to a Loan and Security Agreement dated as of September 10, 2002 (as amended, restated and otherwise modified from time to time, the "Agreement"); and

WHEREAS, Bank and Borrower wish to amend the Agreement as set forth herein;

NOW THEREFORE, the parties hereto, intending to be legally bound hereby, agree as follows:

1. The definition of "Non-Revolving Advance Date" in Exhibit A to the Agreement is hereby amended to read in its entirety as follows:

"Non-Revolving Advance Date" means each of three (3) Business Days following the Closing Date, December 10, 2002, March 10, 2003 and June 10, 2003, or any other date occurring after the Closing Date and prior to September 10, 2003 by which Borrower has accumulated invoices for at least $100,000 of CAPEX Equipment eligible for reimbursement under Section 2.1(d) hereof.

2. Except as expressly modified by this First Amendment, the Agreement remains in full force and effect as originally written.

3. This First Amendment may be executed in multiple counterparts, each of which shall be deemed an original and all of which shall constitute one and the same agreement.

IN WITNESS WHEREOF, the undersigned have executed this First Amendment as of the day and year first above written.

ORASURE TECHNOLOGIES, INC.

By: /s/ *Ronald H. Spair*

Ronald H. Spair
Chief Financial Officer

COMERICA BANK- CALIFORNIA

By: /s/ *Michael T. Wilk*

Michael T. Wilk
First Vice President

Exhibit 23

INDEPENDENT AUDITORS' CONSENT

The Board of Directors
OraSure Technologies, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-102235, No. 333-50340 and No. 333-48662) on Form S-8 and the registration statements (No. 333-106786 and No. 333-73498) on Form S-3 of OraSure Technologies, Inc. of our report dated January 29, 2004, except as to the second paragraph of Note 15, which is as of February 18, 2004, with respect to the balance sheets of OraSure Technologies, Inc. as of December 31, 2003 and 2002, and the related statements of operations, stockholders' equity and comprehensive loss, and cash flows for the years then ended, which report appears in the December 31, 2003 annual report on Form 10-K of OraSure Technologies, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 4, 2004

Exhibit 24

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2003, 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 March 2, 2004.

/s/ *Carter H. Eckert*

Signature

Carter H. Eckert

Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2003, 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 12, 2004.

/s/ *Michael J. Gausling*

Signature

Michael J. Gausling

Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2003, 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 15, 2004.

/s/ *Frank G. Hausmann*

Signature

Frank G. Hausmann

Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2003, 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 17, 2004.

/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 **Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2003, 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 12, 2004.

/s/ *Gregory B. Lawless*

Signature

Gregory B. Lawless

Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2003, 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 12, 2004.

/s/ *Roger L. Pringle*

Signature

Roger L. Pringle

Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints **Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett,** and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2003, 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 March 2, 2004.

/s/ *Douglas G. Watson*

Signature

Douglas G. Watson

Print Name

Exhibit 31.1

Certification

I, Michael J. Gausling, certify that:

1. I have reviewed this annual report on Form 10-K of OraSure Technologies, Inc;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d –15(e)) 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) 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; and
   c) 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 4, 2004

/s/ MICHAEL J. GAUSLING

Michael J. Gausling
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)) 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) 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; and
   c) 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 4, 2004

/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, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael J. Gausling, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ Michael J. Gausling

Michael J. Gausling
President and Chief Executive Officer

March 4, 2004

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, 2003 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 4, 2004