OraSure Technologies, Inc.

diagnostic solutions for the new millennium

2001 Annual Report

The Future is Now

Corporate Profile

OraSure Technologies (Nasdaq: OSUR), Bethlehem, Pennsylvania, develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies and other enzyme immunoassay tests for insurance risk assessment, infectious disease and drugs of abuse testing. The Company also manufactures and sells a medical device to the physician's office therapy market.

The Company's products are sold in the United States and certain foreign countries to clinical laboratories, government agencies, physicians' offices, hospitals, commercial and industrial entities, and various distributors.

Headquartered in Bethlehem, Pennsylvania, OraSure Technologies has operations in Bethlehem, Pennsylvania and Portland, Oregon. The Company also has a sales office in The Netherlands. There were 221 full-time employees at December 31, 2001.

For the year-ending December 31, 2001, the Company had annual revenues of $32.6 million, a net loss of $3.7 million, working capital of $19.8 million, and cash and short-term securities of $15.2 million.

"The Future is Now"

Oral fluid testing for infectious disease and drugs of abuse.

OraSure® is the only FDA-approved oral fluid collection device used with a lab-based enzyme immunoassay ("EIA") screening test for HIV-1 antibody detection. In 2001, the Company sold more than 3 million OraSure® devices into the insurance risk assessment and infectious disease testing markets.

Intercept® is the only FDA-cleared oral fluid collection device used with lab-based EIA screening tests to detect drugs of abuse. In 2001, the Company sold over 500,000 devices and 2.0 million EIA tests to the workplace, criminal justice, and drug rehabilitation markets.

Rapid HIV-1 Antibody Test

Up-Converting Phosphor Technology (UPT™)

OraQuick® is the Company's rapid test platform designed to test an oral fluid or whole blood specimen for the presence of HIV-1 antibodies. In 2001, the Company submitted the OraQuick® HIV-1 fingerstick whole blood product to the FDA for pre-market approval.

UP*link*™ is the Company's rapid, point-of-care system utilizing a collector, lateral flow test cassettes, and an analyzer to provide lab-quality results in about ten minutes on a variety of samples, including oral fluid, blood, serum, urine, and stool samples. In 2001, the Company submitted a 510(k) application to the FDA for an UP*link*™ rapid detection system for up to five drugs of abuse using an oral fluid specimen.

To Our Stockholders,

On January 31, 2002, I was named President and Chief Executive Officer of OraSure Technologies. Prior to that, I served as the Company's President and Chief Operating Officer, a position I held since the merger on September 29, 2000, of STC Technologies and Epitope to form OraSure Technologies.

Prior to the merger, as a founder, principal stockholder, Chairman, and Chief Executive Officer of STC Technologies for more than a decade, I was convinced that, strategically, this merger was essential if we were to create the world's leading oral fluid diagnostics company.

I am proud to say that in 2001, thanks to the efforts of our dedicated employees, we have made extraordinary progress towards achieving our objective.

We are already considered by many to be the best "laboratory-based" oral fluid diagnostics company for infectious disease ("ID") and drugs of abuse ("DOA") testing. With the expected commercialization of UP*link*™ and OraQuick® in 2002, we are also positioned to become the best "point-of-care" oral fluid diagnostics company for ID and DOA testing. **THE FUTURE IS NOW**. We will succeed.

Our basic value proposition starts with the following Mission Statement and strategy for our major technology platforms:

Mission Statement.

To create, combine, and collaborate to be the world's leading oral fluid diagnostics company.

To leverage our success with OraQuick® and UP*link*™ *to become the world's leading point-of-care diagnostics company.*

To deliver superior diagnostic solutions through the use of the most user friendly and technologically advanced sample collection, detection, information, and confirmation technologies.

To be entrepreneurial, build a culture based on our Core Values (Trust, Agility, Innovation, and Quality) and work to exceed stakeholder expectations.

Strategy for Major Technology Platforms.

Expand the use of ***OraSure®*** *and* ***Intercept®*** *for a broad range of laboratory-based oral fluid applications, with a focus on infectious disease, substance abuse, and insurance risk assessment testing.*

Establish ***OraQuick®*** *as the most versatile point-of-care device for infectious disease testing for the global public health marketplace.*

Establish **UP*link*™** *as the most versatile point-of-care testing system available, capable of delivering diagnostic results from virtually any biological specimen, in a broad variety of testing applications.*

Partner to make our Up-Converting Phosphor Technology, or ***UPT™****, the preferred label detection technology for use in a wide range of diagnostic applications.*

A mission statement and business strategy are essential to any company, but what is most important to our stockholders is that we increase stockholder value. On that point, I would like to highlight our 2001 financial and operating accomplishments, discuss our disappointments, and focus on what we need to do in the future.

The 2001 Financial Highlights.

- Total revenues increased 13% to $32.6 million in 2001. Excluding the discontinued Serum Western Blot product, revenues increased roughly 20% over 2000.
- Net Loss was $3.7 million, compared to a net loss of $12.7 in 2000. Merger-related costs in 2000 equaled $7.6 million.
- Our gross margin increased to 62% in 2001 compared to 61% in the previous year.
- Sales of OraSure® and OraQuick® to the infectious disease testing market increased 67% to $5.8 million in 2001.
- Sales of Intercept® and other drug assays and related equipment in the substance abuse testing market increased 119% to $7.0 million in 2001.
- At December 31, 2001, working capital equaled $19.8 million.

The 2001 Operating Highlights.

- Integrated two different corporate cultures (Epitope and STC) on opposite sides of the United States.
- Addressed significant regulatory compliance issues on the west coast, including discontinuing the unprofitable Serum Western Blot product line.
- Moved OraQuick® manufacturing to Bethlehem, Pennsylvania, and completed the clinical trials and submitted a pre-market approval application to the FDA for our OraQuick® HIV-1 fingerstick whole blood test.
- The Centers for Disease Control and Prevention ("CDC") selected OraQuick® for its Maternal Infant Rapid Intervention at Delivery (MIRIAD) Project to test pregnant women in five U.S. metropolitan areas in an effort to reduce mother-to-child HIV-1 transmission.
- OraQuick® was selected for use in the CDC's Life Initiative, an effort to address the AIDS epidemic in certain African countries.
- Achieved substantial post merger cost synergies, estimated at more than $4 million.
- Expanded our senior management team with the additions of Ron Spair, Executive Vice President and Chief Financial Officer, Dr. Sal Salamone, Senior Vice President, Research and Product Development, and Eve Damiano, Vice President, Regulatory Affairs.
- Made great advances toward commercializing the UP*link*™ drugs of abuse rapid detection system for oral fluid, including submission of a 510(k) application to the FDA in June 2001.
- Intercept®, our new lab-based oral fluid drug test, gained great visibility as sales increased from virtually zero to more than $3.4 million in 2001.
- UPT™ continued to gain credibility and visibility as it was featured prominently in several peer review conferences and journals, including the Oak Ridge Conference, Nature Biotechnology, and The Journal of Clinical Chemistry.

The list of accomplishments is substantial, and it bodes well for the future of our Company, but there were also some disappointments that must be overcome, and we must take

steps to improve in several areas. The most important ones are as follows:

Our Disappointments.

- Revenue Shortfalls – Despite a 20% increase in total revenues in 2001 (excluding discontinued products), we fell short of the financial projections we communicated both externally and internally. Whether we can meet our future projections for 2002 will depend on several factors, including timely receipt of regulatory approvals and market acceptance of our new products, and the timely startup of several new distributors.
- Sales of OraQuick® to Africa – Despite extensive efforts to develop international markets for OraQuick®, our African distributor failed to meet its minimum purchase obligations and we were forced to terminate the distributor and record a $600,000 reserve for OraQuick® finished inventory in 2001. As a result, we are reevaluating our international distribution strategy and will likely refocus our sales efforts on public health organizations, such as the World Health Organization and the CDC.
- Delays in UP*link*™ Commercialization – Unfortunately, the development, commercialization and receipt of FDA clearance for the UP*link*™ drugs of abuse rapid detection system has not occurred as quickly as the Company expected. In addition, the development of UP*link*™ applications for infectious disease tests with our partner, Meridian Bioscience, is running behind schedule. We have intensified our efforts to complete these projects in 2002.
- Sales to the Insurance Risk Assessment Market – Insurance risk assessment revenues declined 20% to roughly $11.7 million in 2001, as a result of the discontinuation of the Company's Serum Western Blot confirmatory test, improved customer operating efficiencies, and inventory consolidations resulting from the merger of our two largest insurance customers, Lab*One*, Inc. and Osborne Group, Inc. We consciously discontinued the unprofitable Serum Western Blot product due to regulatory issues, but were surprised by the full impact of the Lab*One* and Osborne merger. Since these customers together accounted for about 29% of our sales in 2001, we need to work with them more closely and accelerate our new product offerings in order to reduce our dependency on them.

Despite these challenges, I remain extremely optimistic about our future and am convinced that we have the right technology platforms and management team to meet our goals. Since becoming the Chief Executive Officer on January 31, 2002, I have met with many of our institutional investors and I have communicated this vision and the following priorities for 2002:

2002 Priorities.

- Sign up additional Intercept® distributors.
- Resubmit UP*link*™ five panel DOA test for FDA review by mid-year and secure clearance by the end of 2002.
- Secure a distribution partner for OraQuick® for the hospital market in the United States.
- Prepare for an FDA inspection of our facility for OraQuick® in the second quarter of 2002.
- Secure FDA approval of OraQuick® for fingerstick whole blood HIV-1 testing, and begin sales in the second half of 2002.
- Begin clinical trials of OraQuick® for oral fluid HIV-1 testing and submit an application for this product to the FDA by the second half of 2002.
- Focus on delivering against expectations for our two UP*link*™ partners, Dräger Safety AG and Meridian Bioscience.
- Seek additional UP*link*™ and OraQuick® partnerships in the second half of 2002.
- Communicate routinely with our investors regarding our progress against these priorities.

If we meet our 2002 priorities, I believe that we will be in a great position to create substantial value for our stockholders.

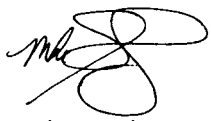
I have gone on record since becoming the Chief Executive Officer that I believe we can increase this Company's revenues to $100 million or more over the next three to five years, by executing our mission to be the world's best oral fluid diagnostics company. We can achieve this near term goal by offering a broad array of both lab-based and point-of-care platforms for testing for infectious disease and drugs of abuse in an oral fluid specimen.

Finally, on the personal side, I want to express my deep appreciation to Bill Hinchey, the Company's Senior Vice President of Marketing, Drugs of Abuse and co-founder and principal stockholder of STC, who retired at the end of 2001, and Dr. Richard George, the Company's Senior Vice President, Research and Development and long-time Chief Science Officer at Epitope, who has recently transitioned to a part-time consulting role with OraSure. Bill and Richard have made significant contributions to our Company over the years and the Company wishes them well in their future endeavors.

There will undoubtedly continue to be bumps along the way, but our purpose is clear, and we will work diligently to exceed the expectations of all our stakeholders. They include our customers, stockholders, employees, families, suppliers, and the communities in which we live.

Thanks for your continued support.

Sincerely,



Mike Gausling,
President and CEO

April 12, 2002

Statements set forth above regarding future events or performance are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The Company's 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 in the sections entitled "Forward-Looking Statements" and "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2001, which accompanies this letter. Readers are cautioned not to place undue reliance on the forward-looking statements as such statements may not be reliable. The Company undertakes no duty to update the forward-looking statements after the date of this letter.

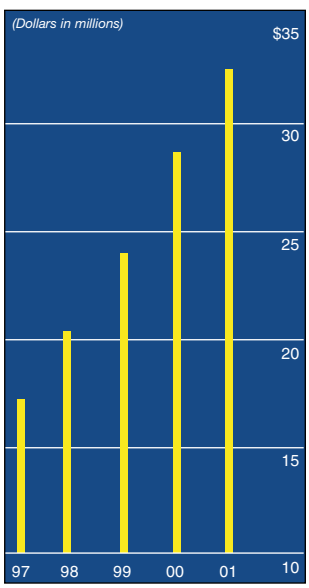
Selected Financial Information

(In thousands, except share data, ratios, and number of employees)

	December 31,		September 30,		
	2001	**2000**	**1999**	**1998**	**1997**
Operating Results for the Year Ended					
Total revenue	$32,573	$28,788	$24,046	$20,444	$17,282
Net loss	$(3,728)	$(12,747)	$(4,233)	$(2,374)	$(23,590)
Net loss per share	$(0.10)	$(0.36)	$(0.14)	$(0.09)	$(0.90)
Weighted average shares outstanding	36,868	35,002	30,597	26,180	26,055
Financial Position as of:					
Working capital	$19,764	$21,440	$16,773	$8,725	$12,470
Total assets	$37,285	$37,736	$30,251	$20,783	$25,978
Long-term debt less current portion	$3,586	$4,644	$5,820	$6,001	$4,026
Total liabilities	$10,744	$11,564	$11,659	$10,082	$8,106
Total stockholders' equity	$26,541	$26,172	$18,592	$10,701	$17,873
Current ratio	3.8:1	4.2:1	4.2:1	3.2:1	4.2:1
Total liabilities to equity	0.4:1	0.4:1	0.6:1	0.9:1	0.5:1
Other Data					
Capital expenditures	$2,764	$3,691	$1,829	$3,569	$1,564
Full-time employees	221	210	171	163	196

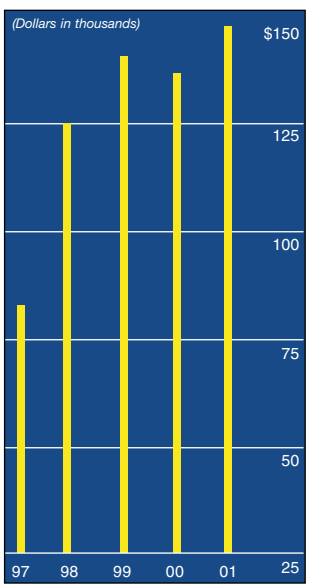
As a result of the merger of STC Technologies, Inc. and Epitope, Inc. into OraSure Technologies, Inc., and the change in fiscal year-end of Epitope from September 30 to December 31, OraSure's financial position as of September 30, 1997, 1998 and 1999, and the operating results for each of the three years in the period ended September 30, 1999, reflect Epitope's previous September 30 fiscal year amounts and STC's December 31 calendar year amounts for the corresponding fiscal years of Epitope. This information should be read in conjunction with OraSure's Financial Statements and notes thereto included in Item 14 of the Company's Annual Report on Form 10-K for the year ended December 31, 2001.

REVENUES



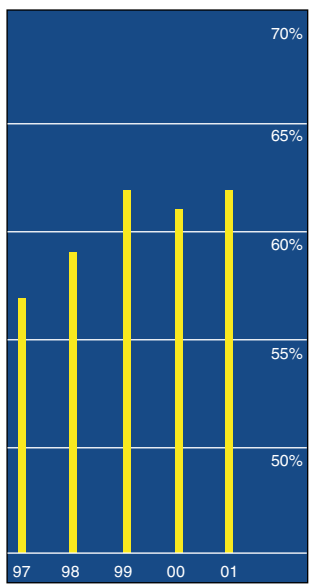
- Revenues increased 13% to $32.6 million in 2001.

REVENUE PER EMPLOYEE



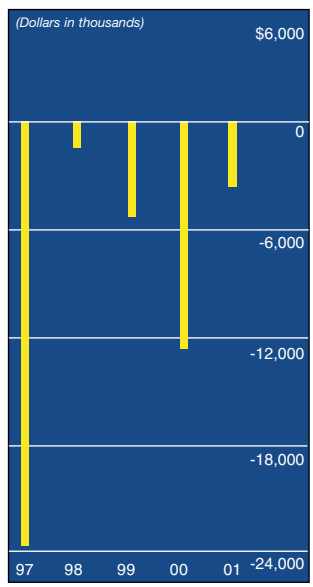
- Revenue per employee approached $150,000 in 2001.

GROSS MARGIN PERCENTAGE



- Gross margin has improved five percentage points from 1997 to 2001.

NET INCOME



- Net loss of $3.7 million in 2001 includes $0.5 million of restructuring related expenses.

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, 2001.

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. 1-10492

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.)**
150 Webster 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. ☐

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, as of March 22, 2002: $182,120,931

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of March 22, 2002: 37,442,541 shares.

Documents Incorporated by Reference:

Portions of Registrant's Definitive Proxy Statement for the 2002 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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Statements contained in this Annual Report on Form 10-K regarding future events or performance are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The Company's 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 the Company, 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.

On September 29, 2000, STC Technologies, Inc., a Delaware corporation (''STC''), and Epitope, Inc., an Oregon corporation (''Epitope''), were merged (the ''Merger'') into OraSure Technologies, Inc. (''OraSure Technologies'' or the ''Company''), a new corporation that was organized on May 5, 2000 under Delaware law solely for the purposes of combining STC and Epitope and changing the state of incorporation of Epitope from Oregon to Delaware. The companies were merged pursuant to an Agreement and Plan of Merger, dated May 6, 2000, by and among Epitope, STC and the Company. The stockholders of STC and Epitope approved the Merger Agreement on September 29, 2000.

Epitope historically reported its financial results on the basis of a fiscal year ending September 30, while STC previously reported its financial results on a calendar year basis. Immediately prior to the Merger, Epitope adopted a calendar year for financial reporting purposes. As a result, financial information presented in this Report for 2001 and 2000 reflect results for the calendar years ended December 31, 2001 and 2000, respectively. Since Epitope did not adopt a calendar year reporting period until 2000, the financial information for 1999 reflects the results of Epitope for the twelve-months ended September 30, 1999 and the results of STC for the twelve months ended December 31, 1999. See Note 1 to the Company's Financial Statements for a discussion of the Merger and the change in fiscal year end.

General

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

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

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

Products

OraSure Technologies' business focuses on the following principal platform technologies: (1) the OraSure® and Intercept® oral fluid collection devices, (2) the OraQuick® rapid diagnostic test device, and (3) the new up-

converting phosphor technology (''UPT''), including its first application, UP*link*™, a lateral flow testing system for various analytes. In addition, the Company sells certain other products, including the Histofreezer® portable cryosurgical system, certain immunoassay tests and reagents for insurance risk assessment, substance abuse testing and forensic toxicology applications, an oral fluid Western Blot confirmatory test for the Human Immunodeficiency Virus Type 1 (''HIV-1''), and the Q.E.D.® saliva alcohol test.

OraSure®/Intercept® Collection Devices

The Company's OraSure® oral fluid collection device is used in conjunction with screening and confirmatory tests for HIV-1 antibodies and other analytes. The 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 antibodies and analytes than saliva. As a result, OMT testing is a highly accurate method for detecting HIV-1 infection and other analytes. The Company believes that oral fluid testing has several significant advantages over blood or urine-based testing systems for both health care professionals and individuals being tested, including 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 eliminating the cost of administration by a trained health care professional.

The Company has received approval from the U.S. Food and Drug Administration (''FDA'') to sell the OraSure® oral fluid collection device for use with a laboratory-based enzyme immunoassay (''EIA'') screening test for HIV-1 antibody detection. HIV-1 antibody detection using the OraSure® collection device involves three steps: (1) collection of an oral fluid specimen using the OraSure® device, (2) screening of the specimen for HIV-1 antibodies at a laboratory with an EIA screening test, and (3) laboratory confirmation of any positive screening test results with the OraSure® 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. The Company has also received FDA clearance for use of the OraSure® collection device with EIAs to test for cocaine and cotinine (a metabolite of nicotine) in oral fluid specimens.

The Company sells the OraSure® collection device in the insurance market for screening life insurance applicants for HIV-1, cocaine and cotinine, and in the public health market for HIV-1 testing.

A collection device substantially similar to the OraSure® device comprises the Company's Intercept® oral fluid drug testing service. The Company has received FDA 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, and phencyclidine (''PCP'')), and for barbiturates and methadone. The Company also sells, or arranges for a third party vendor to sell, equipment required by its laboratory customers to test oral fluid specimens collected with the Intercept® device. Intercept® is sold in the workplace testing, public health, criminal justice and drug rehabilitation markets.

The Company believes that the Intercept® service has several advantages over certain competing products for drugs-of-abuse testing, including its lower cost, 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 workplace administrators to test for employee impairment on demand, eliminate scheduling costs, and streamline the testing process.

OraQuick® Rapid Test

OraQuick® is the Company's rapid test platform designed to test an oral fluid, whole blood or serum/plasma sample for the presence of various antibodies or analytes. The device includes a porous flat pad used to collect an oral fluid specimen. After collection, the pad is inserted into a vial containing a pre-measured amount of

developer solution and allowed to develop. When whole blood is to be tested, a loop collection device is used to collect a drop of blood and mix it in the developer solution, after which the collection pad is inserted into the solution. The specimen and solution then flow through the testing device where test results are observable in approximately 20 minutes. The OraQuick® device is a screening test and requires a confirmation test where a positive result is obtained.

The Company's first product utilizing this technology is the OraQuick® HIV device, a rapid test for the presence of antibodies against HIV. On June 23, 2000, the Company received approval for an Investigational Device Exemption (''IDE'') from the FDA authorizing the commencement of formal clinical trials for the OraQuick® HIV device. Due to the critical need for an FDA-approved rapid HIV test, the Company, after consultation with the FDA and the Centers for Disease Control and Prevention (''CDC''), submitted an initial application on June 29, 2001 for pre-market approval for testing of whole blood for HIV-1. The Company expects to submit an application to the FDA for approval of an OraQuick® test for HIV-1 in oral fluid in 2002.

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

At the CDC's Rapid Diagnostic's Meeting in February 2001, the CDC released the most recent results of its ongoing multi-product, rapid HIV test study, which was conducted independently from the Company's clinical trials used for its FDA submission. These results indicated a 100% sensitivity and 99.5% specificity for the OraQuick® device with whole blood samples. In addition, at the 9th Conference on Retroviruses and Opportunistic Infections in February 2002, the CDC released additional clinical results which indicated a 98.6% sensitivity and 98.9% specificity for the OraQuick® device with oral fluid samples. Sensitivity is a measure of the accuracy in detecting positive samples and specificity is a measure of the accuracy in measuring negative samples.

In July 2000, the Company introduced the OraQuick® HIV device for sale outside the United States at the International AIDS Conference in Durban, South Africa. Clinical tests for the OraQuick® HIV device using oral fluid specimens have been completed in Thailand, with the results demonstrating 100% sensitivity and 99.9% specificity. The World Health Organization is presently evaluating the OraQuick® HIV device.

The Company intends to market the OraQuick® HIV device, either directly or through distributors, in the hospital, physician office and public health markets in the United States and internationally. Agreements with distributors will be necessary for the Company to fully exploit domestic and international opportunities.

The Company initially intends to sell an OraQuick® device for the detection of HIV-1 in the United States and certain developed countries, and an OraQuick® device for the detection of both HIV-1 and the Human Immunodeficiency Virus Type 2 (''HIV-2') in certain foreign countries. The Company may need to obtain licenses or other rights under, or to enter into distribution or other business arrangements in connection with, certain patents related to HIV-2 and lateral flow technology, in order to market the OraQuick® HIV device in the United States and certain other countries. See the Section entitled ''Risk Factors—Patent Issues Affecting OraQuick®'' for a further discussion of these issues.

UPT™ and UP*link*™

Up-Converting Phosphor Technology. Up-Converting Phosphor Technology (''UPT™'') is a proprietary label detection platform being developed by the Company 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. The Company and its research partners have developed phosphorescent particles that up-convert infrared light to visible light, which the Company believes is a platform technology with broad applications.

Phosphor particles have been used for decades in television screens and in fluorescent light bulbs. When high energy ultraviolet light strikes the phosphor-coated area in a screen or bulb, it excites the particles and low energy visible colored light is produced. The Company's 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 colored light signal creates 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 colored light (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.

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

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

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

UP*link*™. UP*link*™ is the Company's first product application based on UPT™. UP*link*™ is designed to be a rapid, point-of-care system utilizing a collector, lateral flow test cassette, and analyzer, which provides instrument-read quantitative results in about 10 minutes on a variety of samples, including oral fluid, blood, serum, urine and stool samples.

In March 2000, the Company signed a research and development agreement with Dräger Safety AG & Co. KGaA (formerly Dräger Sicherheitstechnik GmbH) (''Dräger''), a European manufacturer and supplier of medical and safety technology products for health care and industrial applications, to develop and optimize an UP*link*™ system for rapid detection of drugs of abuse in oral fluid. The UP*link*™ system developed with Dräger is expected to be marketed initially to law enforcement officials as a system 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. As part of the research and development agreement, the Company received a non-refundable fee and will receive additional fees upon achievement of technical milestones. Upon successful completion of such research and development activities, Dräger has the option to become the Company's exclusive distributor of the UP*link*™ drugs of abuse rapid detection system in Europe and certain other countries in the markets described above.

In June 2001, the Company submitted an application for 510(k) clearance from the FDA for its UP*link*™ analyzer and six oral fluid drugs-of-abuse assays—cocaine, opiates, amphetamines, methamphetamine, PCP and marijuana. The FDA subsequently requested additional data for the analyzer and each of the six drug assays. On January 31, 2002, the Company resubmitted to the FDA an application containing the additional data for the UP*link*™ analyzer and the assay for opiates, and expects to resubmit one or more applications for the remaining UP*link*™ assays in 2002. The UP*link*™ drug testing system is expected initially to be marketed by the Company in the United States in the unregulated criminal justice market. After receipt of FDA clearance for all of the six oral fluid drugs-of-abuse assays, this product will be marketed by the Company or its distributors in the regulated workplace market in the United States.

In September 2000, OraSure Technologies signed a research and development agreement with Meridian Bioscience, Inc. (formerly Meridian Diagnostics, Inc.) (''Meridian''), a medical diagnostics company. Under this agreement, the Company and Meridian plan to develop a broad range of UP*link*™ point-of-care tests for the rapid detection of parasites, and gastrointestinal and upper respiratory diseases. Pursuant to a related supply agreement, Meridian will serve as a worldwide distributor of the analyzers and lateral flow cassettes developed under the research and development agreement. The Company has received and is eligible in the future to receive payments upon achievement of certain milestones and royalties from the sale of the analyzers and testing devices. OraSure Technologies has commenced work on the development of two tests under the research and development agreement and expects Meridian to submit an application for FDA 510(k) clearance of the first such test in 2002. UP*link*™ products developed with Meridian will be manufactured by the Company and are expected to be marketed by Meridian in the hospital market.

Histofreezer®

In 1991, the Company became the exclusive United States distributor of the Histofreezer® portable cryosurgical system, a low-cost alternative to liquid nitrogen and other eradication methods for removal of warts and other benign skin lesions. In June 1998, the Company acquired the Histofreezer® product from Koninklijke, Utermöhlen, N.V., The Netherlands. As part of the acquisition, the Company established a sales office in Reeuwijk, The Netherlands, and is selling the Histofreezer® product through a dealer network in more than 20 countries worldwide.

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 lesion for 15 to 40 seconds (depending on the type of lesion) creating localized destruction of the target area. Histofreezer® is sold in several canister sizes. Sales of this product have been targeted to primary care physicians such as pediatricians, general and family practitioners, and other physician segments that traditionally referred patients to dermatologists to remove warts. The Company has established a national network of distributors to reach the physician office market in the United States.

Immunoassay Tests and Reagents

The Company develops and sells immunoassay tests in two formats, MICRO-PLATE and AUTO-LYTE®, to meet the specific needs of its customers.

AUTO-LYTE® tests are sold in the form of bottles of liquid reagents. The 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 laboratories to detect certain drugs or chemicals in urine. Test results are produced quickly, allowing for high throughput.

In the MICRO-PLATE kit, the sample to be tested is placed into a small plastic receptacle, called a microwell, along with the reagents. The result of the test is determined by the color of the microwell upon completion of the reaction. Controlling the reaction involves the use of a variety of reagents by laboratory personnel. Test results are analyzed by any of a variety of commercially available laboratory instruments which may also be provided by the Company. OraSure Technologies has used this testing format to develop tests that detect substances in urine, serum, sweat, and oral fluid specimens.

OraSure Technologies currently markets the MICRO-PLATE oral fluid test for use in screening life insurance applicants to test for two of the most important underwriting risk factors: cocaine and cotinine (a metabolite of nicotine). The Company sells the reagents to insurance testing laboratories, which provide the laboratory testing to insurance companies, often in combination with the OraSure® oral fluid collection device. AUTO-LYTE® tests are marketed for use in testing urine samples for cocaine and cotinine and for performing a variety of urine chemistries for insurance risk assessment purposes.

The Company also develops, manufactures, and sells toxicology and drugs-of-abuse tests in the MICRO-PLATE format. These 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. The Company's toxicology and drugs-of-abuse test products are currently sold in the forensic toxicology, criminal justice, drug rehabilitation, and workplace testing markets.

Whenever possible, the Company enters into multi-year sales agreements with its customers. These agreements generally are entered into with a laboratory which has agreed to purchase a minimum number of tests over a two-to-five-year period. The Company also offers these customers the option of a reagent rental agreement pursuant to which the Company sells 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.

Western Blot HIV-1 Confirmatory Test

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

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

Q.E.D.® Saliva Alcohol Test

The Q.E.D.® saliva alcohol test is an on-site, cost-effective test device that is an alternative to breath or blood alcohol testing. The test is a quantitative, saliva-based method for the detection of ethanol, and has been cleared for sale by the FDA and the U.S. Department of Transportation (''DOT''). In 1997, the product also received a waiver under the Clinical Laboratory Improvement Act of 1988. Each Q.E.D.® test kit contains a collection stick which 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.

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.

Products Under Development

OraSure®/Intercept® Applications

Oral mucosal transudate contains many constituents found in blood and serum, although in lower concentrations. The Company therefore believes the OraSure® and Intercept® devices are a platform technology with a wide variety of potential applications, where laboratory testing is available. For example, the OraSure® device may be useful for the diagnosis of a variety of infectious diseases or conditions in addition to HIV-1, such as viral hepatitis and diabetes. OraSure Technologies has entered into an agreement with LabOne, Inc. to develop a laboratory-based oral fluid screening test for Hepatitis C using the OraSure® collection device. The Company is developing an alcohol assay and has an application pending with the FDA for 510(k) clearance of an assay for benzodiazepine, each of which would be used in connection with the Intercept® drug testing service. Based on a reassessment of marketability, the Company has discontinued development of an improved formulation of the OraSure® device, known as OraSure® II, and a laboratory-based oral fluid screening test for syphilis.

OraQuick® Platform

The Company believes that OraQuick® has significant potential as a rapid test for physicians' offices, hospitals, and other professional use. Like the OraSure® device, the Company believes that OraQuick® provides a platform technology that can be modified for detection of a variety of infectious diseases in addition to HIV, such as viral hepatitis and other diseases.

The National Institutes of Health (''NIH'') previously approved a grant of approximately $1 million to fund Phase II of the Company's project to develop a screening and confirmation test for syphilis. Although initially intended to fund a lab-based test using the OraSure® collection device, the NIH approved the use of this grant instead for development of a screening test for syphilis using the OraQuick® platform. During the first quarter of 2002, the Company reevaluated the marketability of a syphilis test and, based on that reevaluation, has elected to terminate this project.

UPT™ and UP*link™ Development*

The Company is in the final stages of developing the UP*link™* drugs-of-abuse rapid detection system under its agreement with Dräger and for its own commercial applications in the United States. The Company has commenced development of two tests for infectious diseases and expects to commence development of

additional tests for other infectious diseases under its agreement with Meridian. The Company has identified other potential applications of UPT™, including human clinical testing for cancer, allergies, and thyroid and cardiac conditions, therapeutic drug monitoring, biological warfare testing, food and environmental testing, pharmaceutical research, genomics and pharmacogenomics, veterinary testing, and surgical imaging. In addition, the Company is studying the feasibility of using UPT™ labels for the detection of infectious diseases with DNA probes. The Company has not yet chosen which potential UPT™ applications to pursue or the manner in which these opportunities will be pursued, but believes it will need to enter into partnering arrangements with other entities to exploit the potential of UPT™.

Western Blot HIV-1 Confirmatory Test

The Company believes its existing oral fluid Western Blot confirmatory test for HIV-1 can be used for testing of serum plasma specimens and is contemplating expanding the use of this product for these applications. Whether the Company elects to do so will depend on a further assessment of the market for these applications, the Company's ability to overcome the low production yields and quality control issues which led to the discontinuation of its Serum Western Blot HIV-1 confirmatory test in 2001, and the Company's ability to obtain FDA approval for these new uses.

Research and Development

In 2001, research and development activities focused on the continued development of the UP*link*™ analyzer, test cassette and collector, the development of certain UP*link*™ drugs of abuse and infectious disease assays, DNA feasibility studies, and clinical trials for the OraQuick® rapid HIV-1 test.

The Company supplements its own research and development activities by funding external research. The Company has funded research at Leiden University, SRI International, Lehigh University and certain other entities, and intends to continue funding external research.

Research and development expenses totaled approximately $9.4 million in 2001, $10.4 million in 2000 and $5.6 million in 1999.

Sales and Marketing

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

The Company markets its products in the United States and internationally. Revenues attributable to customers in the United States amounted to $27.3 million, $24.8 million and $21.4 million in 2001, 2000 and 1999, respectively. Revenues attributable to international customers amounted to $5.3 million, $4.0 million and $2.7 million, in 2001, 2000 and 1999, respectively.

Insurance Risk Assessment

The Company currently markets 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. The Company sells the devices to insurance testing laboratories, which in turn provide the devices to insurance companies, usually in combination with testing services. The Company also maintains a direct sales force that promotes use of the OraSure® device directly to insurance companies. Insurance companies then make their own decision regarding which laboratory to use to supply their collection devices and testing services. The Company's OraSure® Western Blot confirmatory test is distributed through BMX and is used to confirm oral fluid specimens that 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. The Company's sales force continues to encourage additional insurance companies to use OraSure® and to extend the use of the product by existing customers. Several companies have expanded use of OraSure® to the $1 million and higher dollar policy amounts. This expansion is attributable to several factors, including increasing acceptance of the reliability of oral fluid testing, the high quality of test results, the low cost of oral fluid testing relative to blood tests, and the ease of use of the OraSure® device.

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

Infectious Disease Testing

The Company's sales personnel market products directly to customers in the public health market primarily for HIV-1 testing. This market consists of a broad range of clinics and laboratories and includes states, counties, and other governmental agencies, colleges and universities, correctional facilities and the military. There are also a number of organizations in the public health market such as AIDS service organizations and various community-based organizations set up primarily for the purpose of encouraging and enabling HIV-1 testing. To better serve this market, the Company has entered into agreements with Lab*One*, Inc. and Heritage Labs to provide prepackaged OraSure® test kits, with prepaid laboratory testing and specimen shipping costs included. The Company has sold the OraSure® and OraQuick® HIV devices in the international public health markets.

Substance Abuse Testing

The Company's substance abuse products are marketed into the workplace testing, forensic toxicology, criminal justice, and drug rehabilitation markets, through direct sales and distributors. The forensic toxicology market consists of 250-300 laboratories including federal, state and county crime laboratories, medical examiner laboratories, and reference laboratories. The criminal justice market consists of a wide variety of entities in the criminal justice system that require drug screening, such as pre-trial services, parole and probation officials, police forces, drug courts, prisons, drug treatment programs and community/family service programs. The Company has entered into agreements for the distribution of Intercept® collection kits and associated reagents for drugs-of-abuse testing in the workplace testing market in the United States and Canada through several laboratory distributors, including Lab*One*, Inc., Quest Diagnostics, Clinical Reference Laboratory and NWT, Inc., and internationally for workplace and forensic toxicology testing through Bio-Rad Laboratories, Altrix Plc and other distributors. The Company also distributes its Q.E.D.® saliva alcohol test primarily in the workplace testing market through various distributors.

Physicians' Offices

The Company sells the Histofreezer® product line to distributors that market to more than 150,000 primary care physicians and podiatrists in the United States. Major U.S. distributors include Cardinal Healthcare, McKesson HBOC, Physicians Sales & Service, Bergen Brunswig, and Henry Schein. Internationally, the Company markets Histofreezer® in a number of countries through a network of distributors.

International Markets

The Company sells a number of its products into international markets primarily through distributors with knowledge of their local markets. Principal markets include physicians' offices, insurance risk assessment, public

health, and laboratory testing. The Company assists its distributors in registering the products and obtaining required regulatory approvals in each country and provides training and support materials. The Company's 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 the Company's financial performance, accounting for 15% or more of total revenues during the past three years. The Company's OraSure® and Intercept® oral fluid collection devices, Histofreezer®, and immunoassay tests and reagents accounted for total revenues of approximately $13.0 million, $6.7 million and $7.4 million in 2001, $11.2 million, $6.8 million, and $6.7 million in 2000, and $7.8 million, $5.7 million, and $6.2 million in 1999, respectively. As new products are developed and commercialized, the Company expects to reduce its dependence on the products referred to above.

The Company has one customer, Lab*One*, Inc., that has accounted for 10% or more of total revenues. Lab*One* recently acquired Osborne Group, Inc., another customer of the Company in the insurance testing market. During 2001, the Company's sales to Lab*One*, Inc. and Osborne Group, Inc. together accounted for approximately 29% of the Company's total revenues. As a result of its acquisition of Osborne, Lab*One* has achieved certain operating efficiencies and reduced its overall inventory levels which in turn lowered purchases of the Company's insurance testing products during the fourth quarter of 2001. While the Company believes that its relationship with Lab*One* is good, there can be no assurance that sales to this customer will not decrease further or that this customer will not choose to replace the Company's products with those of competitors. The loss of this customer or a significant decrease of products purchased by it would have a material adverse effect on the Company.

Supply and Manufacturing

The Company has entered into an agreement with a contractor in the United States for the assembly and supply of OraSure® and Intercept® oral fluid collection devices through December 31, 2002. This agreement will automatically renew for additional annual periods unless either party provides timely notice of termination prior to the end of an annual period. The Company believes that other firms or the Company would be able to manufacture the OraSure® and Intercept® devices on terms no less favorable than those set forth in the agreement with the contractor in the event that this contractor were to be unable or unwilling to continue manufacturing this product. A change in manufacturer of these devices would require FDA review and approval which could require significant time to complete and could disrupt the Company's ability to manufacture and sell the OraSure® and Intercept® devices. The Company expects to transfer manufacturing of its OraSure® and Intercept® collection devices to its Bethlehem, Pennsylvania facility during 2003.

In the second quarter of 2001, the Company completed a realignment of its manufacturing operations, which included the elimination of the manufacturing of OraQuick® in the Beaverton, Oregon facility, the installation of automated manufacturing equipment for OraQuick® in Bethlehem, Pennsylvania, and the addition of contract manufacturing capacity in Thailand. In connection with this realignment, the Company entered into a supply agreement for the manufacture of the OraQuick® HIV testing device in Thailand. This agreement has an initial term of one year, and will automatically renew for additional annual periods unless either party provides a timely notice of termination prior to the end of an annual period. The Company believes that other firms would be able to manufacture the OraQuick® test on terms no less favorable than those set forth in the agreement in the event that the Thailand contractor would be unable or unwilling to continue manufacturing this product.

The Company can purchase the HIV antigen required for the OraQuick® product only from a limited number of sources. This antigen is currently purchased from a contract supplier under a long-term agreement with an initial term ending in January 2010 and one-year automatic renewal terms thereafter. If for any reason the supplier should no longer be able to supply the Company's antigen needs, the Company believes that an

alternative supply could be obtained at a competitive cost. However, a change in the antigen would require FDA approval which could require significant time to complete and could disrupt the Company's ability to manufacture and sell the OraQuick® device in the United States.

The Company expects to assemble analyzers, test cassettes and collectors used in the Company's UP*link*™ drugs of abuse rapid detection system and to package this product for shipment at the Company's Bethlehem, Pennsylvania facilities.

The Company's oral fluid Western Blot HIV-1 confirmatory test is manufactured in the Company's Beaverton, Oregon facility. The HIV antigen needed to manufacture the Company's Western Blot HIV-1 confirmatory test kits is available from only a limited number of sources. The Company purchases antigen and certain other materials for this product from BMX, which is also the exclusive distributor of the test kits. BMX is required to supply the Company's requirements for antigen and other materials for the term of its distribution agreement with the Company, which originally expired on March 31, 2001. OraSure Technologies and BMX are currently negotiating certain amendments to the agreements, including an extension of their terms. If for any reason BMX is no longer able to supply the Company's antigen and other material needs, the Company would be able to obtain alternate supplies at a competitive cost, although a change in the antigen would require FDA approval which could require significant time to complete and could disrupt the Company's ability to manufacture and sell its Western Blot HIV-1 confirmatory test.

Histofreezer® is manufactured in The Netherlands by Koninklijke, Utermöhlen, N.V. (''Utermöhlen''), the company from which the Company acquired the product in 1998. The Company purchases the product pursuant to an exclusive production agreement between the two companies. The production agreement provides that Utermöhlen shall be the exclusive supplier of the Histofreezer® product until at least December 31, 2006. The Company believes that additional manufacturers of the Histofreezer® product are available on terms no less favorable than the terms of the production agreement with Utermöhlen in the event that Utermöhlen would be unable or unwilling to continue manufacturing the Histofreezer® product.

The Company's AUTO-LYTE® and MICRO-PLATE assays are manufactured at its Bethlehem, Pennsylvania, facility. The Company manufactures the test components and assembles and packages the tests for distribution. The Company's tests require the production of highly specific and sensitive antibodies corresponding to the antigen of interest. Substantially all of the Company's antibody requirements are provided by contract suppliers. However, in 1999, the Company began to develop its own in-house monoclonal and polyclonal antibody capabilities. The Company believes that it maintains adequate reserves of antibody supplies and believes it has access to sufficient raw materials for these products.

AUTO-LYTE® test kits are manufactured by adding specific antibodies to chemical solutions which are then packaged as a defined volume of liquid in a plastic container to be run on laboratory equipment. MICRO-PLATE test kits are produced by placing purified antibodies into plastic microwells which are sent to customers in multiples of 96 tests along with a set of reagents necessary to control the reaction.

The Q.E.D.® saliva alcohol test is manufactured, packaged, and shipped from the Company's Bethlehem, Pennsylvania facility.

Employees

As of December 31, 2001, the Company had 221 full-time employees, including 46 in sales, marketing, and client services; 80 in research and development; 77 in operations, manufacturing, quality control, purchasing and shipping; and 18 in administration and finance. Sixteen of the Company's employees hold Ph.D. degrees. The Company's employees are not represented by a collective bargaining agreement.

During 2001, the Company completed a realignment of its manufacturing operations, pursuant to which employee headcount was reduced in its Beaverton, Oregon facility by approximately 33%. The reduction was

accomplished primarily through layoffs and attrition during the first half of 2001. During the first quarter of 2002, the Company implemented a 10% reduction in force as a result of lower than anticipated sales levels during 2001 and the elimination of certain development projects.

Competition

The diagnostic industry is a multi-billion dollar international industry and is intensely competitive. Many of the Company's competitors are substantially larger and have greater financial, research, manufacturing, and marketing resources. Important competitive factors for the Company's products include product quality, price, ease of use, customer service, and reputation. Industry competition is based upon scientific and technological capability, proprietary know-how, access to adequate capital, the ability to develop and market products and processes, the ability to attract and retain qualified personnel, and the availability of patent protection.

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

Competition is expected 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 the Company's products impractical, uneconomical or obsolete. There can be no assurance that the Company's competitors will not succeed in developing or marketing technologies and products that are more effective than those developed by the Company or that would render its technologies and products obsolete or otherwise commercially unattractive. In addition, there can be no assurance that competitors will not succeed in obtaining regulatory approval for these products, or in introducing or commercializing them before the Company. Such developments could have a material adverse effect on the Company's business, financial condition, and results of operations.

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

Several companies market or have announced plans to market oral specimen collection devices and tests outside the United States. The Company expects the number of devices competing with its OraSure® device to increase as the benefits of oral specimen-based testing become more widely accepted.

The FDA has approved an HIV-1 screening test for use with a urine sample. In June 1998, the FDA notified Cambridge Biotech Corp. (acquired by Calypte, Inc. in December 1998) that it had approved the use of its HIV-1 Western Blot confirmatory test for use with urine samples. Urine testing will compete in the same markets as the Company's products. The Company believes that urine collection can be logistically more difficult, inconvenient, and potentially embarrassing for the individual being tested, and that privacy and chain-of-custody issues are further impediments to routine use of urine-based HIV tests. The Company cannot predict the impact of the availability of urine-based tests on the HIV testing market or on sales of the Company's products.

Significant competitors in the rapid assay HIV testing market include Abbott Laboratories, the Ortho Diagnostics division of Johnson & Johnson, Bio-Rad Laboratories, Trinity Biotech Plc, MedMira Laboratories, Inc. and Chembio Diagnostic Systems, Inc.

In the insurance risk assessment market, the Company's AUTO-LYTE® homogeneous assays for cocaine and cotinine compete with reagents from Microgenics, Inc. (a subsidiary of Sybron Lab Products). The Company's AUTO-LYTE® homogeneous assays for beta-blockers and thiazide as well as MICRO-PLATE heterogeneous assays specifically designed for the detection of cocaine, cotinine, and IgG in oral fluid are the only assays available in the marketplace. In urine chemistries, the Company's significant competitors include The Diagnostics Systems Group of Olympus America Inc.

The Company's 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. The Company's 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 are offered to these customers.

In the forensic toxicology market, the Company competes with both homogeneous and heterogeneous tests manufactured by a host of companies. Significant competitors in the market for these assays include Dade Behring, Microgenics, Inc., Abbott Laboratories, Roche Diagnostics, and Immunalysis.

The Intercept® drug testing system competes with a wide variety of drug testing products and services. These competitors can be divided into two groups: 1) rapid tests, and 2) laboratory-based services. Within each product or service group, drug testing can be further divided into testing matrices such as urine, hair, sweat and oral fluid. Major competitors in the laboratory-based urine drug testing market are Quest Diagnostics, Lab*One*, Inc., LabCorp., Psychemedics, PharmChem, and Medtox Laboratories. The Company's UP*link*™ product will also compete with other on-site, rapid drug assays. Major competitors in the rapid drug testing market include American Biomedica, Roche Diagnostics, Biosite Diagnostics, Avitar, Inc., LifePoint, Inc. and eScreen.

Within the sub-segment of oral fluid drugs-of-abuse testing, Intercept® and UP*link*™ will compete with Avitar, Inc., which markets a rapid drug test to the workplace and criminal justice markets, Ansys Technologies, Inc., which markets saliva alcohol and drug tests, and LifePoint, Inc., which has announced plans to sell a reader-based saliva test panel that will include alcohol testing.

Q.E.D.® has two direct competitors, Roche Diagnostics and Chematics. These companies offer semi-quantitative saliva-based alcohol tests and have received DOT approval. Indirect competitors who offer breath testing equipment include Intoximeters, Dräger, 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 the Company's Q.E.D.® test.

The Histofreezer® product's delivery system and warmer operating temperature than liquid nitrogen provide the Company with the opportunity to target sales to primary care physicians, such as family practitioners, pediatricians, and podiatrists. The Company does 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. 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. and Aurium Pharma Inc. In addition, liquid nitrogen is used by medical professionals to remove warts and other benign skin lesions. Lastly, patients may purchase various over-the-counter products to treat warts at home.

Patents and Proprietary Information

The Company seeks patent and other intellectual property rights to protect and preserve its proprietary technology and its right to capitalize on the results of its research and development activities. The Company also relies upon trade secrets, know-how, continuing technological innovations, and licensing opportunities to provide

it with competitive advantages in its selected markets and to accelerate new product introductions. Respecting the patent and intellectual property rights of others, the Company regularly searches for third-party patents in its fields of endeavor to shape its 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.

The Company has ten 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. The Company has also applied for additional patents, in both the United States and certain foreign countries, on such products and technology. The Company has one patent for the OraQuick® rapid HIV test in the United States and intends to apply for other patents for this product. The Company may need to obtain licenses or other rights under, or enter into distribution or other business arrangements in connection with, certain HIV-2 and lateral flow patents in order to market the OraQuick® HIV test in the United States and certain other countries. See the Section entitled, ''Risk Factors—Patent Issues Affecting OraQuick®,'' for a further discussion of these issues.

In April 1995, the Company received exclusive worldwide rights under patents and know-how owned by SRI International to develop and market products that involve the use of UPT™. The Company 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™. The Company has the right to sublicense these rights under the agreements subject to consent from SRI and Sarnoff.

Under the agreement with SRI, OraSure Technologies is required to make license, maintenance and royalty payments to SRI. The Company made an initial license payment to SRI in 1995 and paid research fees in 1995 and 1996 in connection with development projects in which SRI participated. The Company is obligated to make annual maintenance payments on each anniversary of the agreement following the completion of the development period until the first commercial sale of a product. The Company also must 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 SRI's license to the Company. The Company believes that the royalty rates payable by the Company are comparable to the rates generally payable by other companies under similar arrangements. The Company's agreement with SRI terminates upon the expiration of the Company's obligation to pay royalties to SRI.

In 1999, the Company paid $1.5 million to TPM Europe Holding B.V., its 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.

The Company has or has licensed rights under nine United States patents and numerous foreign patents for methods, compositions, and apparatuses relating to phosphor technologies. Several additional UPT™ patent applications remain pending in the United States and abroad. The Company expects to continue to expand its UPT™ patent portfolio in 2002. Several new patent applications were also filed by the Company in the U.S. for the design and methods used in the UP*link*™ rapid detection platform.

The Company has one U.S. patent relating to the Company's method for detecting blood in urine specimens and the Company's AUTO-LYTE® products.

The Company has three U.S. patents and numerous foreign patents issued for apparatuses and methods for the topical removal of skin lesions relating to its Histofreezer® device.

The Company has five U.S. patents and numerous foreign patents and patent applications for the analog-to-digital threshold signaling 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.

It is the Company's policy to require its employees, consultants, outside collaborators, and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with the Company. These agreements provide that all confidential information developed by or made known to the individual during the course of the individual's relationship with the Company, 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 at the Company will be the exclusive property of the Company.

The Company owns rights to trademarks and service marks that it believes are necessary to conduct its business as currently operated. The Company is the owner in the United States of trademarks, including UPT™, UP*link*™, OraSure®, Intercept®, OraQuick®, Histofreezer®, Q.E.D.®, and AUTO-LYTE®. The Company also is the owner of many of these marks and others in several foreign countries. The Company is not aware of any pending claims of infringement or other challenges to the Company's rights to use its marks in the United States or in other countries as currently used by the Company.

Although important, the issuance of a patent or existence of trademark or trade secret protection does not in itself ensure the Company's success. Competitors may be able to produce products competing with a patented Company product without infringing on the Company's 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 to the Company or to a licensor 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, and, if the outcome of such litigation is adverse to the owner of the patent, the owner's rights could be diminished or withdrawn. Trade secret protection does not prevent independent discovery and exploitation of the secret product or technique.

Government Regulation

General

Most of the Company's existing and proposed diagnostic 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 the Company's FDA-regulated products require some form of action by the FDA before they can be marketed in the United States, and, after approval or clearance, the Company 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.

Domestic Regulation

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

There are two review procedures by which medical devices can receive FDA clearance or approval. Some products may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, in which the manufacturer provides a pre-market notification that it intends to begin marketing the product, and shows 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 such 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 implementing regulations to have an approved application), the FDA must approve a pre-market approval application (''PMA'') before marketing can begin. PMAs must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA is typically a complex submission, including the results of preclinical and clinical studies. Preparing a PMA is a detailed and time-consuming process. Once a PMA has been submitted, the FDA is required to review the submission within 180 days. However, the FDA's review may, and often is, much longer, often requiring one year or more, and may include requests for additional data.

Biologic products must be the subject of an approved biologics license application (''BLA'') before they can be marketed. The FDA approval process for a biologic product is similar to the PMA approval process, involving a demonstration of the product's safety and effectiveness based in part on both preclinical and clinical studies.

Many of the insurance testing products are used for non-medical purposes and many of the drugs-of-abuse products sold to state crime labs are for forensic use. The Company intends initially to sell its UP*link*™ rapid drug detection system for law enforcement purposes into the criminal justice market. The FDA does not currently regulate products used for these purposes.

Every company that manufactures biologic products or 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. Compliance with QSRs is required before the FDA will approve an application, and these requirements also apply to marketed products. Companies are also subject to other post-market and general requirements, including compliance with restrictions imposed on marketed products, compliance with promotional standards, recordkeeping, and reporting of certain adverse reactions. The FDA regularly inspects companies to determine compliance with QSRs and other post-approval requirements. Failure to comply with statutory requirements and the FDA's regulations can lead to substantial penalties, including monetary penalties, 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. The Company's 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. Although a voluntary standard, compliance with UL3101 will support the Company's 510(k) submission for the UP*link*™ analyzer. The Company has retained Underwriters Laboratories Inc. to examine and test the UP*link*™ analyzer and certify that it meets the FDA requirements and UL3101.

The Clinical Laboratory Improvement Act of 1988 (''CLIA'') prohibits 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. Although a certificate is not required for OraSure Technologies, the Company considers the applicability of the requirements of CLIA in the design and development of its products. In addition, the Company has obtained a waiver of the CLIA requirements for its Q.E.D.® alcohol saliva test and may seek similar waivers for certain of its other products. A CLIA waiver will remove certain quality control and other requirements that must be met for certain customers to use the Company's products.

In June 2000, the FDA issued observations of deficiencies following an inspection of OraSure Technologies' manufacturing facility in Beaverton, Oregon, stating the FDA's view that the Company's Serum Western Blot product was not manufactured in compliance with the QSRs. The FDA had previously issued a warning letter in September 1998, and observations of deficiencies in January 1999 to the Company based on prior inspections of the Oregon facility. The FDA questioned the Company's compliance with the QSRs in areas such as process validation, purchasing controls, complaint handling, and equipment controls at the Oregon facility. The Company has undertaken a substantial review of its manufacturing and quality systems, and has either already made changes or has developed plans to make changes, to satisfy the FDA's concerns with respect to its QSR compliance. This was communicated to the FDA in a written reply in September 2000.

On October 20, 2000, the FDA sent a letter to the Company regarding the Serum Western Blot product voicing the agency's concern over the previously observed deficiencies and stating its intent to revoke the Company's license to manufacture this product if the problems were not corrected in sufficient time. The FDA acknowledged the receipt of the Company's written responses and found that those items which had been completed appeared to be adequate, but required the Company to submit a comprehensive report on corrective action plans and the schedule to address the remaining items. The Company submitted such a report in November 2000, and believes that it either has already implemented changes or has appropriate plans in place to implement changes that will adequately address the FDA's concerns.

Production of the Serum Western Blot product line was voluntarily discontinued by the Company and, in response to this voluntary action by the Company, the associated biologics license was revoked on October 12, 2001. However, OraSure Technologies has recognized that the basic changes to the overall quality system needed to remedy the FDA's observations would also assist in the quality for all of the Company's product lines, and therefore has devoted a considerable amount of time and resources to improving quality procedures throughout the Company. Even with the substantial efforts and the progress made to date, there is a risk that the FDA will not be satisfied with the Company's efforts. If the FDA is not satisfied, it could take action intended to force OraSure Technologies to stop manufacturing its products at the Oregon facility (which consists solely of the manufacture of Company's oral fluid Western Blot HIV-1 confirmatory test) until the FDA believes the Company is in compliance with QSR requirements. Also, although the FDA has granted the Company permission to obtain certificates needed for export of products, the FDA could refuse export permission in the future if the agency determines that the Company's progress toward QSR compliance is not sufficient.

International

The Company is 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. The extent of potentially adverse governmental regulation affecting the Company that might arise from future legislative or administrative action cannot be predicted. The Company will pursue approval only in those countries that have a significant market opportunity.

The International Organization for Standardization (''ISO'') is a worldwide federation of national standards bodies from some 130 countries, established in 1947. The mission of ISO is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services. ISO certification is evidenced by the CE mark and indicates that the Company's quality system complies with standards applicable to activities ranging from initial product design and development through production and distribution. ISO certification is a prerequisite to obtaining a CE mark, which is required for distribution of medical devices in the European common markets.

In the first quarter of 1999, the Company received approval to use the CE mark for the OraSure® and Intercept® collection devices. In December 2000, the Company's Bethlehem facility received final certification for the European Medical Device Directive (93/42/EEC), ISO 9001, ISO 13485, and EN46001. The Company has also received authorization to use the CE mark for its Histofreezer® product line.

In order to obtain the CE mark for a product containing electrical equipment, that product would need to meet several international safety and performance standards (IEC 60825-1; IEC/EN 61010-1, CSA C 22.2, IEC 1010-1, EN 61000). The Company's UP*link*™ analyzer will need to meet these standards in order to obtain its CE mark. The Company has retained Underwriter Laboratories, Inc. and Laird Technologies to examine and test the UP*link*™ analyzer and certify that it meets these international standards.

The Company must also submit evidence of marketing approval or clearance by the FDA to Health Canada's Therapeutic Products Programme prior to commencing sales in Canada. The Company has completed this process for several of its current products which require FDA review.

Environmental Regulation

Because of the nature of its current and proposed research, development, and manufacturing processes, the Company is 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. The Company believes that it has complied with these laws and regulations in all material respects and has not been required to take any action to correct any noncompliance.

Forward-Looking Statements

This Report contains certain ''forward-looking statements,'' within the meaning of the Federal securities laws. These may include statements about 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 or market conditions, other factors that could affect future operations or financial position, and statements that 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 obtain and timing of obtaining necessary regulatory approvals; ability to develop product distribution channels; uncertainty relating to patent protection and potential patent infringement claims; 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; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; 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 Orasure Technologies undertakes no duty to update these statements.

Risk Factors

The following is a discussion of certain significant risk factors that could potentially affect the Company's financial condition, performance and prospects.

Competing Products

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. The Company's principal competitors have considerably

greater financial, technical, and marketing resources. As new products enter the market, the Company's products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold than the Company's. If OraSure Technologies fails to maintain and enhance its competitive position, its customers may decide to use products developed by competitors which could result in a loss of revenues.

Ability to Develop New Products

In order to remain competitive, the Company must commit substantial resources each year to research and development. The research and development process generally takes a significant amount of time from inception to commercial product launch. This process is conducted in various stages, and during each stage there is a substantial risk that the Company will not achieve its goals and will have to abandon a product in which it has invested substantial amounts.

During 2001, 2000 and 1999, the Company incurred $9.4 million, $10.4 million and $5.6 million, respectively, in research and development expenses. The Company expects to continue to incur significant costs in its research and development activities. Moreover, there can be no assurance that OraSure Technologies will succeed in its research and development efforts. If the Company fails 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 the Company's competitors, which would result in a loss of revenues.

Market Acceptance of Oral Fluid Testing Products

The Company has made significant progress in gaining acceptance of oral fluid testing for HIV in the insurance and public health markets. The Company has also made significant progress in gaining acceptance of oral fluid testing for drugs of abuse in the workplace and criminal justice testing markets. Other markets, particularly the physician office market, may resist the adoption of oral fluid testing as a replacement for other testing methods in use today. In addition, certain state laws prohibit or restrict the use of oral fluid testing for drugs of abuse in certain markets. There can be no assurance that the Company will be able to expand the use of its oral fluid testing products in these or other markets.

Loss or Impairment of Sources of Capital

Although the Company has made significant progress in the past toward controlling expenses and increasing product revenue, historically the Company has depended, to a substantial degree, on capital raised through the sale of equity securities and bank borrowings to fund its operations. The Company's future liquidity and capital requirements will depend on numerous factors, including, but not limited to, the costs and timing of the expansion of manufacturing capacity, the success of product development efforts, the costs and timing of expansion of sales and marketing activities, the timing of 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, the Company 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 the Company on satisfactory terms, if at all.

Ability of the Company to Develop Product Distribution Channels

The Company has marketed many of its products by collaborating with laboratories, diagnostic companies and distributors. For example, the Company's OraSure® oral fluid collection device is distributed to the insurance industry through major insurance testing laboratories. One of these laboratories, Lab*One*, Inc., acquired another insurance laboratory customer, Osborne Group, Inc., in 2001 and these customers together accounted for approximately 29%, 30%, and 28% of the Company's revenues for the years 2001, 2000, and 1999, respectively. The Company's sales depend to a substantial degree on its ability to sell products to these customers and develop

new product distribution channels, and on the marketing abilities of the companies with which it collaborates. In addition, some of the Company's distributors have recently consolidated, and such consolidation has had, and may continue to have, an adverse impact on the level of orders for the Company's products. There can be no assurance that such companies will continue to be able to purchase or distribute the Company's products or maintain historic order volumes, or that new distribution channels will be available on satisfactory terms.

Obtaining and Maintaining Regulatory Approvals and Clearances

As described more fully above under ''Government Regulation,'' many of the Company's proposed and existing products are subject to regulation by the FDA and other governmental or public health agencies. In particular, the Company is subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of its products. The process of obtaining required approvals or clearances from governmental or public health agencies varies according to the nature of, and uses for, the specific product and can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities, and other costly, time-consuming procedures. The submission of an application to a regulatory authority does not guarantee that it will grant an approval or clearance to market the product. 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.

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

Changes in government regulations could also require the Company to undergo additional trials or procedures, or could make it impractical or impossible for the Company to market its products for certain uses, in certain markets, or at all. Other changes in government regulations, such as the adoption of the FDA's Quality System Regulation, may adversely affect the Company's financial condition and results of operations by requiring that the Company incur the expense of changing or implementing new manufacturing and control procedures.

In addition, the European Union has established a requirement that diagnostic medical devices used to test biological specimens must receive regulatory approval known as a CE mark by December 31, 2003. After that date, export to the European community of products without the CE mark will be stopped or delayed until the mark is received. This requirement will affect many of OraSure Technologies' products. OraSure Technologies will not be permitted to make European sales of its products for which a CE mark is not obtained by December 31, 2003, which could lead to the termination of strategic alliances for sales of those products in Europe. While the Company intends to apply for CE marks for certain of its existing and future products, and is not aware of any material reason why such approvals will not be granted, there can be no assurance that any CE marks will be received prior to the deadline.

At the present time, the Company has received FDA clearance or approval for the OraSure® and Intercept® oral fluid collection devices, the Histofreezer® portable cryosurgical system, the Q.E.D.® saliva alcohol test, the OraSure® oral fluid Western Blot confirmatory test for HIV-1, and various other tests. The Company has also received CE mark approval for the OraSure®, Intercept® and Histofreezer® products. The Company has submitted to the FDA an application for pre-market approval of its OraQuick® rapid HIV-1 test using whole blood and expects to file an application for oral fluid applications in 2002. The Company has also submitted an application to the FDA for 510(k) clearance of the UP*link*™ drugs of abuse rapid detection system, has resubmitted additional data requested by the FDA for the UP*link*™ analyzer and opiates assay, and is in the process of gathering additional data requested by the FDA for the full NIDA-5 drug panel for that product. See the Sections entitled ''Products'' and ''Government Regulation'' for a further discussion of regulatory approvals and clearances obtained for the Company's products.

Regulatory Compliance

The Company can manufacture and sell many of its products, both in the United States and in some cases abroad, only if it complies with regulations of government agencies such as the FDA. The Company has implemented a quality system that is intended to comply with applicable regulations. The FDA has issued warning letters with respect to the Serum Western Blot product, stating that the Company is not in compliance with the FDA's regulations. The Company has responded to each of these letters and voluntarily discontinued this product. Although the Company believes that it has satisfactorily addressed the points raised by the FDA, the FDA could force the Company to stop manufacturing products at its Oregon facility if the FDA concludes that the Company remains out of compliance with applicable regulations. In addition, until the FDA agrees that the Company has resolved all points raised in the letters, the Company may not be able to obtain regulatory clearance certificates needed in certain foreign countries. The FDA could also require the Company to recall products if it fails to comply with applicable regulations, which could force the Company to stop manufacturing such products. See the Section entitled ''Government Regulation'' for a further discussion of regulatory compliance matters.

History of Losses and Projected Profitability

The Company has not achieved full-year profitability. The Company incurred net losses of approximately $3.7 million, $12.7 million and $4.2 million in 2001, 2000 and 1999, respectively, and as of December 31, 2001, the Company had an accumulated deficit of approximately $126.1 million.

The Company's limited combined operating history makes it difficult to forecast future operating results. In order to achieve sustainable profitability, the Company's revenues will have to continue to grow at a significant rate. The Company's ability to achieve revenue growth will be dependent upon a number of factors including, without limitation, creating market acceptance for and selling increasing volumes of the OraSure® collection device, the Intercept® and UP*link*™ drugs-of-abuse products, and the OraQuick® rapid HIV-1 test, achieving growth in international markets with the Company's OraQuick® rapid HIV-1 test and other products, obtaining timely FDA approval or clearance for the OraQuick® rapid HIV-1 test and UP*link*™ drugs-of-abuse rapid detection system, and commercially developing, and obtaining regulatory approval and creating market acceptance for, UPT™ and other products in a time frame consistent with the Company's objectives. The Company has not yet fully achieved these objectives. In the event that the Company cannot create a significant commercial market for its OraQuick® test, the Intercept® and UP*link*™ products, or its other products, or to the extent other events described in this Section occur, the Company's revenue, and consequently profitability, could be lower than estimated. Even if the Company achieves profitability, there is no assurance that such profitability can be sustained in the future.

Stock Price Volatility

Because the Company's stock price may be volatile, the stock price could experience substantial declines. The market price of the Company's common stock has historically experienced and might continue to experience volatility in the future in response to a number of factors, including quarter-to-quarter variations in operating results, analysts' reports, the relative low trading value for the Company's stock, market conditions in the industry, regulatory developments affecting the Company's products, changes in governmental regulations, and changes in general conditions in the economy or in the financial or stock markets.

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

Ability to Market New Products

OraSure Technologies' future success will depend, in part, on the market acceptance, and the timing of such acceptance, of new products such as the Intercept® drug testing service, the OraQuick® rapid HIV-1 test, products

currently under final development such as the UP*link*™ drugs of abuse rapid detection system and other products using up-converting phosphor technology, and other new products or technologies that may be developed or acquired and introduced in the future. To achieve market acceptance, OraSure Technologies must make substantial marketing efforts and spend significant funds to inform potential customers and the public of the perceived benefits of these products. The Company currently has limited evidence on which to evaluate the market reaction to products that may be developed, and there can be no assurance that any products will meet with market acceptance and fill the market need that is perceived to exist.

Reliance on Patents and Other Proprietary Rights

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. The Company's success depends, in part, on its ability to develop and maintain a strong intellectual property portfolio or obtain licensing to patents and other technology for products and technologies both in the United States and in other countries.

As appropriate, the Company intends to file patent applications and obtain patent protection for its proprietary technology. These patent applications and patents will cover, as applicable, compositions of matter for the Company's products, methods of making those products, methods of using those products, and apparatus relating to the use or manufacture of those products. The Company will also rely on trade secrets, know-how, and continuing technological advancements to protect its proprietary technology. The Company has entered, and will continue to enter, into confidentiality agreements with its employees, consultants, advisors and collaborators. However, these parties may not honor these agreements and the Company may not be able to successfully protect its rights to unpatented trade secrets and know-how. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to the Company's trade secrets and know-how.

Many of the Company's employees, including scientific and management personnel, were previously employed by competing companies. Although the Company encourages and expects all of its employees to abide by any confidentiality agreement with a prior employer, competing companies may allege trade secret violations and similar claims against OraSure Technologies.

The Company may incur substantial costs and be required to expend substantial resources in asserting or protecting its intellectual property rights, or in defending suits against it 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 of the Company's rights to a patent, an invention, or trademark.

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

Patent Issues Affecting OraQuick®

There are several factors that will affect the specific countries in which the Company will be able to sell its OraQuick® rapid HIV test and therefore the overall sales potential of the test. One factor is whether the Company can arrange a sublicense or distribution agreement related to patents for detection of the HIV-2 virus. HIV-2 is a type of the HIV virus estimated to represent a small fraction of the known HIV cases worldwide. Nevertheless, HIV-2 is considered to be an important component in the testing regimen for HIV in many markets. HIV-2

patents are in force in most of the countries of North America and Western Europe, as well as in Japan, Korea, South Africa, and Australia. Access to a license for one or more HIV-2 patents may be necessary to sell HIV-2 tests in countries where such patents are in force, or to manufacture in countries where such patents are in force and then sell into non-patent markets. Since HIV-2 patents are in force in the United States, the Company may be restricted from manufacturing an OraQuick® rapid HIV-2 test in the United States and selling into other countries, even if there were no HIV-2 patents in those other countries.

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

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

Another factor that may affect the specific countries in which the Company will be able to sell an OraQuick® rapid HIV-1 or HIV-2 test, and therefore the overall sales potential, concerns whether the Company can arrange a sublicense or distribution agreement related to any patents which claim lateral flow assay methods and devices covering the OraQuick® rapid HIV 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® assay and are in force in the United States and other countries. The Company may not be able to make the OraQuick® test in the United States and sell it in countries where there is no patent on the device. The Company has obtained or intends to obtain licenses under several lateral flow patents, which it believes should be sufficient to permit the manufacturing and sale of the OraQuick® device as currently contemplated.

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, the Company may be able to modify the OraQuick® rapid HIV test such that a license would not be necessary. However, this alternative could delay introduction of the OraQuick® rapid HIV test into the United States and other markets.

Loss of Key Personnel

The Company's success will depend to a large extent upon the contributions of its executive officers, management, and sales, marketing, and scientific staff. The Company 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 the Company is not able to attract and retain the necessary personnel to accomplish its business objectives, the Company may experience constraints that will adversely affect its ability to effectively sell and market its products, to meet the demands of its strategic partners in a timely fashion, or to support internal research and development programs. In particular, product development programs depend on the ability to attract and retain highly skilled scientists, including molecular biologists, biochemists and engineers, and sales and marketing efforts depend on the ability to attract and retain skilled and experienced sales and marketing representatives. Recruiting qualified personnel can be an intensely competitive and time-consuming process. Although OraSure Technologies believes it 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 its ability to do so on acceptable terms.

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

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

International Marketing and Manufacturing

The Company intends to increase international sales of its products. The Company's international revenues accounted for approximately $5.3 million or 16% of total revenues for 2001, approximately $4 million or 14% of total revenues for 2000, and approximately $2.7 million or 11% of total revenues for 1999.

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

- Regulatory requirements (including compliance with applicable customs regulations) may slow, limit, or prevent the offering of products in foreign jurisdictions;
- Cultural and political differences may make it difficult to effectively market, sell and gain acceptance of products in foreign jurisdictions;
- Inexperience in international markets may slow or limit the Company's 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 the Company's 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 and the absence of available funding sources may slow or limit the Company's ability to sell its products in foreign countries;
- International markets often have long sales cycles, especially sales to foreign governments, quasi-governmental agencies and international public health agencies, thereby delaying or limiting the Company's ability to sell its products; and
- The Company may be at a disadvantage if competitors in foreign countries sell competing products at prices at or below such competitors' or the Company's cost.

The Company has entered into a contract for the manufacture and supply of the OraQuick® HIV device in Thailand. However, the Company does not have significant direct experience with the use of international manufacturers. Factors such as economic and political conditions and foreign regulatory requirements may slow or prevent the manufacture of the Company's products in countries other than the United States. Interruption of the supply of the Company's products could reduce revenues or cause the Company to incur significant additional expenses in finding an alternative source of supply.

Product Liability Exposure

The Company may be held liable if any of its products, or any product which is made with the use or incorporation of any of the technologies belonging to the Company, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. Although the Company has

obtained product liability insurance, this insurance may not fully cover potential liabilities. As the Company brings new products to market, the Company may need to increase its product liability coverage. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could affect the Company's decision to commercialize products developed by the Company or its strategic partners.

Ability to Fully Commercialize UPT™

The Company's up-converting phosphor technology is new and, except for the UP*link*™ rapid detection system, is in the early stage of development. Commercial development of UPT™ for certain other applications may not be successful. Successful products require significant development and investment, including testing, to demonstrate their cost-effectiveness or other benefits prior to commercialization. In addition, regulatory approval must be obtained before most products based upon UPT™ 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. Accordingly, because of these uncertainties, products based upon UPT™ may not be commercialized. The failure to develop UPT™ products with commercial potential would negatively affect OraSure Technologies' future revenues.

Dependence on Strategic Partners

Although the Company intends to pursue some product opportunities independently, opportunities that require a significant level of investment for development and commercialization or a distribution network beyond the Company's existing sales force may necessitate involving one or more strategic partners. In particular, the Company's strategy for development and commercialization of UPT™ and certain other products, such as the OraQuick® rapid HIV test, may entail entering into additional arrangements with distributors or other corporate partners, universities, research laboratory licensees, and others. OraSure Technologies may be required to transfer material rights to such strategic partners, licensees, and others. While the Company expects that its current and future partners, licensees, and others have and will have an economic motivation to succeed in performing their contractual responsibilities, the amount and timing of resources to be devoted to these activities will be controlled by others. Consequently, there can be no assurance that any revenues or profits will be derived from such arrangements.

Dependence on Third Party Licenses and Rights

The Company has licensed the worldwide rights to up-converting phosphor compositions, methods, and apparatuses for use in diagnostic applications, which are the subject of numerous United States and 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. OraSure Technologies cooperates 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 the Company, or if the license agreement is terminated, the Company could lose the opportunity to develop UPT™.

Recent Economic Downturn and Terrorist Attacks

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

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

Restructuring of Operations

The Company may from time to time restructure and consolidate various aspects of its operations in order to achieve cost savings and other efficiencies. For example, during 2001 the Company completed a restructuring of its manufacturing operations which included the transfer of OraQuick® manufacturing from the Beaverton, Oregon facility to Bethlehem, Pennsylvania. In addition, the Company plans to close the Oregon facility during 2003 and transfer all remaining manufacturing operations, which are solely related to the Western Blot HIV-1 confirmatory test, and research and development activities to Pennsylvania. The transfer of operations may result in the loss of scientific or other personnel and thereby delay the transfer or disrupt the continuation of operations thereafter. The Company will also be required to obtain FDA approval to transfer certain operations to another location, which could delay the transfer or disrupt continued operations. Any delay or disruption of operations, and in particular manufacturing operations, could result in increased costs or could prevent the Company from selling certain products and thereby result in a loss of revenue.

The previous discussion of the Company's business should be read in conjunction with the Financial Statements and accompanying notes included in Item 14 of this Annual Report on Form 10-K.

ITEM 2. Properties.

On April 30, 1999, the Company signed a five-year lease to rent 25,845 square feet of space at the John M. Cook Technology Center in Bethlehem, Pennsylvania, which the Company uses as its main corporate, sales and marketing, and research and development offices. Annual rent for the first five years of this lease is approximately $270,000. The lease also includes a five-year renewal option and a ten-year purchase option.

The Company owns a 33,500 square foot building in Bethlehem, Pennsylvania which is used for manufacturing, engineering, information systems and accounting activities. The Company rents additional warehouse space on an as-needed basis. The Company leases space for a sales office in Reeuwijk, The Netherlands.

The Company leases approximately 30,500 square feet of office, manufacturing, and laboratory space in Beaverton, Oregon, under a lease that expires on January 31, 2005. The Company has base lease obligations under the lease, which escalate during the term of the lease and average approximately $375,000 per year. The Company also leases 2,265 square feet of warehouse space in Oregon to store inventory and equipment under a lease expiring September 30, 2002. The Company expects to consolidate the research and development and manufacturing operations currently performed in Oregon with the Company's Bethlehem operation during 2003.

The Company has executed a lease for an approximate 48,000 square foot manufacturing, research and development and office facility to be constructed on property adjacent to its existing corporate headquarters in Bethlehem, Pennsylvania. Construction of the facility is expected to be completed during the summer of 2002. The lease has an initial term of 10 years and base rental rate starting at $480,000 and increasing to $528,000 per year over the initial term. The lease also has a five-year renewal option and a ten-year purchase option.

The Company believes that its existing and proposed facilities are adequate for its requirements.

ITEM 3. Legal Proceedings.

The Company is from time to time involved in legal proceedings arising in the ordinary course of business. In the Company's opinion, based on the advice of counsel, these proceedings are not expected to have a material adverse effect on the Company's financial position or results of operations.

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

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

PART II

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

The Company's 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. Prices for quarters ending prior to the September 29, 2000 Merger with Epitope and STC, represent the high and low sales prices reported by NASDAQ for the common stock of the Company's predecessor, Epitope, which traded under the symbol EPTO.

	Year ended December 31			
	2001		2000	
	High	Low	High	Low
First Quarter	$10.000	$5.875	$18.188	$5.563
Second Quarter	12.640	6.688	14.375	7.000
Third Quarter	15.000	7.260	15.938	9.938
Fourth Quarter	12.880	8.890	13.500	5.563

On March 22, 2002, there were 787 holders of record and, based on mailings for the 2001 Annual Meeting of Stockholders, approximately 9,500 holders in street name of the Common Stock, and the closing price of the Common Stock was $6.48 per share. The Company has never paid any cash dividends, and the Board of Directors does not anticipate paying cash dividends in the foreseeable future. The Company intends to retain any future earnings to provide funds for the operation and expansion of its business.

ITEM 6. Selected Financial Data.

The following table sets forth selected financial data of the Company. See Note 1 to the Company's Financial Statements for a discussion of the Merger with Epitope and STC and change in the fiscal year end of Epitope. The data below for the year ended September 30, 1997 includes discontinued operations of two of Epitope's former subsidiaries, Agritope, Inc. and Andrew and Williamson Sales, Co. The charge for discontinued operations during this period includes the operating losses of these subsidiaries through their disposition dates and final losses on disposal incurred by Epitope. This information should be read in conjunction with the Financial Statements and notes thereto included in Item 14 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,		
	2001	2000	1999	1998	1999	1998	1997
Operating Results:							
Revenues	$ 32,573	$ 28,788	$ 6,822	$ 5,138	$ 24,046	$ 20,444	$ 17,282
Costs and expenses	36,906	42,917	7,105	5,857	28,138	22,721	23,295
Other income (expense), net	634	1,407	(138)	(159)	(91)	(98)	782
Loss from continuing operations before income taxes	(3,699)	(12,722)	(421)	(878)	(4,183)	(2,374)	(5,231)
Loss from continuing operations	(3,728)	(12,747)	(471)	(878)	(4,233)	(2,374)	(5,231)
Discontinued operations	—	—	—	—	—	—	(18,359)
Net loss	(3,728)	(12,747)	(471)	(878)	(4,233)	(2,374)	(23,590)
Per Share of Common Stock:							
Loss from continuing operations	$ (0.10)	$ (0.36)	$ (0.02)	$ (0.03)	$ (0.14)	$ (0.09)	$ (0.20)
Loss from discontinued operations	—	—	—	—	—	—	(0.70)
Basic and diluted net loss	(0.10)	(0.36)	(0.02)	(0.03)	(0.14)	(0.09)	(0.90)
Shares used in per share calculations:	36,868	35,002	30,887	26,246	30,597	26,180	26,055
Financial position:							
Working capital	$ 19,764	$ 21,440	$ 16,314	$ 8,255	$ 16,773	$ 8,725	$ 12,470
Total assets	37,285	37,736	29,626	20,075	30,251	20,783	25,978
Long-term debt	3,586	4,644	5,820	6,001	5,820	6,001	4,026
Accumulated deficit	(126,092)	(122,365)	(109,618)	(105,603)	(109,104)	(104,903)	(96,837)
Stockholders' equity	26,541	26,172	18,238	10,264	18,592	10,701	17,873

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. The Company's actual results could be quite different from those expressed or implied by the forward-looking statements. Factors that could affect results are discussed more fully under the Sections entitled "Forward-Looking Statements" and "Risk Factors" in Item 1 and elsewhere in this Annual Report on Form 10-K. Although forward-looking statements help to provide complete information about the Company, 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.

On September 29, 2000, STC Technologies, Inc. (''STC''), a privately held company, and Epitope, Inc. (''Epitope''), a public company whose stock was traded on the Nasdaq Stock Market, were merged into the Company (the ''Merger''). The Merger was structured as an all stock transaction and was accounted for as a ''pooling of interests.''

Epitope previously reported its financial results on the basis of a fiscal year ending September 30, while STC previously reported its financial results on a calendar year basis. Immediately prior to the Merger, Epitope adopted a calendar year for financial reporting purposes. As a result, the Financial Data for 2001 and 2000 reflect results for the calendar years ended December 31, 2001 and 2000, respectively. Since Epitope did not adopt a calendar year reporting period until 2000, the Financial Data for 1999 reflects the results of Epitope for the twelve-months ended September 30, 1999 and the results of STC for the twelve months ended December 31, 1999. See Note 1 to the Company's Financial Statements for a discussion of the Merger and the change in fiscal year end.

In selecting the presentation of results for 1999, the Company determined that it was not necessary to restate the Epitope 1999 results on a calendar year basis. To do so would have required the addition of Epitope's results for the three months ended December 31, 1999 and the elimination of Epitope's results for the three months ended December 31, 1998. A comparison of the results for these three-month periods demonstrated that there were no events, transactions or economic changes that caused the Epitope results for these periods to be materially different. Accordingly, a restatement of the Epitope results would not have materially affected the comparison of STC results for the twelve months ended December 31, 1999 and Epitope results for the twelve months ended September 30, 1999.

Certain reclassifications have been made to prior period market segment revenues to conform to the current year presentation. The following discussion should be read in conjunction with the financial statements contained herein and the notes thereto, along with the Section entitled, ''Critical Accounting Policies and Estimates'' set forth below.

Results of Operations—2001 Compared to 2000

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

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

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

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

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

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

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

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

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

2000, licensing and product development revenues consisted primarily of income from a collaboration with Lab*One*, Inc. related to the Intercept® drug testing service, development work with Dräger on the UP*link*™ drugs-of-abuse rapid detection system, and the first phase of the NIH grant. Under its agreements with Dräger and Meridian Bioscience, the Company expects to receive additional development revenues if it meets certain milestones in 2002.

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

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

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

Sales and marketing expenses increased 14% to approximately $7.9 million in 2001 from approximately $6.9 million in 2000. This increase was primarily the result of additional costs associated with increased staffing levels and related expenses, and the expansion of the Company's customer service functions.

General and administrative expenses remained flat at approximately $6.9 million in both 2001 and 2000. Higher professional fees associated with certain partnering activities in 2001 were offset by cost savings from the elimination of duplicative overhead structures as a result of the Merger. During the first quarter of 2002, the Company will record a charge of approximately $0.6 million relating to severance payments, including approximately $480,000 for Robert D. Thompson, the Company's former Chief Executive Officer, who resigned on January 31, 2002, and approximately $100,000 in severance payments in connection with a 10% workforce reduction implemented during that period.

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

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

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

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

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

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

Results of Operations—2000 Compared to 1999

Total revenue increased 20% to approximately $28.8 million in 2000 from approximately $24.0 million in 1999. The table below shows the amount (in thousands) and percentage of the Company's total revenue contributed by each of its principal markets and by licensing and product development activities.

	Dollars		Percentage Change	Percentage of Total Revenues (%)	
	2000	1999	Inc. (Dec.)	2000	1999
Market sales					
Insurance risk assessment	$14,693	$12,364	19%	51%	51%
Infectious disease testing	3,453	2,549	35	12	11
Substance abuse testing	3,172	2,491	27	11	10
Physicians' office therapies	6,777	5,744	18	24	24
	28,095	23,148	21	98	96
Licensing and product development	693	898	(23)	2	4
Total revenues	$28,788	$24,046	20%	100%	100%

Sales to the insurance risk assessment market increased by 19% to approximately $14.7 million in 2000 from approximately $12.4 million in 1999, as a result of increased market acceptance of the OraSure® oral fluid collection device and higher sales of the associated immunoassay tests.

Sales to the infectious disease testing market increased 35% to approximately $3.5 million in 2000 from approximately $2.5 million in 1999, as a result of increased penetration of the Company's higher priced public health HIV-1 kit.

Sales to the substance abuse testing market increased 27% to approximately $3.2 million in 2000 from approximately $2.5 million in 1999, as a result of the market introduction of the Intercept® drug testing service and increased Q.E.D.® and forensic toxicology sales.

Sales to the physicians' office therapies market, which consisted solely of the Histofreezer® portable cryosurgical system, increased 18% to approximately $6.8 million in 2000 from approximately $5.7 million in 1999, as a result of price and volume increases both domestically and internationally.

As a percentage of total revenues, international revenues increased to approximately 14% in 2000 from 12% in 1999, as a result of increased international sales of the Histofreezer® product and the OraSure® collection devices. Lab*One*, Inc. and Osborne Group Inc., which was acquired by Lab*One*, Inc. in 2001, together accounted for approximately 30% and 28% of the total revenues in 2000 and 1999, respectively.

Licensing and product development revenue decreased 23% to $0.7 million in 2000 from $0.9 million in 1999, reflecting a different mix of development work performed in 2000. During 2000, licensing and product development revenue primarily consisted of income from a collaboration with Lab*One*, Inc. related to the Intercept® drug testing service, development work with Dräger on the UP*link*™ drugs-of-abuse rapid detection system, and receipt of the first phase of the NIH grant for the development of an oral fluid syphilis test. During 1999, the Company received licensing and product development revenue in connection with a research agreement to collaborate on the development of analytes for point-of-care testing, a business and technology assessment of UPT™ for food pathogen applications, and the Company's collaboration with Lab*One* for the Intercept® drug testing service.

The Company's gross margin declined slightly to 61% in 2000 from 62% in 1999. The decline was the result of the Company's write off of approximately $0.5 million of expired OraSure® collection device inventory and $0.6 million of obsolete, expired, or unsaleable Serum Western Blot inventory, and manufacturing inefficiencies related to the start up of the OraQuick® product line. Partially offsetting these factors in 2000 were favorable changes in product mix and greater revenues compared to the Company's fixed costs.

Research and development expenses increased 86% to approximately $10.4 million in 2000 from approximately $5.6 million in 1999. Research and development efforts in 2000 were focused on development of the OraQuick® rapid HIV test, development of the UP*link*™ analyzer, test cassette and collector for drugs-of-abuse applications, DNA feasibility studies, and regulatory compliance. In addition, the Company also performed research and development activities with respect to additional Intercept® products, new antibody development, and improvements to existing products.

Sales and marketing expenses increased approximately 22% to approximately $6.9 million from approximately $5.7 million in 1999. This increase was primarily the result of costs associated with cultivating foreign markets for the OraQuick® rapid HIV test, which was launched in July 2000, launching the Intercept® drug testing service in the United States in February 2000, and expanded sales activities for the Company's other product lines.

General and administrative expenses increased 10% to approximately $6.9 million in 2000 from approximately $6.2 million in 1999. This increase was the result of increased staffing levels and operating expenses associated with a facility expansion in Bethlehem, Pennsylvania.

In 1999, the Company recorded a $1.5 million charge for acquired in-process technology from TPM Europe Holding B.V., its sublicensor, relating to 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 securing a direct research, development, and license arrangement with Leiden University. The Company accounted for the purchase price of the technology as acquired in-process technology expense, because at the date of the transaction, the technology rights acquired by the Company had not progressed to a stage where the technology, or any alternative future use of the technology, had met technological feasibility. Furthermore, there existed a significant amount of uncertainty as to the Company's ability to complete the development of this technology and achieve market acceptance of any related commercial products within a reasonable timeframe. There were no such expenses in 2000.

Merger-related expenses were approximately $7.6 million in 2000. These costs included fees for investment bankers, attorneys and accountants, filing fees, proxy solicitation expenses, employee severance, and integration costs. There were no such expenses in 1999.

Interest expense decreased to $490,000 in 2000 from $545,000 in 1999, as a result of loan principal repayments and the refinancing of certain debt.

Interest income increased to approximately $1.3 million in 2000 from approximately $0.6 million in 1999, as a result of higher cash and cash equivalents available for investment generated by the exercise of stock options and warrants.

Gain on the sale of securities was $600,000 in 2000 as a result of a gain on the sale of A&W preferred stock the Company had received as a part of a settlement with A&W in 1997. There was no similar item in 1999.

During 2000 and 1999, provisions for foreign income taxes were recorded.

Results of Operations—Three Months Ended December 31, 1999 Compared to 1998

Total revenues increased 33% to approximately $6.8 million for the three months ended December 31, 1999 from approximately $5.1 million for the comparable period in 1998. This increase resulted from increased sales across all market segments, including a $400,000 increase in sales to the infectious disease market, a $300,000 increase in sales to the substance abuse testing market, and increased licensing and product development revenue.

The Company's gross margin increased to approximately 63% for the three months ended December 31, 1999 from approximately 59% in 1998. This increase was primarily the result of a more favorable product mix and higher product sales and licensing and product development revenue.

Operating expenses increased 23% to approximately $4.6 million for the three months ended December 31, 1999 from approximately $3.8 million in 1998, primarily as a result of a general increase in overall sales and marketing expenses, including additional costs associated with preparation for the Company's national launch of the Intercept® drug testing service in February 2000.

Other expenses decreased to approximately $138,000 for the three months ended December 31, 1999 from approximately $159,000 in 1998, primarily as a result of lower interest expense and increased interest income, partially offset by higher foreign currency losses.

During the three months ended December 31, 1999, a provision for foreign income taxes of $50,000 was recorded.

Liquidity and Capital Resources

General. The Company's cash, cash equivalents, and short-term investments position was approximately $15.2 million at December 31, 2001, a decrease of approximately $4.9 million from the Company's position at December 31, 2000. This decrease was principally attributable to the Company's net loss of $3.7 million, increased accounts receivable and inventory levels, capital investment into new manufacturing facilities and equipment, and loan principal repayments, partially offset by proceeds from the exercise of stock options. At December 31, 2001, the Company's working capital was approximately $19.8 million.

The Company recorded lower than anticipated product sales in 2001 and expects its revenues for the first two quarters of 2002 to be roughly comparable to revenue levels recorded for the same periods in 2001. In addition, the Company hired personnel during 2001 to support a sales level higher than that now anticipated through mid-2002. Consequently, in the first quarter of 2002, the Company terminated certain development projects and implemented an approximate 10% reduction in its workforce.

Net cash used in operating activities was approximately $5.3 million in 2001, a decrease of approximately $4.8 million from 2000. The $5.3 million of cash used in operating activities resulted primarily from the Company's net loss of $3.7 million, the build up of higher inventory levels of OraQuick® raw materials and

electronic components for UP*link*™ readers in anticipation of sales growth, and an increase in accounts receivable levels.

Net cash used in investing activities during 2001 was $66,000. The Company purchased approximately $2.8 million of property and equipment and funded this through net proceeds of approximately $2.1 million of short-term investments and $637,500 the Company received upon the sale of Lab*One*, Inc. common stock. Capital expenditures are anticipated to increase during 2002 as a result of additional commitments the Company has made for the purchase and installation of manufacturing equipment for UP*link*™, and additional tenant fit out costs expected in connection with its existing facilities and a new facility the Company has leased in Bethlehem, Pennsylvania.

Net cash provided by financing activities was approximately $2.7 million, reflecting the proceeds received from the exercise of stock options of approximately $3.9 million, offset by approximately $1.1 million of loan principal repayments.

At December 31, 2001, the Company had a $1.0 million working capital line of credit in place that accrues interest at LIBOR plus 235 basis points and a $3.0 million equipment line of credit that accrues interest at a rate fixed at prime at the time of draw down. There were no borrowings under these lines of credit outstanding at December 31, 2001. The credit facilities require, among other items, the maintenance of minimum financial ratios and a first lien position on the Company's accounts receivable and the financed equipment. The Company's lines of credit expire on April 30, 2002 and are expected to be extended and/or replaced with other credit or bank facilities, although there can be no assurance of renewal or extension.

The Company believes that it has sufficient cash, cash equivalents, and short-term investments for the foreseeable future. The Company's future liquidity and capital requirements will depend on numerous factors, including, but not limited to, the costs and timing of the expansion of manufacturing capacity, the success of product development efforts, the timing of receipt of regulatory approvals, the costs and timing of expansion of sales and marketing activities, the timing of 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, the Company may seek to raise funds through the sale of equity or other securities, bank borrowings or otherwise. There can be no assurance that financing through the sale of securities, bank borrowings or otherwise will be available to the Company on satisfactory terms, if at all.

Contractual Obligations and Commercial Commitments. The following sets forth the Company's approximate aggregate obligations at December 31, 2001 for future payments under contracts and other contingent commitments, for the years 2002 and beyond:

		Payments due by December 31,				
Contractual Obligations	**Total**	**2002**	**2003**	**2004**	**2005**	**Thereafter**
Long-term debt(1)	$ 4,644,030	$1,057,572	$2,236,923(2)	$ 247,842	$ 92,421	$1,009,272
Operating leases(3)	7,012,252	934,225	1,131,534	1,142,514	579,979	3,224,000
Employment contracts(4)	3,287,469	2,090,305	1,197,164	—	—	—
Capital expenditures(5)	644,995	644,995	—	—	—	—
Minimum commitments under contracts(6)	2,100,000	300,000	225,000	225,000	225,000	1,125,000
Total contractual obligations	$17,688,746	$5,027,097	$4,790,621	$1,615,356	$897,400	$5,358,272

(1) Represents principal repayments required under notes payable to the Company's lenders. See Note 8 to the financial statements included herein.

(2) $1,903,211 of the $2,236,923 represents a note payable which is subject to a call option in December 2003. If the note is not called in December 2003, payments of $577,542, $643,829 and $681,840 would be due in 2003, 2004, and 2005, respectively.

(3) Represents payments required under the Company's operating leases. See Notes 11 and 12 to the financial statements included herein.

(4) Represents salary, retention bonus or severance payments payable under the terms of employment agreements executed by the Company. See Note 11 to the financial statements included herein.

(5) Represents payments required by non-cancelable purchase orders related to capital expenditures. See Note 11 to the financial statements included herein.

(6) Represents payments required pursuant to certain research, licensing and royalty agreements executed by the Company. See Note 11 to the financial statements included herein.

Critical Accounting Policies and Estimates

Management's Discussion and Analysis of Financial Condition and Results of Operations discusses the Company's financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to 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, management evaluates its judgments and estimates, including those related to bad debts, inventories, investments, intangible assets, income taxes, revenue recognition, restructuring costs, contingencies, and litigation. Management bases its 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.

The Company's significant accounting policies are described in Note 2 to the financial statements included in Item 14 of this Report. Management considers the following policies to be most critical in understanding the more complex judgments that are involved in preparing the Company's financial statements and the uncertainties that could impact its results of operations, financial condition, and cash flows.

Revenue Recognition. The Company follows U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101, ''Revenue Recognition in Financial Statements'' (''SAB 101''). This bulletin draws on existing accounting rules and provides specific guidance on revenue recognition of up-front non-refundable licensing and development fees. The Company licenses certain products or technology to outside third parties, in return for which the Company receives up-front licensing fees, some of which can be significant. In accordance with SAB 101, the Company is required to defer immediate recognition of these fees as revenue, and instead ratably recognize this revenue over the related license period.

The Company also enters into research and development contracts with corporate, government or private entities. These contracts generally provide for payments to the Company 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.

The Company recognizes product revenues when products are shipped. The Company does not grant price protection or product return rights to its customers, except for warranty returns. Where a product fails to comply with its limited warranty, the Company 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, the Company expenses warranty returns as incurred. While such returns have been immaterial in the past, management cannot guarantee that the Company will continue to experience the same rate of warranty claims as it has in the past. Any significant increase in product warranty claims could have a material adverse impact on the Company's operating results for the period in which such 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, management performs credit evaluations of the Company's customers and adjusts credit limits based upon the customer's payment history and creditworthiness, as determined by a review of their current credit information. The Company continuously monitors collections and payments from its customers. Based upon the Company's historical experience and any specific customer collection issues that are identified, management uses its judgment to establish and evaluate the adequacy of the Company's allowance for estimated credit losses. While such credit losses have been within the Company's expectations and the allowance provided, the Company cannot guarantee that it will continue to experience the same credit loss rates as it has in the past. Furthermore, some of the Company's accounts receivable have resulted from sales to distributors located in foreign countries in South Africa and South America. Also, at December 31, 2001, approximately $1.3 million or 21.4% of the Company's accounts receivable were due from one major customer. Any significant changes in the liquidity or financial position of this customer, or the economies of these foreign nations, could have a material adverse impact on the collectibility of the Company's accounts receivable and its future operating results.

Inventories. The Company's 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 the Company's inventories are subject to expiration dating. The Company continually evaluates the carrying value of its 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. Management bases these decisions on the level of inventories on hand in relation to the Company's estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. Although the Company makes every effort to ensure the accuracy of its forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of the Company's inventories and its reported operating results.

Income Taxes. The Company has a history of losses, which has generated a sizeable federal tax net operating loss (''NOL'') carryforward of approximately $69.1 million as of December 31, 2001. Generally accepted accounting principles require the Company to record a valuation allowance against the deferred tax asset associated with this NOL carryforward if it is more likely than not that the Company will not be able to utilize the NOL carryforward to offset future taxes. Due to the size of the NOL carryforward in relation to the Company's history of unprofitable operations, the Company has not recognized any of this net deferred tax asset.

It is possible that the Company could be profitable in the future at levels which would cause management to conclude that it is more likely than not that the Company will realize all or a portion of the NOL carryforward.

Upon reaching such a conclusion, the Company would immediately record the estimated net realizable value of the deferred tax asset at that time and would then begin to provide for income taxes at a rate equal to the Company's combined federal and state effective rates, which management believes would approximate 40%. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause the Company's provision for income taxes to vary significantly from period to period.

Certain Relationships and Related Transactions

The Company has entered into a Commercial Lease (the ''Lease'') with Tech III Partners, LLC (''Tech Partners''), which provides for the construction of a 48,000 square foot facility on land adjacent to the Company's Bethlehem, Pennsylvania headquarters, and the lease of that facility to the Company. 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 is expected to house manufacturing, research and development, and administrative operations required to support the expected growth of the Company's business. Construction of the facility is expected to be completed during the summer of 2002.

The Lease has an initial 10-year term commencing after completion of construction and a base rent starting at $480,000 and increasing to $528,000 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. The Company has not guaranteed any debt incurred by Tech Partners. The Lease also provides the Company with options to renew the Lease for an additional five years at a rental rate of $600,000 per year, and to purchase the facility at any time during the initial ten-year term at a fair value. Prior to deciding to enter into the Lease, the Company's Board of Directors retained Imperial Realty Appraisal LLC, an independent commercial real estate appraisal firm, to evaluate the proposed base rental rate under the Lease. Imperial Realty issued an opinion indicating that the annual base rent set forth in the Lease is below the market rental rate the Company 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 the commercial lease entered into by the Company with a third party for its existing Bethlehem, Pennsylvania headquarters.

On January 31, 2002, the employment agreement with Robert D. Thompson, the Company's former Chief Executive Officer, was terminated, and Mr. Thompson resigned from the Company. The Company and Mr. Thompson have entered into a severance agreement pursuant to which Mr. Thompson will receive approximately $480,000. The severance agreement provides that a $75,000 interest-free loan previously made to Mr. Thompson in connection with his relocation from Portland, Oregon, will be repaid by application of an amount equal to his net bi-weekly salary commencing on or after April 17, 2002.

Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board (''FASB'') issued Statement of Financial Accounting Standards (''SFAS'') No. 141, ''Business Combinations'' (''SFAS No. 141''), which requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. Business combinations accounted for under the pooling of interests method prior to June 30, 2001 will not be affected. The adoption of SFAS No. 141 will not have any impact on the Company's financial position or results of operations.

In June 2001, the FASB issued SAFS No. 142, ''Goodwill and Other Intangible Assets'' (''SFAS No. 142''). SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired in a business combination and the accounting for goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized and that goodwill and intangible assets with indefinite lives not be amortized, but rather be tested at least annually for impairment. The adoption of SFAS No. 142 will not have any impact on the Company's financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, ''Accounting for the Impairment or Disposal of Long-Lived Assets'' (''SFAS No. 144''). SFAS No. 144 addresses the financial accounting and reporting for the impairment or disposal of long-lived assets and replaces SFAS No. 121, ''Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of.'' SFAS No. 144 provides updated guidance concerning the recognition and measurement of an impairment loss for certain types of long-lived assets and modifies the accounting and reporting of discontinued operations. The adoption of SFAS No. 144 will not have any impact on the Company's financial position or results of operations.

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

The Company does not hold any amounts of derivative financial instruments or derivative commodity instruments, and accordingly has no material market risk to report under this Item.

The Company's holdings of financial instruments are comprised of U.S. corporate debt, certificates of deposit, government securities, and commercial paper. All such instruments are classified as securities available for sale. The Company's debt security portfolio represents funds held temporarily pending use in its business and operations. The Company seeks 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, the Company could decide to hold the security to maturity or sell the security. The Company's holdings are also exposed to the risks of changes in the credit quality of issuers. The Company typically invests in the shorter end of the maturity spectrum.

The Company does not currently have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. The Company has operations in The Netherlands which are subject to foreign currency fluctuations. As currency rates change, translation of income statements of these operations from Euros to U.S. dollars affects year-to-year comparability of operating results. The Company's operations in The Netherlands represented approximately $2.0 million or 1% of the Company's revenues for the year ended December 31, 2001. Management does 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 the Company's Financial Statements included in Item 14 of this Annual Report on Form 10-K.

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

None.

PART III

The Company has omitted from Part III the information that will appear in the Company's Definitive Proxy Statement for its 2002 Annual Meeting of Stockholders (the ''Proxy Statement''), which will be filed within 120 days after the end of the Company's fiscal year pursuant to Regulation 14A.

ITEM 10. Directors and Executive Officers of the Registrant.

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

ITEM 11. Executive Compensation.

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

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

The information required by this item with respect to the securities ownership of certain beneficial owners and management is incorporated by reference to the information under the caption ''Principal Stockholders'' 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.

PART IV

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

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

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

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

1. Current Report on Form 8-K dated October 24, 2001, attaching a press release that announced third quarter 2001 financial results and disclosed certain ''Frequently Asked Questions'' and answers to those questions.

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 28, 2002.

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 28, 2002, 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**	Controller (Principal Accounting Officer)
/s/ *MICHAEL G. BOLTON **Michael G. Bolton**	Director
/s/ *WILLIAM W. CROUSE **William W. Crouse**	Director
/s/ *CARTER H. ECKERT **Carter H. Eckert**	Director
/s/ *FRANK G. HAUSMANN **Frank G. Hausmann**	Director
/s/ *GREGORY B. LAWLESS **Gregory B. Lawless**	Director
/s/ *ROGER L. PRINGLE **ROGER L. PRINGLE**	Director

*By: /s/ *RONALD H. SPAIR
Ronald H. Spair
(Attorney-in-Fact)

INDEX TO FINANCIAL STATEMENTS

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)

REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Shareholders of
OraSure Technologies, Inc.

In our opinion, the consolidated statements of operations, of changes in shareholders' equity and of cash flows of Epitope, Inc. (the Company) (not presented herein) present fairly, in all material respects, the Company's results of operations and cash flows for the three months ended December 31, 1999 and for the year ended September 30, 1999, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion. We have not audited the consolidated financial statements of the Company for any period subsequent to December 31, 1999.

PricewaterhouseCoopers LLP

Portland, Oregon
January 15, 2001

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31, 2001	December 31, 2000
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,426,346	$ 5,095,639
Short-term investments	12,764,903	14,956,779
Accounts receivable, net of allowance for doubtful accounts of $209,492 and $114,685	6,057,927	5,276,772
Notes receivable from officer	75,000	175,649
Inventories	4,444,772	1,495,604
Prepaid expenses and other	1,038,511	1,113,691
Total current assets	26,807,459	28,114,134
PROPERTY AND EQUIPMENT, net	7,800,137	6,738,034
PATENTS AND PRODUCT RIGHTS, net	2,042,533	2,402,386
OTHER ASSETS	634,546	481,618
	$ 37,284,675	$ 37,736,172
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,057,572	$ 1,125,138
Accounts payable	2,874,061	2,120,534
Accrued expenses	3,111,886	3,428,862
Total current liabilities	7,043,519	6,674,534
LONG-TERM DEBT	3,586,458	4,644,098
OTHER LIABILITIES	114,025	245,464
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, 37,403,269 and 36,434,004 shares issued and outstanding	37	36
Additional paid-in capital	152,758,591	148,767,789
Accumulated other comprehensive loss	(125,664)	(231,247)
Accumulated deficit	(126,092,291)	(122,364,502)
Total stockholders' equity	26,540,673	26,172,076
	$ 37,284,675	$ 37,736,172

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

	For the year ended December 31,		For the three months ended December 31,	For the year ended September 30,
	2001	2000	1999	1999
REVENUES:				
Product	$ 31,095,850	$ 28,095,408	$ 6,460,501	$ 23,147,808
Licensing and product development	1,477,494	692,808	361,153	898,213
	32,573,344	28,788,216	6,821,654	24,046,021
COST OF PRODUCTS SOLD	12,333,695	11,102,096	2,491,760	9,125,995
Gross profit	20,239,649	17,686,120	4,329,894	14,920,026
OPERATING EXPENSES:				
Research and development	9,389,313	10,399,120	1,412,288	5,590,807
Sales and marketing	7,880,496	6,932,068	1,682,030	5,696,673
General and administrative	6,852,326	6,876,516	1,518,488	6,224,408
Acquired in-process technology	—	—	—	1,500,000
Merger—related	—	7,607,158	—	—
Restructuring—related	450,000	—	—	—
	24,572,135	31,814,862	4,612,806	19,011,888
Operating loss	(4,332,486)	(14,128,742)	(282,912)	(4,091,862)
INTEREST EXPENSE	(402,686)	(490,415)	(135,357)	(544,643)
INTEREST INCOME	933,050	1,315,666	183,855	594,928
FOREIGN CURRENCY GAIN (LOSS)	3,122	(18,696)	(186,873)	(141,687)
GAIN ON SALE OF SECURITIES	100,000	600,000	—	—
Loss before income taxes	(3,699,000)	(12,722,187)	(421,287)	(4,183,264)
INCOME TAXES	28,789	24,363	50,000	50,000
NET LOSS	$ (3,727,789)	$ (12,746,550)	$ (471,287)	$ (4,233,264)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.10)	$ (0.36)	$ (0.02)	$ (0.14)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	36,868,101	35,002,283	30,887,007	30,596,882

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance at September 30, 1998	26,228,340	$ 26	$115,589,348	$ 15,042	$(104,902,963)	$ 10,701,453
Sale of common stock, net of expenses	5,720,003	6	8,851,345	—	—	8,851,351
Common stock issued upon exercise of options	632,580	1	3,028,575	—	—	3,028,576
Common stock issued as compensation	6,233	—	29,996	—	—	29,996
Common stock issued under Employee Stock Purchase Plan and Savings Plan	28,965	—	135,172	—	—	135,172
Compensation expense for stock option grants	—	—	321,006	—	—	321,006
Comprehensive loss:						
Net loss	—	—	—	—	(4,233,264)	(4,233,264)
Currency translation adjustment	—	—	—	(74,260)	—	(74,260)
Net unrealized loss on marketable securities	—	—	—	(200,000)	—	(200,000)
Total comprehensive loss						(4,507,524)
Balance at September 30, 1999	32,616,121	33	127,955,442	(259,218)	(109,136,227)	18,560,030
Common stock issued upon exercise of options	12,846	—	58,250	—	—	58,250
Common stock issued under Employee Stock Purchase Plan and Savings Plan	3,944	—	21,689	—	—	21,689
Compensation expense for stock option grants	—	—	87,200	—	—	87,200
Comprehensive loss:						
Net loss	—	—	—	—	(471,287)	(471,287)
Currency translation adjustment	—	—	—	(38,298)	—	(38,298)
Net unrealized loss on marketable securities	—	—	—	(131,250)	—	(131,250)
Adjustment for change in year-end	—	—	(7,092)	169,548	(10,438)	152,018
Total comprehensive loss						(488,817)
Balance at December 31, 1999	32,632,911	33	128,115,489	(259,218)	(109,617,952)	18,238,352
Common stock issued upon exercise of options	1,319,624	1	5,720,997	—	—	5,720,998
Common stock issued upon exercise of warrants	2,405,907	2	13,865,364	—	—	13,865,366
Common stock issued under Employee Stock Purchase Plan and Savings Plan	75,562	—	273,254	—	—	273,254
Compensation expense for stock option grants	—	—	792,685	—	—	792,685
Comprehensive loss:						
Net loss	—	—	—	—	(12,746,550)	(12,746,550)
Currency translation adjustment	—	—	—	(61,140)	—	(61,140)
Net unrealized gain on marketable securities	—	—	—	89,111	—	89,111
Total comprehensive loss						(12,718,579)
Balance at December 31, 2000	36,434,004	36	148,767,789	(231,247)	(122,364,502)	26,172,076
Common stock issued upon exercise of options	968,729	1	3,851,805	—	—	3,851,806
Common stock issued under Employee Stock Purchase Plan and Savings 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

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

	For the year ended December 31,		For the three months ended December 31,	For the year ended September 30,
	2001	2000	1999	1999
OPERATING ACTIVITIES:				
Net loss	$ (3,727,789)	$(12,746,550)	$ (471,287)	$ (4,233,264)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Stock based compensation expense	136,874	792,685	87,200	321,006
Common stock issued as compensation for services	—	62,409	—	105,471
Amortization of deferred revenue	(179,167)	(143,334)	(40,313)	(107,500)
Acquired in-process technology	—	—	—	1,500,000
Depreciation and amortization	2,175,055	2,243,001	448,654	1,855,479
Gain on sale of securities and disposition of investment in affiliated company	(116,853)	(600,000)	—	—
(Gain) loss on disposition of property and equipment	173,975	10,844	42,245	(36,952)
Provision for reserve for excess and obsolete inventories	600,000	1,141,351	—	—
Deferred income taxes	—	—	91,497	—
Changes in assets and liabilities—				
Accounts receivable	(1,118,408)	(1,853,514)	(261,924)	(985,070)
Inventories	(3,549,168)	(231,516)	237,956	(300,882)
Prepaid expenses and other	175,829	(153,631)	(76,981)	31,817
Accounts payable	443,050	308,789	(199,275)	47,904
Accrued expenses and other	(269,248)	1,125,020	482,312	843,381
Net cash provided by (used in) operating activities	(5,255,850)	(10,044,446)	340,084	(958,610)
INVESTING ACTIVITIES:				
Purchases of property and equipment	(2,763,639)	(3,071,565)	(626,036)	(1,701,520)
Proceeds from the sale of property and equipment	33,231	—	78,250	98,250
Purchase of patents and product rights	—	(619,589)	(18,024)	(1,627,377)
Purchase of short-term investments	(21,297,303)	(24,869,468)	(1,250,261)	(37,624,613)
Proceeds from sale of short-term investments	23,420,432	22,339,595	2,016,757	29,383,614
Proceeds from sale of securities	637,500	600,000	—	—
Proceeds from disposition of investment in affiliated company	106,102	—	—	—
Investment in affiliated companies	—	(20,404)	(32,181)	(17,435)
(Increase) decrease in other assets	(202,819)	50,000	—	195,273
Net cash provided by (used in) investing activities	(66,496)	(5,591,431)	168,505	(11,293,808)
FINANCING ACTIVITIES:				
Proceeds from term debt	—	—	—	2,219,433
Repayment of term debt	(1,125,206)	(1,054,194)	(250,374)	(1,872,475)
Net proceeds from issuance of common stock	3,853,929	19,797,206	79,939	11,939,624
Net cash provided by (used in) financing activities	2,728,723	18,743,012	(170,435)	12,286,582
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(75,670)	(61,140)	(38,298)	(74,260)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,669,293)	3,045,995	299,856	(40,096)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	5,095,639	2,049,644	1,749,788	2,370,469
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 2,426,346	$ 5,095,639	$ 2,049,644	$ 2,330,373

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

NOTES TO THE FINANCIAL STATEMENTS

1. BACKGROUND:

The Company

OraSure Technologies, Inc. (the ''Company'') develops, manufactures and markets oral specimen collection devices using its proprietary oral fluid technologies, proprietary diagnostic products including *in vitro* diagnostic tests, and other medical devices. These products are sold in the United States and certain foreign countries to government agencies, clinical laboratories, physician offices, hospitals, commercial and industrial entities and various distributors.

Merger

On September 29, 2000, STC Technologies, Inc. (''STC'') and Epitope, Inc. (''Epitope'') were merged (the ''Merger'') into the Company, a newly formed subsidiary of Epitope 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 companies were merged pursuant to an Agreement and Plan of Merger, dated May 6, 2000, by and among Epitope, the Company and STC, which was subsequently approved by both companies' stockholders on September 29, 2000. 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. Information concerning common stock, employee stock plans and per share data has been restated on an equivalent share basis. The financial statements as of September 30, 1999 and for the year then ended include Epitope's previous September 30 fiscal year amounts and STC's December 31, 1999 calendar year amounts.

Change in year-end

On September 29, 2000, the Board of Directors of Epitope approved a change in the fiscal year-end of Epitope 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'') preceded the start of the 2000 fiscal year. References to ''1999'' mean the year ended September 30, 1999 and include Epitope's previous September 30 fiscal year amounts and STC's December 31, 1999 calendar year amounts. References to ''2001'' and ''2000'' mean the combined results of the two companies for the years ended December 31, 2001 and 2000, respectively. 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 1999 and for the Transition Period. Included in the statement of stockholders' equity is a $152,018 adjustment for the change in fiscal year-end, which represents STC's results of operations for the three months ended December 31, 1999 that is included in both 1999 and the Transition Period.

A reconciliation of revenues, operating income (loss) and net income (loss) of Epitope and STC for the periods prior to the combination is as follows:

	Three months ended December 31, 1999	Year ended September 30, 1999
Revenues:		
Epitope	$2,669,026	$10,031,020
STC	4,152,628	14,015,001
Combined	$6,821,654	$24,046,021
Operating income (loss):		
Epitope	$ (549,488)	$ (3,515,544)
STC	266,576	(576,318)
Combined	$ (282,912)	$ (4,091,862)
Net income (loss):		
Epitope	$ (481,725)	$ (3,237,644)
STC	10,438	(995,620)
Combined	$ (471,287)	$ (4,233,264)

There were no material adjustments required to conform the accounting policies of the two companies. Certain amounts of Epitope have been reclassified to conform to the current presentation. The amounts depicted above for both companies have been adjusted to reflect the elimination of intercompany transactions between Epitope and STC.

In connection with the Merger, during the year ended December 31, 2000, the Company recorded Merger-related expenses of $7.6 million, which were comprised of the following:

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

Transaction costs include investment banking, legal, accounting, printing and other direct costs of the Merger. Employee costs represent severance benefits paid to terminated employees whose responsibilities were deemed redundant as a result of the Merger, as well as certain relocation expenses. Other integration costs include financial system conversion costs and integration-related travel expenses. Stock-based compensation represents the amount of unamortized deferred compensation on certain nonqualified options granted by Epitope in prior years, which were immediately accelerated upon the closing of the Merger under terms of the grants. Of the $7.6 million Merger-related expenses incurred, $690,750 was accrued at December 31, 2000 and paid in 2001.

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 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

The Company considers all highly liquid investments purchased with an original maturity of ninety days or less to be cash equivalents. As of December 31, 2001 and 2000, cash equivalents consisted of certificates of deposit, commercial paper and U.S. government and agency obligations.

Short-term Investments

The Company considers 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, U.S. government and agency obligations and corporate bonds with original maturities greater than ninety days and less than one year. Available-for-sale securities are carried at fair value, based upon quoted market prices with unrealized gains and losses reported in stockholders' equity as a component of accumulated other comprehensive income (loss).

The following is a summary of available-for-sale securities at December 31, 2001 and 2000:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2001				
Certificates of deposit	$ 2,398,963	$ 709	$ —	$ 2,399,672
Government and agency bonds	5,027,637	70,200	—	5,097,837
Corporate bonds	5,267,939	37,109	(37,654)	5,267,394
Total current available-for-sale securities	$12,694,539	$108,018	$(37,654)	$12,764,903
December 31, 2000				
Certificates of deposit	$ 2,864,038	$ —	$ —	$ 2,864,038
Government and agency bonds	6,587,463	49,785	—	6,637,248
Corporate bonds	5,366,167	89,326	—	5,455,493
Total current available-for-sale securities	$14,817,668	$139,111	$ —	$14,956,779

In addition, at December 31, 2000, certain available-for-sale marketable securities with a carrying value of $287,500, including an unrealized loss of $250,000, were classified as other assets due to the Company's intent to hold these securities for greater than one year. In 2001, the Company recorded a gain of $100,000 upon the sale of these securities.

Supplemental Cash Flow Information

For 2001, 2000, the Transition Period and 1999, the Company paid interest of $402,686, $490,410, $135,357 and $565,025, respectively.

For 2001, 2000, the Transition Period and 1999, the Company recorded provisions for bad debts of $100,000, $0, $0 and $8,851, respectively. The Company had deductions of $5,193, $4,269, $0 and $0 against the allowance for doubtful accounts in 2001, 2000, the Transition Period and 1999, 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 the Company's inventories are subject to expiration dating. The Company continually evaluates quantities on hand and the carrying value of its 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. The Company currently buys its entire Histofreezer® product line from a foreign vendor, with such purchases payable in Euros. Changes in the exchange rate of the Euro could impact the Company's product cost.

Property and Equipment

Property and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets or the lease term, whichever is shorter. Buildings are depreciated over 20 years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over three to ten years. Leasehold improvements are generally amortized over the shorter of the estimated useful lives or the terms of the related leases. When assets are sold or otherwise disposed of, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the statement of operations.

Patents and Product Rights

Patents and product rights consist of costs associated with the acquisition of patents and product distribution rights and direct costs associated with patent submissions. Patents and product rights are amortized using the straight-line method over estimated useful lives of five to ten years. Amortization expense for 2001, 2000, the Transition Period and 1999 was $359,853, $816,111, $123,366 and $482,106, respectively.

Revenue Recognition

The Company recognizes product revenues when products are shipped. The Company does not grant price protection or product return rights to its customers, except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, the Company expenses warranty returns as incurred.

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

In accordance with Emerging Issues Task Force (''EITF'') Issue No. 00-10, ''Accounting for Shipping and Handling Fees and Costs,'' the Company records shipping and handling charges billed to customers as revenue.

Significant Customer Concentration

In 2001, 2000 and 1999, one customer accounted for approximately 29 percent, 30 percent and 28 percent of total revenues, respectively. The same customer accounted for approximately 21 percent and 24 percent of accounts receivable as of December 31, 2001 and 2000, respectively.

Research and Development

Research and development costs are charged to expense as incurred.

Income Taxes

The Company follows SFAS No. 109, ''Accounting for Income Taxes'' (''SFAS No. 109''), pursuant to which the liability method is used in accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates that are expected to be in effect when the differences reverse.

Foreign Currency Translation

Pursuant to SFAS No. 52, ''Foreign Currency Translation,'' the assets and liabilities of the Company's 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.

Stock-Based Compensation

The Company accounts 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. The Company accounts for stock-based compensation to nonemployees using the fair value method in accordance with SFAS No. 123, ''Accounting for Stock-Based Compensation'' (''SFAS No. 123'') and EITF Issue No. 96-18, ''Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring or in Conjunction with Selling, Goods or Services'' (''EITF No. 96-18'').

Net Loss Per Common Share

The Company has presented basic and diluted net loss per share pursuant to SFAS No. 128, ''Earnings per Share'' (''SFAS 128''). In accordance with SFAS 128, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is generally computed assuming the conversion or exercise of all dilutive securities such as common stock options and warrants; however, outstanding common stock options and warrants to purchase 3,915,233, 4,677,357, 6,907,212 and 7,002,673 shares were excluded from the computation of diluted net loss per common share for 2001, 2000, the Transition Period and 1999, respectively, because they were anti-dilutive due to the Company's losses.

Impairment of Long-Lived Assets

In accordance with SFAS No. 144, ''Accounting for the Impairment or Disposal of Long-Lived Assets'' (''SFAS No. 144''), if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets, which include property and equipment and patents and product rights, by determining whether the carrying value of such assets can be recovered through the sum of the undiscounted future operating cash flows and eventual disposition of the asset. If impairment is indicated, the Company measures 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. Management believes the future cash flows to be received from the long-lived assets will exceed the assets' carrying value, and accordingly the Company has not recognized any impairment losses through December 31, 2001.

Other Comprehensive Income (Loss)

The Company follows 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 retained earnings and additional paid-in capital, in the equity section of the balance sheet.

Restructuring-related Expenses

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

Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board (''FASB'') issued SFAS No. 141, ''Business Combinations'' (''SFAS No. 141''), which requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. Business combinations accounted for under the pooling of interests method prior to June 30, 2001 will not be changed. The adoption of SFAS No. 141 by the Company will not have any impact on the Company's financial position or results of operations.

In June 2001, the FASB issued SAFS No. 142, ''Goodwill and Other Intangible Assets'' (''SFAS No. 142''). SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired in a business combination and the accounting for goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized, and that goodwill and intangible assets with indefinite lives not be amortized, but rather be tested at least annually for impairment. The adoption of SFAS No. 142 will not have any impact on the Company's financial position or results of operations.

In June 2001, the FASB issued SFAS No. 143, ''Accounting for Asset Retirement Obligations'' (''SFAS No. 143''). SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of long-lived assets and the associated asset retirement costs. SFAS No. 143 requires the fair value of a liability associated with an asset retirement be recognized in the period in which it is incurred, with the associated retirement costs capitalized as part of the carrying amount of the long-lived asset and subsequently depreciated over its useful life. The adoption of SFAS No. 143 will not have any impact on the Company's financial position or results of operations.

Gain on Sale of Securities

In December 2001, the Company 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 entered into by the Company and Lab*One*, Inc. in April 1999. The Company's original investment associated with these shares was $537,500. The Company no longer holds any common shares or warrants of Lab*One*, Inc.

In December 1996, a subsidiary of the Company completed a merger with Andrew and Williamson Sales, Co. (''A&W''), which was rescinded on May 27, 1997. The Company received A&W preferred stock in the recission, which had been carried at zero value due to the circumstances surrounding A&W's financial condition at the time the stock was received in 1997. In 2000, the Company sold the A&W preferred stock for $600,000.

Reclassifications

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

3. INVENTORIES:

	December 31, 2001	December 31, 2000
Raw materials	$ 2,918,825	$ 473,575
Work in process	644,397	348,819
Finished goods	881,550	673,210
	$ 4,444,772	$ 1,495,604

4. PROPERTY AND EQUIPMENT:

	December 31, 2001	December 31, 2000
Building and leasehold improvements	$ 5,464,353	$ 4,599,859
Machinery and equipment	9,935,897	7,848,905
Computer equipment	2,131,606	2,134,411
Furniture and fixtures	1,205,750	1,096,176
Construction in progress	698,675	942,937
	19,436,281	16,622,288
Less—Accumulated depreciation and amortization	(11,636,144)	(9,884,254)
	$ 7,800,137	$ 6,738,034

Depreciation expense was $1,815,202, $1,426,890, $325,288 and $1,373,373 for 2001, 2000, the Transition Period and 1999, respectively.

5. PATENTS AND PRODUCT RIGHTS:

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

6. ACCRUED EXPENSES:

	December 31, 2001	December 31, 2000
Payroll and related benefits	$ 1,728,651	$ 1,331,545
Professional fees	271,112	372,211
Deferred revenue	401,060	741,295
Other	711,063	983,811
	$ 3,111,886	$ 3,428,862

7. CREDIT FACILITIES:

The Company has a $1,000,000 revolving line of credit with a bank which bears interest at LIBOR plus 235 basis points. Borrowings under this line are collateralized by the Company's accounts receivable. The line expires on April 30, 2002. There were no borrowings against the line at December 31, 2001 or 2000.

The Company also has a $3,000,000 equipment facility with a bank, with interest fixed at the bank's prime rate on the date of commencement. Borrowings under this line are collateralized by the equipment financed. There were no outstanding borrowings under this facility as of December 31, 2001 or 2000. The unused portion of the equipment facility expires on April 30, 2002.

These credit facilities require, among other items, the maintenance of certain financial covenants.

8. LONG-TERM DEBT:

	December 31,	
	2001	**2000**
Note payable to bank, interest at 8%, monthly installments of principal and interest of $59,219 through December 2003, at which point the remaining principal is subject to a call option by the lender or payable in monthly installments of principal and interest based on the prime rate plus 1% through December 2005, secured by certain property and equipment, inventory and intangible assets	$ 2,435,902	$ 2,927,226
Note payable to bank, interest at 8%, monthly installments of principal and interest of $8,181 through December 2003, with remaining monthly installments of principal and interest based on the prime rate plus 1% through December 2018, subject to call options by the lender every five years commencing March 31, 2010, secured by the Company's building	904,238	928,021
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 the Company's building	442,285	491,518
Note payable to bank, interest at 7.8%, monthly installments of principal and interest of $23,146 through July 2004, secured by certain property and equipment, inventory and intangible assets	647,779	864,937
Note payable to bank, interest at 7.75%, monthly installments of principal and interest of $31,271 through July 2002, secured by certain property and equipment, inventory and intangible assets	213,826	557,534
	4,644,030	5,769,236
Less—Current portion	(1,057,572)	(1,125,138)
	$ 3,586,458	$ 4,644,098

Long-term debt maturities as of December 31, 2001 are as follows:

2002	$1,057,572
2003	2,236,923
2004	247,842
2005	92,421
2006	95,800
Thereafter	913,472
	$4,644,030

These notes payable require, among other items, the maintenance of certain financial covenants.

9. INCOME TAXES:

At December 31, 2001, the Company had net operating loss carryforwards for federal income tax purposes of approximately $69.1 million that have begun to expire and will continue to expire through 2021. The Tax Reform Act of 1986 contains provisions that may limit the annual amount of net operating loss carryforwards available to be used in any given year in the event of significant changes in ownership. In connection with the Merger, a change in ownership occurred. Management believes the annual limitation will not have a material effect on the Company's ability to utilize its loss carryforwards. Given the Company's losses in recent years, management believes a valuation allowance is needed as of December 31, 2001.

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

	December 31	
	2001	2000
Deferred tax asset:		
Net operating loss carryforwards	$ 26,949,000	$ 24,901,000
Stock based compensation	2,643,000	2,253,000
Accruals and reserves currently not deductible	1,696,000	1,384,000
Patent costs	445,000	491,000
Research and development credit carryforwards	1,850,000	1,677,000
Valuation allowance on deferred tax assets	(33,583,000)	(30,706,000)
	$ —	$ —

10. STOCKHOLDERS' EQUITY:

Stock Options

As a result of the Merger, the Epitope, Inc. 2000 Stock Award Plan was adopted by the Company and renamed 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 common stock may be granted to eligible employees, including officers of the Company. To date, options have generally been granted with ten-year exercise periods and an exercise price not less than the fair market value on date of grant. Options generally vest over four years, with one quarter of the options vesting one year after grant with 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. For the discounted nonqualified options issued, the Company amortizes, on a straight-line basis over the vesting period of the options, the difference between the exercise price and the fair market value of a share of stock on the date of grant.

The Company applies APB Opinion No. 25 and the related interpretations in accounting for stock options granted to employees. Accordingly, compensation expense is recognized for the intrinsic value (the difference between the exercise price and the fair value of the Company's common stock) on the date of grant. Compensation, if any, is deferred and charged to expense over the respective vesting period. In 2000, the Company issued an executive an option to purchase 375,000 shares of common stock for $4.59 per share. The fair market value of the Company's common stock at the date of issuance was $6.13. The Company recorded

deferred compensation of $577,500 on the date of grant to be amortized over the vesting period of three years. However, the options immediately vested upon the closing of the Merger in accordance with change in control rights contained in the stock option grant. As a result, the Company recorded $577,500 of compensation expense in 2000 related to the options. The Company recorded an additional $215,185 of compensation expense in 2000 due to the amortization of deferred compensation related to other stock options due to the change in control rights provided under the applicable stock option grants.

Under SFAS No. 123, compensation expense related to stock options granted to employees and directors is computed based on the fair value of the stock option at the date of grant using an option valuation methodology, typically the Black-Scholes pricing model. Pursuant to the disclosure requirements of SFAS No. 123, had compensation expense for the Company's common stock option plan been determined based upon the fair value of the options at the date of grant, the Company's net loss for 2001, 2000 and 1999 would have increased as follows:

	Year ended December 31,		Year ended September 30,
	2001	2000	1999
Net loss:			
As reported	$ (3,727,789)	$ (12,746,550)	$ (4,233,264)
Pro forma	$ (6,640,938)	$ (17,611,122)	$ (6,553,202)
Basic and diluted net loss per share:			
As reported	$ (0.10)	$ (0.36)	$ (0.14)
Pro forma	$ (0.18)	$ (0.50)	$ (0.21)

The weighted average fair value of the options granted during 2001, 2000 and, 1999, is estimated at $7.10, $4.96 and $2.44 per share, respectively, using the Black-Scholes option pricing model with the following assumptions: dividend yield of zero; volatility of 65 percent, 64 percent and 55 percent, respectively; weighted average risk-free interest rate of 4.86 percent, 6.13 percent and 5.31 percent, respectively; and an expected life of 7.0, 7.0 and 4.3 years, respectively.

The Company accounts for stock-based compensation to non-employees using the fair value method, in accordance with SFAS No. 123 and EITF No. 96-18. In 2001, the Company recorded compensation expense related to options to purchase 19,000 shares of the Company's common stock granted to members of a non-employee advisory board and an outside consultant. Compensation expense of $136,874 was computed based on the estimated fair value of the stock options at the date of grant, using the Black-Scholes option pricing model.

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

	Shares	Price per Share
Balance, September 30, 1998	3,958,199	$1.29-18.17
Granted	1,331,869	0.80- 6.84
Exercised	(632,580)	3.54- 6.31
Canceled	(242,122)	0.80-18.17
Balance, September 30, 1999	4,415,366	0.80- 3.97
Granted	584,143	0.80- 3.97
Exercised	(17,846)	3.22- 5.04
Canceled	(184,228)	0.80-18.17
Adjustment for change in year end	(427,530)	0.80- 2.83
Balance, December 31, 1999	4,369,905	0.80-18.17
Granted	1,596,142	4.59-15.03
Exercised	(1,319,624)	0.80- 6.00
Canceled	(139,066)	0.80-18.17
Balance, December 31, 2000	4,507,357	0.80-15.03
Granted	357,000	7.88-12.95
Exercised	(968,729)	0.80- 9.47
Canceled	(150,395)	0.80-14.81
Balance, December 31, 2001	3,745,233	$0.80-15.03

At December 31, 2001, 1,272,909 shares were available for future grants under the 2000 Plan. The following table summarizes information about stock options outstanding at December 31, 2001:

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	490,703	7.39	$ 0.80	226,658	$ 0.80
$ 2.83-$4.17	539,176	12.34	3.70	539,176	3.70
$ 4.22-$4.59	397,800	11.23	4.56	397,800	4.56
$ 4.72-$4.97	153,194	6.98	4.79	153,194	4.79
$ 5.04	541,123	12.67	5.04	541,123	5.04
$ 5.50-$6.84	177,851	7.06	6.49	177,851	6.49
$ 7.09	927,176	8.95	7.09	275,151	7.09
$ 7.30-$10.71	398,460	9.36	9.89	84,818	9.47
$10.92-$14.84	117,750	9.01	12.69	27,750	12.87
$15.03	2,000	8.52	15.03	2,000	15.03
	3,745,233	9.89	$ 5.57	2,425,521	$ 4.84

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 the Company. 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 each fiscal year of the Company. 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, 2001 and 2000, 8,804 and 9,832 shares of common stock, respectively, were subscribed for through one offering. These shares may be purchased over 24 months at an initial subscription price of $3.96. During the years ended December 31, 2001 and 2000, 536 and 70,253 shares, respectively, were issued at prices ranging from $2.74 to $4.78 per share under the 1993 ESPP.

Common Stock Warrants

As of December 31, 2001, the following warrants to purchase shares of common stock were outstanding:

Date of Issuance	Shares	Exercise Price	Expiration Date
July 15, 1992	50,000	$16.44	July 15, 2002
September 30, 1998	120,000	$ 6.13	September 30, 2008
	170,000		

11. COMMITMENTS AND CONTINGENCIES:

Phosphor Agreements

In April 1995, the Company entered into several research, licensing and royalty agreements (collectively the ''Phosphor Agreements''), related to development and commercialization of the Company's up-converting phosphor technology (''UPT™''). Under the terms of the Phosphor Agreements, as amended, the Company is 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 the Company. Upon the first commercial sale of a UPT™-based product or service, the Company is then 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 the Company's minimum royalty obligation of $100,000 per year.

In July 1999, the Company paid approximately $1,500,000 to acquire certain rights (the ''Rights'') related to UPT™. The Company accounted for the purchase price of the Rights as acquired in-process technology expense, because at the date of the transaction, the Rights acquired by the Company had not progressed to a stage where the technology, or any alternative future use of the technology, had met technological feasibility. Furthermore, there existed a significant amount of uncertainty as to the Company's ability to complete the development of this technology and achieve market acceptance of any related commercial products within a reasonable timeframe. In connection with this acquisition of this in-process technology, the Company is required to pay sponsored research funds of $125,000 in 2002 and $50,000 per year thereafter, as well as royalties of $25,000 per year, until the Rights expire in 2008. During 2001, the Company finalized development of its first commercial product utilizing this technology.

Leases

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

2002	$ 654,225
2003	651,534
2004	662,514
2005	99,979
2006 and thereafter	—
	$2,068,252

Rent expense for 2001, 2000 and 1999 was $805,878, $716,748 and $461,105, respectively.

Capital Expenditures

As of December 31, 2001, the Company had outstanding non-cancelable purchase commitments of $644,995 related to capital expenditures.

Employment Agreements

Under terms of employment agreements with certain executive officers and other employees, extending through 2003, the Company is required to pay each individual a base salary and for some individuals, a retention bonus, for continuing employment with the Company. The agreements require payments of $2,090,305 and $1,197,164, in 2002 and 2003, respectively, which include the severance payments discussed below.

On January 31, 2002, the Company terminated an employment agreement with an executive officer. During the first quarter of 2002, the Company will record $480,063 in severance expenses, of which, $269,010 and $211,053 is payable in 2002 and 2003, respectively. These expenses include continued salary and benefit premium payments to this officer, related employment taxes, and the value of certain computer equipment transferred to this individual. As of January 31, 2002, the Company held a $75,000 note receivable from this officer, which he has agreed to repay in bi-weekly principal installments of approximately $7,000, commencing in April 2002 (See Note 12).

Litigation

From time-to-time, the Company is 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 the Company's future financial position or results of operations.

12. RELATED-PARTY TRANSACTIONS:

Officer Notes

In March and October 2000, the Company issued notes receivable to an officer of the Company (''Officer Notes'') for $75,000 and $100,649, respectively, for relocation purposes. The Officer Notes do not bear interest if they are repaid on or before the earlier of the tenth day following the close of sale on the officer's previous residences or the due date of the Officer Notes, as extended. In May 2001, this officer repaid the Officer Note having an outstanding balance of $100,649. In January 2002, this same officer resigned from the Company and as part of his severance agreement, agreed to repay the remaining $75,000 balance in bi-weekly principal installments of approximately $7,000, commencing in April 2002. (See Note 11).

Facility Lease

Effective March 1, 2002, the Company signed a 10-year operating lease with Tech III Partners, LLC, an entity owned and controlled by two of the Company's executive officers. Under the terms of this lease, the

Company will lease a 48,000 square foot facility currently being constructed on land adjacent to the Company's headquarters, at a base rent of $480,000 per year, increasing to $528,000 per year, during the initial 10-year term. The lease also provides for certain renewal and purchase options.

13. RETIREMENT PLANS:

As a result of the Merger, during 2000 and a portion of 2001, the Company maintained two distinct retirement plans covering substantially all of its 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. During the prior periods reported, generally all employees of Epitope were eligible to participate in a profit sharing and deferred savings plan. The plan provided for a Company matching contribution (either in cash, Company 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. The Company contributed 5,309, 2,691 and 12,693 shares valued at $62,409, $17,492 and $75,475 during 2000, the Transition Period, and 1999, respectively, to this plan. During the prior periods reported, generally all employees of STC were eligible to participate in a profit sharing plan. The plan provided for the Company, subject to the Board of Directors' discretion, to match employee contributions up to $3,000 or 8% of a participant's salary, whichever is less. Company contributions to the plan were $75,789, $122,903, $19,247, and $113,708 for 2001, 2000, the Transition Period, and 1999, respectively.

On May 1, 2001, the Company 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 employer's current taxable income under provisions of Internal Revenue Code Section 401(k) and the regulations thereunder. The New Plan also provides for the Company to match employee contributions up to the lesser of $4,000 or 10% of the employee's salary. Contributions to the New Plan were $239,402 in 2001.

14. GEOGRAPHIC INFORMATION:

Under the disclosure requirements of SFAS No. 131, ''Segment Disclosures and Related Information,'' the Company operates within one segment, medical devices and products. The Company's products are sold principally in the United States and Europe. Operating income and identifiable assets are not applicable since all of the Company's revenues outside the United States are export sales.

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

	For the year ended December 31,		For the three months ended December 31,	For the year ended September 30,
	2001	2000	1999	1999
United States	$27,321	$24,763	$5,912	$21,382
Europe	3,510	2,507	659	1,816
Other regions	1,742	1,518	251	848
	$32,573	$28,788	$6,822	$24,046

15. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2001 and 2000, as well as the Transition Period and the comparable three-month period ended December 31, 1998. These quarterly results are unaudited, but in the opinion of management, have been prepared on the same basis as the Company's 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).

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

	2000 Results				
	Three months ended				Year ended December 31, 2000
	March 31, 2000	June 30, 2000	September 30, 2000	December 31, 2000	
Revenues	$ 6,619	$ 7,161	$ 7,222	$ 7,786	$ 28,788
Costs and expenses	7,512	8,313	15,435	11,657	42,917
Operating loss	(893)	(1,152)	(8,213)	(3,871)	(14,129)
Other income, net	115	771	302	219	1,407
Loss before income taxes	(778)	(381)	(7,911)	(3,652)	(12,722)
Income taxes	56	(44)	13	—	25
Net loss	$ (834)	$ (337)	$(7,924)	$(3,652)	$(12,747)
Basic and diluted net loss per share	$ (0.03)	$ (0.01)	$ (0.22)	$ (0.10)	$ (0.36)
Weighted average number of shares outstanding	33,442	34,818	35,370	36,361	35,002

	Three months ended December 31,	
	1999	1998
Revenues	$ 6,822	$ 5,138
Costs and expenses	7,105	5,857
Operating loss	(283)	(719)
Other expense	(138)	(159)
Loss before income taxes	(421)	(878)
Income taxes	50	—
Net loss	$ (471)	$ (878)
Basic and diluted net loss per share	$ (0.02)	$ (0.03)
Weighted average number of shares outstanding	30,887	26,246

Board of Directors

William W. Crouse
Chairman of the Board, OraSure Technologies, Inc.
Managing Director, HealthCare Ventures LLP

Michael G. Bolton (1, 2)
Chief Executive Officer and Managing Director, PA Early Stage Partners

Michael J. Gausling
President and Chief Executive Officer, OraSure Technologies, Inc.

Frank G. Hausmann (2)
Chairman and Chief Executive Officer, CenterSpan Communications Corporation

Carter H. Eckert
Former President and Chief Executive Officer, Knoll Pharmaceutical Company

Roger L. Pringle (1, 2)
President, The Pringle Company

Gregory B. Lawless (1)
Managing Partner, Collins Mabry & Co.

Committees of the Board
1. Compensation
2. Audit

Executive Officers

Michael J. Gausling
President and Chief Executive Officer

William D. Block
Senior Vice President, Sales and Marketing

R. Sam Niedbala, Ph.D.
Executive Vice President and Chief Science Officer

Jack E. Jerrett
Vice President, General Counsel and Secretary

Ronald H. Spair
Executive Vice President and Chief Financial Officer

Mark L. Kuna
Controller, Assistant Treasurer and Assistant Secretary

P. Michael Formica
Senior Vice President, Operations

Independent Public Accountants

Arthur Andersen LLP
1601 Market Street
Philadelphia, PA 19103-2499

Investor Relations

OraSure Technologies, Inc.
Attention: Shannon Morin
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www.orasure.com

Mission

To create, combine and collaborate to be the world's leading oral fluid diagnostics company.

To leverage our success with OraQuick® and UPlink™ to become the world's leading point-of-care diagnostics company.

To deliver superior diagnostic solutions through the use of the most user friendly and technologically advanced sample collection, detection, information, and confirmation technologies.

To be entrepreneurial, build a culture based on our Core Values, and work to exceed stakeholder expectations.

Core Values

Trust *– Develop trust by delivering total quality, solving problems quickly, and resolving issues equitably.*

Agility *– Respond quickly and efficiently to capture opportunities, and adapt our operating plans to meet unpredictable and inevitable change.*

Innovation *– Encourage risk taking and create partnerships to achieve the most user-friendly and technologically advanced solutions possible.*

Quality *– Maintain the highest level of quality in every aspect of our business, always striving to exceed marketplace expectations.*

Transfer Agent

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South Hackensack, NJ 07606
800-522-6645
TDD for hearing impairment
800-231-5469
Foreign Stockholders
201-329-8660

Stock Information

The Company's common stock is traded on the National Market tier of The Nasdaq Stock Market under the symbol OSUR.
Options in the Company's common stock are traded on the American Stock Exchange and on the Chicago Board Options Exchange.

Form 10-K

A copy of the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission, is available without charge by writing the Investor Relations Department at OraSure Technologies, Inc.

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