SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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# FORM 10-K

(Mark one)

[X] Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2000

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<br>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 [X] No [ ]

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, as of March 16, 2001: $176,268,488

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of March 16, 2001: 36,502,385 shares.

Documents Incorporated by Reference:

Portions of Registrant's Definitive Proxy Statement for the 2001 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 (the "Merger Agreement"), by and among Epitope, STC and the Company. The stockholders of STC and Epitope approved the Merger Agreement on September 29, 2000.

The Merger was structured as an all-stock transaction valued at $260 million. As a result of the Merger, (i) each share of STC common stock was converted into the right to receive five and two hundred ninety-six one thousandths (5.296) shares of the Company's Common Stock and (ii) each share of Epitope common stock was converted into the right to receive one share of the Company's Common Stock. The Merger has been accounted for as a "pooling of interests."

The Merger is expected to leverage the Company's expertise in oral fluid technology, infectious disease testing and substance abuse testing. By building upon the complementary product portfolios, technologies and sales infrastructures of Epitope and STC, the Company intends to open up new markets in the United States and other countries and strengthen its position in key markets such as the rapidly expanding point-of-care market. In particular, the proprietary up-converting phosphor technology contributed by STC has broad applications for oral fluid testing. With the increased sensitivity and accuracy of this technology, the Company believes it can continue to expand the menu of tests available for oral fluid point-of-care testing. This same basic technology is also expected to be of significant benefit to other medical diagnostic manufacturers outside the expertise contributed by Epitope and STC. For many of these additional applications, OraSure Technologies plans to license these other companies to provide an ongoing revenue stream of license fees and royalties.

#### Products

OraSure Technologies develops, manufactures and markets oral fluid 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 public and private-sector clients, clinical laboratories, physician offices, and hospitals, and for workplace testing.

OraSure Technologies' business focuses on the following principal platform technologies: (1) the OraSure® oral fluid collection device, (2) the OraQuick® rapid diagnostics 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® cryosurgical system, certain immunoassay tests and reagents for insurance risk assessment and forensic toxicology applications, an oral fluid Western Blot confirmatory test for HIV-1, and the Q.E.D.® Saliva Alcohol Test.

OraSure® Collection Device

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 OraSure device consists of a small, treated cotton-fiber pad on a nylon

handle that is placed in a person's mouth for two minutes. The device collects oral mucosal transudate ("OMT"), a serum-derived fluid that contains higher concentrations of antibodies than saliva. As a result, OMT testing is a highly accurate method for detecting HIV infection and other analytes. The Company believes that oral fluid testing has several significant advantages over blood or urine-based testing systems for both healthcare professionals and individuals being tested, including eliminating the risks 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 a trained healthcare professional to administer.

The Company has received clearance from the U.S. Food and Drug Administration ("FDA") to sell the OraSure oral fluid collection device to professional markets 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 confirmatory test (described below). A trained healthcare professional then conveys test results and provides appropriate counseling to the individual who was tested. The Company has also received clearance for use of the OraSure collection device with EIAs to test for cocaine and for cotinine (a metabolite of nicotine) in oral fluid specimens.

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

A collection device substantially similar to the OraSure device is included as part of the Company's Intercept™ oral fluid drug test service. The Company has received FDA clearance to use the Intercept collection device with EIAs to test for drugs of abuse commonly known as the NIDA-5 (i.e. cannabinoids (marijuana), cocaine, opiates, amphetamines, and phencyclidine ("PCP")) and for benzodiazepines, barbiturates, and methadone. Intercept was launched for the workplace testing, public health, criminal justice and drug rehabilitation markets in February 2000. In 1999, the Company entered into an exclusive agreement with Lab*One*, Inc., pursuant to which the Company agreed to exclusively sell, and Lab*One* agreed to exclusively purchase and distribute, Intercept collection devices and associated reagents for drugs-of-abuse testing in the workplace testing market in the United States and Canada. Under the agreement, Lab*One* provides all laboratory services necessary to test oral fluid specimens collected by customers including screening and confirmatory studies. The term of the agreement runs until December 31, 2002, with automatic yearly renewals unless either party gives notice at least 180 days prior to the end of the then-current term.

The Company believes that the Intercept service has several advantages over certain competing products for drugs-of-abuse testing, including its non-invasive nature, the ease of maintaining a chain-of-custody without embarrassment to the person being tested, and the lack of requirement for specially prepared collection facilities. The availability of an oral fluid test is intended to allow workplace administrators to test for impairment on demand, eliminate scheduling costs, and streamline the testing process.

OraQuick®

The OraQuick device is the Company's recently developed rapid test designed to test an oral fluid, whole blood or serum/plasma sample for the presence of various antigens. 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, serum or plasma is to be tested, a loop collection device is used to collect the sample 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. No laboratory-based EIA is required, as the OraQuick test is visually read shortly after the specimen is collected.

The first product utilizing this technology is the OraQuick HIV-1/2 device, a rapid test for the presence of antibodies against HIV-1 and HIV-2. 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-1/2

device. Clinical trials in the United States are underway, although the Company has experienced difficulty in recruiting a sufficient number of known positive subjects. Due to the critical need for an FDA-cleared rapid HIV test, the Company, after consultation with the FDA and the Centers for Disease Control and Prevention ("CDC"), has decided to submit an initial application for FDA clearance for testing of whole blood, serum and plasma during the second quarter of 2001. This decision was based on OraSure Technologies' belief that a whole blood clinical trial could be completed more quickly than one involving oral fluid. The Company is continuing its oral fluid clinical trials and expects to submit an application for FDA clearance of oral fluid tests during the third quarter of 2001.

The Company has received approval from the CDC to use the OraQuick HIV-1/2 test in a CDC-sponsored IDE. The CDC has identified several key areas for use of the OraQuick HIV-1/2 device in the IDE, including certain public hospitals in five U.S. metropolitan areas with relatively high HIV sero-prevalence among pregnant women, AIDS service organizations, community-based organizations, outreach programs, and selected hospital emergency departments and outpatient clinics. 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. These results indicated a 100% sensitivity and 99.5% specificity for the OraQuick device with whole blood samples.

In July 2000, the Company introduced the OraQuick HIV-1/2 device for sale outside the United States at the International AIDS Conference in Durban, South Africa. Clinical tests for the OraQuick HIV-1/2 device have been completed in Thailand, with the results demonstrating 100% sensitivity and 99.9% specificity.

The Company intends to market the OraQuick HIV-1/2 product in the hospital, physician office and public health markets focusing initially on international markets. The Company recently entered into an agreement for the distribution of the OraQuick HIV-1/2 device in Sub-Saharan Africa, with $5 million in revenues expected from minimum quantities required to be purchased under the agreement during the first year. Distribution agreements have been entered into or are being pursued in numerous other 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 HIV-2 and lateral flow patents, some of which have been obtained, in order to market the OraQuick HIV-1/2 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*™

*UPT™ Technology*. UPT is a proprietary label detection platform being developed by the Company that uses phosphor particles to detect minute quantities of various substances such as drugs, proteins, and DNA. UPT is based on the use of a unique patented technology which is used to detect the presence of specific substances in tests designed by the Company. 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. OraSure Technologies and its research partners have developed phosphorescent particles that up-convert infrared light to visible light, which the Company is using to develop several applications.

Phosphor particles have been used for decades in television screens and in fluorescent light bulbs. When ultraviolet light strikes the phosphor-coated area in a screen or bulb, it excites the particles and colored light is produced. The Company's patented improvements on this base technology employ chemical changes inside the phosphor particles so that infrared light can be used to produce a colored signal. 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. UPT particles also offer the following other key competitive features:

- Ability to detect biological markers for several substances simultaneously
- Stability in a variety of biological specimens
- A permanent test record not subject to fading
- Applicability to a variety of instrument platforms
- A low-cost detection method that is easy to use
- 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 begin experiments on the simultaneous detection of multiple biological markers to permit multiplexing, demonstrating initial feasibility for the use of UPT particles in drugs-of-abuse, infectious disease, cancer, and limited DNA detection applications, and developing a UPT collector, test cassette and reader for a variety of applications.

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 reader, which provides instrument-read quantitative results in about 10 minutes on a variety of samples, including without limitation oral fluid, blood, serum, urine and stool samples.

In March 2000, the Company signed a research and development agreement with 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 the 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 to law enforcement officials as a system for rapidly assessing whether a subject is under the influence of one or more drugs of abuse. 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 worldwide distributor of the UP*link* drugs-of-abuse test cassette and reader developed under the research and development agreement to law enforcement officials for use in rapidly assessing whether a subject is taking one or more drugs-of-abuse substances.

In December 2000, the Company submitted an application for 510(k) clearance from the FDA for its UP*link* reader and three oral fluid drugs-of-abuse assays – cocaine, opiates and amphetamines. A similar application for two additional oral fluid assays – marijuana and PCP – is expected to be submitted to the FDA during the second quarter of 2001. The Company expects to commence commercial sales of UP*link* for oral fluid drugs-of-abuse testing in the second half of 2001.

In September 2000, OraSure Technologies signed a research and development agreement with Meridian Bioscience, Inc. (formerly Meridian Diagnostics, Inc.) ("Meridian"), a fully integrated 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 distribute worldwide the readers and lateral flow cassettes developed under the research and development agreement. The Company will receive payments upon achievement of certain milestones and royalties from the sale of the readers and testing devices. OraSure Technologies has commenced work on the development of

two tests under the research and development agreement and expects to submit an application for FDA 510(k) clearance of a number of tests in the third quarter of 2001. The Company also expects to begin shipping tests for international distribution by Meridian during the second half of 2001.

Histofreezer®

In 1991, the Company became the exclusive U.S. distributor of the Histofreezer Portable Cryosurgical System, a low-cost alternative to liquid nitrogen and other eradication methods for removal of benign epidermal 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 now integrating a dealer network in more than 20 countries worldwide.

Histofreezer is a mixture of 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 –55C. The frozen bud is then applied to the lesion for 20 to 40 seconds creating localized destruction of the target area. Histofreezer is sold in two sizes of canisters. Histofreezer sales 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. Both types of assays are sold as finished kits.

AUTO-LYTE tests are sold as bottles of reagents. The reagents are used with commercially available automated analytical instruments which are manufactured by a variety of third parties. AUTO-LYTE tests provide medium sensitivity to detect substances comprised of small molecules. AUTO-LYTE is typically used in high volume, automated, commercial reference laboratories. Test results are produced faster, allowing for higher throughput.

In the MICRO-PLATE kit, the sample to be tested is placed into 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 are generally not provided by the Company. The test kit is commonly used for high sensitivity measurement of substances comprised of both large and small molecules. OraSure Technologies has used this testing format to develop tests that detect substances in urine, serum, and oral fluid specimens. The MICRO-PLATE assays generally have greater sensitivity than the AUTO-LYTE assays.

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 may in turn 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 purchase agreements and reagent rental 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 provides the tests as well as analytical laboratory equipment.

Western Blot Confirmatory Tests

The Company markets an oral-based HIV-1 Western Blot confirmatory test that received FDA clearance 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 Organon Teknika Corporation.

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 has been consistently unprofitable because of low production yields and the high cost of ensuring the quality of the end product.

Q.E.D.® Saliva Alcohol Test

The Q.E.D. Saliva Alcohol Test is an on-site, cost-effective test device which 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"). The product received a Clinical Laboratory Improvement Act of 1988 ("CLIA") waiver in 1997. 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 line comes in two testing ranges, 0 to 0.145% and 0 to 0.30% blood alcohol, and produces results in two to five 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 businesses 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 Applications

Oral mucosal transudate contains many constituents found in blood serum, although in lower concentrations. The Company therefore believes the OraSure device is a platform technology with a wide variety of potential applications beyond HIV-1 and drugs-of-abuse testing. 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, syphilis and diabetes. The National Institutes of Health ("NIH") 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 using an oral fluid sample collected with the OraSure device. The Company previously received a grant of $118,000 from the NIH as funding for Phase I of this project, which was completed in 2000. OraSure Technologies has also entered into an agreement with Lab*One* to develop a laboratory-based oral fluid screening test for Hepatitis C using the OraSure collection device. The Company is presently developing an improved formulation of the OraSure device, to be called OraSure II, which will be designed to improve the effectiveness of collecting and preserving human antibodies in oral fluid for infectious disease testing and is expected to be more cost effective.

The Company is also developing additional drug assays to be used in connection with its Intercept product line in the insurance testing, criminal justice and drug rehabilitation markets.

OraQuick Platform

The Company believes that OraQuick has significant potential as a rapid test for physician offices, hospitals and other professional use. Like OraSure, 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, syphilis and other diseases.

UPT and UP*link* Development

The Company is in the final stages of developing an UP*link* system for rapid drugs-of-abuse testing under its agreement with Dräger and for its own commercial applications in the U.S. The Company has commenced development of three tests for infectious diseases and expects to commence development of additional tests later in 2001 for other infectious diseases under its agreement with Meridian. Other potential applications of UPT include thyroid testing, cancer testing, cardiac testing and therapeutic drug monitoring. In addition, the Company is studying the feasibility of using UPT labels for the detection of infectious diseases with DNA probes.

Western Blot Confirmatory Test

The Company is developing an improved Western Blot confirmatory test for HIV-1, which will be designed for use on oral fluid, whole blood, and serum\plasma specimens.

## Research and Development

In 2000, research and development activities focused on the development of the OraQuick HIV-1/2 rapid test (including significant clinical trials, validation and scale-up expenses), development of the UP*link* reader, 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.

The Company supplements its own research and development activities by funding external research. The Company has been funding, and will continue to fund, research at Leiden University, SRI International, and Lehigh University.

Research and development expenses totaled approximately $10.4 million in 2000, $5.6 million in 1999, and $4.5 million in 1998.

## 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 to each target market.

The Company markets its products in the United States and internationally. Product revenue attributable to customers in the United States amounted to $24.8 million, $21.4 million, and $17.8 million in 2000, 1999 and 1998, respectively. Revenues attributable to international customers amounted to $4.0 million, $2.7 million, and $2.6 million in 2000, 1999 and 1998, respectively.

Insurance Testing

The Company currently markets the OraSure oral fluid collection device for use in screening life insurance applicants in the U.S. and internationally to test for three of the most important underwriting risk factors: HIV-1, cocaine, and cotinine (a metabolite of nicotine). 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 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.

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-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 in "Preferred" products in addition to the $1 million and higher dollar policy amounts. This expansion is attributable to several factors, including increasing comfort with the reliability of oral fluid testing following its successful use, the high quality of test results, the low cost of oral fluid testing relative to blood tests, and the ease of use of OraSure.

The Company also sells its AUTO-LYTE and MICRO-PLATE assays and reagents in the insurance testing market directly to laboratories. 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.

Public Health and Physician Office Markets

The Company's sales personnel market its products directly to customers in the public health market. 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 similar 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* and Heritage Labs to provide prepackaged OraSure test kits, with prepaid laboratory testing and specimen shipping costs included. The Company also began distributing the OraQuick HIV-1/2 device in the public health markets internationally through independent distributors in December 2000.

The Company sells the Histofreezer product line to distributors that market to more than 150,000 primary care physicians and podiatrists in the U.S. Major U.S. distributors include 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, the largest of which is B. Braun.

Substance Abuse

The Company's substance abuse products are marketed into the workplace testing, forensic toxicology, criminal justice, and drug rehabilitation markets. The forensic toxicology market consists of 250 – 300 laboratories including federal, state and county crime laboratories, medical examiner laboratories, and reference laboratories. The criminal justice market consists of a wide variety of entities in the criminal justice system that require drug screening, such as pre-trial services, parole and probation officials, drug courts, prisons, drug treatment programs and community/family service programs. The Company has entered into a contract with Lab*One* to assemble and distribute Intercept collection kits and associated reagents for drugs-of-abuse testing in the workplace testing market in the United States and Canada. Intercept and Q.E.D. are also marketed through direct sales and other 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 insurance testing, public health and laboratory testing. The Company assists its distributors in registering the products 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 oral fluid collection devices, Histofreezer, and immunoassay tests and reagents accounted for total revenues of approximately $11.2 million, $6.8 million, and $6.7 million in 2000, $7.8 million, $5.7 million, and $6.2 million in 1999, and $7.2 million, $4.8 million, and $4.8 million in 1998, respectively.

The Company has one customer that has accounted for 10% or more of total revenues. During 2000, the Company's sales to Lab*One*, Inc., accounted for approximately 23% of the Company's total revenues. The Company believes that its relationship with this customer is strong and that it will purchase comparable or increasing values of the Company's products for the foreseeable future. However, there can be no assurance that sales to this customer will not decrease 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 could have a material adverse effect on the Company.

**Supply and Manufacturing**

The Company has entered into an agreement with a contractor in Oregon for the assembly and supply of OraSure oral fluid collection devices until 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 device on terms no less favorable than those set forth in the agreement with the Oregon contractor in the event that this contractor were to be unable to continue manufacturing this product, although a change in manufacturer of the OraSure device would require FDA review and clearance which could require significant time to complete.

In February 2001, the Company announced its plans to realign its manufacturing operations, which will include 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 manufacturing capacity in Thailand. In connection with this realignment, the Company has entered into a supply agreement for the manufacture of OraQuick HIV-1/2 testing devices in Thailand. This agreement has an initial term of one year from the date production commences, which 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 Thailand agreement in the event that the Thailand contractor were to be unable to continue manufacturing this product.

The Company expects to assemble readers, test cassettes and collectors used in the Company's UP*link* rapid test and to package this product for shipment at the Company's Bethlehem facilities.

The Company's oral fluid Western Blot HIV confirmatory test is manufactured in the Company's Beaverton, Oregon facilities. The HIV-1 antigen needed to manufacture the Company's Western Blot HIV confirmatory test kits is available from only a limited number of sources. Organon Teknika Corporation, the exclusive distributor of the test kits, is required to supply the Company's requirements for antigen for the term of its distribution agreement with the Company, which originally extended to March 31, 2001. OraSure Technologies and Organon Teknika are currently negotiating certain amendments to the agreements, including an extension of their terms. If for any reason Organon Teknika should no longer be able to supply the Company's antigen needs, management believes the Company would be able to obtain its own supply of antigen at a competitive cost, although a change in the antigen would require FDA approval.

Histofreezer is manufactured in The Netherlands by Koninklijke, Utermöhlen, N.V., 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 Koninklijke, Utermöhlen, N.V. shall be the exclusive supplier of the Histofreezer product until June 1, 2003. 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 Koninklijke, Utermöhlen, N.V. in the event that Koninklijke, Utermöhlen, N.V. were to be unable 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. Antibodies are produced commercially by injecting a vaccine consisting of a purified, specific antigen into one of a variety of animals. The injected animal's immune system then manufactures antibodies, which are contained in blood samples and are collected on a routine basis, purified through the use of a chemical process, and prepared for use in various diagnostic products. Substantially all of the Company's antibody requirements are produced 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 for use in laboratory equipment. MICRO-PLATE test kits are produced by placing purified antibodies onto a plastic container which is sent to customers in multiples of ninety-six tests along with a set of reagents necessary to control the reaction. The reaction container is sealed in a foil package and placed in a box with the reagents.

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

**Employees**

As of December 31, 2000, the Company had 210 full-time employees, including 42 in sales, marketing, and client services; 73 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.

On February 1, 2001, the Company announced that in connection with the realignment of its manufacturing operations, employee headcount would be reduced in its Beaverton, Oregon office by approximately 35 persons, or 33% of staffing at that facility. This reduction is expected to occur through layoffs and attrition during the first half of 2001. The Company expects to increase staffing at its Bethlehem, Pennsylvania facility as a result of the start-up of manufacturing operations at that location.

**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, finally, 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, 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 may intensify as technological advances are made and become more widely known and as products reach the market in greater numbers. 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 and have announced plans to seek FDA approval of such tests in 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. Although the sensitivity and specificity are less than blood-based or oral fluid tests, 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.

Calypte, Inc. and Bio-Rad Laboratories, Inc. manufacture HIV Western Blot confirmatory tests, and Waldheim Pharmazeutika manufactures immuno-fluroescent HIV confirmatory tests, which competed with the Company's HIV-1 Western Blot serum-based confirmatory test kits and could compete with the Company's improved Western Blot confirmatory test once developed.

Significant competitors in the rapid assay HIV testing market include Abbott Laboratories, the Ortho Diagnostics division of Johnson & Johnson, and Trinity Biotech.

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 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. and Roche Diagnostics.

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, and are delivered to the laboratory as a complete "system package" of reagents and instrumentation (known as a "reagent rental" transaction) to meet the specific needs of each customer. Rental reagent transactions are usually offered only by companies significantly larger than OraSure Technologies.

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 homogeneous assays include Dade Behring, Abbott Diagnostics, Roche Diagnostics, and Immunalysis.

The Intercept drug testing service 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 drug testing market are Quest Diagnostics, LabCorp., Psychemedics, PharmChem, and Medtox Laboratories. The drugs-of-abuse application of UP*link* will compete with other rapid drug assays. Major competitors in the rapid drug testing market include American Biomedica, Roche Diagnostics, Inc., and Biosite Diagnostics.

Within the sub-segment of oral fluid drugs-of-abuse testing, Intercept competes with Avitar, Inc., which markets a rapid test called Oral Screen™ to the workplace and criminal justice markets, 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, Inc. and Chematics. These companies offer semi-quantitative saliva-based alcohol tests and both 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 patented 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 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. Competition for the Histofreezer product includes portable cryosurgical systems from CryoSurgery, Inc. and Ellman International. 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 six United States patents and numerous foreign patents for the OraSure collection device and related technology, and has applied for additional patents, in both the United States and certain foreign countries, on such product and technology. The Company has one patent application pending for OraQuick HIV-1/2 in the United States and has obtained or is seeking licenses under existing patents held by third parties with respect to that product and technology. 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, some of which have been obtained, in order to market the OraQuick HIV-1/2 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 (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 (1) 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 (2) to secure a direct research, development, and license arrangement with Leiden University.

The United States and European Patent Offices have issued licensors nine patents for methods, compositions, and apparatuses relating to phosphor technologies. Several additional UPT patent applications remain pending in the U.S. and abroad. The Company expects to continue to expand its UPT patent portfolio in 2001.

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 four 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 clearance, the Company must continue to comply with other FDA requirements applicable to marketed products. Both before and after 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 Western Blot HIV-1 confirmatory test is regulated as a biologic product.

There are two review procedures by which medical devices can receive FDA clearance. Some products may qualify for clearance under a Section 510(k) procedure, in which the manufacturer provides a premarket 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. Clearance under this procedure may be granted within 90 days, although in some cases as much as a year or more may be required.

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 a Class III device required by statute and the FDA's implementing regulations to have an approved application for premarket approval), the FDA must approve a premarket approval application ("PMA") before marketing can begin. PMAs must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA is typically a complex submission, including the results of preclinical and clinical studies. Preparing a PMA is a detailed and time-consuming process. Once a PMA has been submitted, the FDA's review may be lengthy, 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 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 labeled for "forensic use only." The FDA does not currently regulate these products.

Every company that manufactures biological products or medical devices distributed in the United States must comply with the FDA's Good Manufacturing Practices ("GMP") regulations (also known as the Quality System Regulations). These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation, and purchasing. Compliance with GMPs is generally required before the FDA will approve a PMA or BLA, 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 GMPs 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.

In June 2000, the FDA issued observations of deficiencies following an inspection of OraSure Technologies' manufacturing facilities in Beaverton, Oregon, stating the FDA's view that some of the Company's products were not manufactured in compliance with GMP regulations. The FDA 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 facilities. The FDA has questioned the Company's compliance with GMP regulations in areas such as process validation, purchasing controls, complaint handling, and equipment controls at the Oregon facilities. The Company has undertaken a substantial review of its manufacturing and quality assurance, and has either already made changes or has changes in process, to satisfy the FDA's regulations with respect to its GMP compliance. These plans were 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 changes in process that will adequately address the FDA's concerns.

Although production of the Serum Western Blot product line has been suspended, OraSure Technologies has recognized that the basic changes to the overall quality systems 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 by the Company's efforts. If the FDA is not satisfied, it could take action intended to force OraSure Technologies to stop manufacturing its Western Blot or other products until the FDA believes the Company is in compliance with GMP requirements. Also, although the FDA has recently 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 GMP compliance is not sufficient.

The Company has voluntarily recalled Q.E.D. tests on two occasions. In both instances, the Q.E.D. tests were recalled because the Company did not believe that the materials met its quality standards. Both recalls were conducted according to FDA guidelines. The FDA investigated the initial recall in December 1996 and did not take any action against the Company. The FDA investigated the second recall in March 1998 and issued a 483 Notice due to the Company's failure to confirm to the FDA that the corrective actions taken by the Company to remedy the deficiencies leading to the March 1998 recall had corrected the problems. The Company has confirmed with the FDA that its corrective actions addressed the issues that led to the recall. If violations of the applicable regulations are noted during future FDA inspections of the Company's manufacturing facility, or the manufacturing facilities of a contract manufacturer, the continued marketing of the Company's products may be adversely affected.

International

The Company is also subject to regulations in foreign countries governing products, human clinical trials and marketing. 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 has complied with standards applicable 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 also received authorization to use the CE mark for its Histofreezer product line.

The Company must also submit evidence of marketing 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 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; 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; equipment failures and ability to obtain needed raw materials and components; and general 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. 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 also expects that oral fluid testing for drugs of abuse will be accepted 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. There can be no assurance that the Company will be able to expand 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, the Company has historically depended to a substantial degree on capital raised through the sale of equity securities to fund its operations. The Company's future liquidity and capital requirements will depend on numerous factors, including 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 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 securities. There can be no assurance that financing through the sale of equity securities, or otherwise, will be available 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 diagnostic companies and distributors. For example, the Company's OraSure Western Blot confirmatory tests are distributed through Organon Teknika, and the OraSure collection device is distributed to the insurance industry through major insurance testing laboratories. The Company's sales depend to a substantial degree on its ability to develop product distribution channels and on the marketing abilities of the companies with which it collaborates. There can be no assurance that such companies will continue to be able to distribute the Company's products or that new distribution channels will be available on satisfactory terms.

Ability to Obtain and Timing of Regulatory Approvals

The Company is subject to strict government controls on the development, manufacture, labeling, distribution and marketing of its products. The Company often must obtain and maintain regulatory approval for a product from a country's national health or drug regulatory agency before the product may be sold in a particular country. The submission of an application to a regulatory authority does not guarantee that it will grant a license to market the product. Each authority may impose its own requirements and delay or refuse to grant approval, even though a product has been approved in another country.

In the Company's principal markets, the approval process for a new product can be complex and lengthy. The time taken to obtain approval varies depending on the nature of the application and may result in the passage of a significant period of time from the date of application. This increases the cost of developing new products and increases the risk that the Company will not succeed in introducing or selling them.

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 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 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 a CE mark will be received prior to the deadline.

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 quality assurance and other systems that are intended to comply with applicable regulations. The FDA has issued warning letters and a letter of intent to revoke the Company's license 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. 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 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. See the Section entitled "Government Regulation" for a further discussion of regulatory compliance matters.

Changes in Federal or State Law or Regulations

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 agencies. The process of obtaining required approvals from these agencies varies according to the nature of and uses for the product and can involve lengthy and detailed laboratory and clinical testing, sampling activities, and other costly and time-consuming procedures. Changes in government regulations could 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 not affect the Company's products directly but may nonetheless 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.

Ability to Market New Products

OraSure Technologies' future success will depend partly on the market acceptance, and the timing of such acceptance, of recently introduced products such as the Intercept oral fluid drug test service, the OraQuick rapid oral fluid test, products currently under development such as UP*link* 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 for products and technologies both in the United States and in other countries. Litigation or other legal proceedings may be necessary to defend against claims of infringement or to enforce intellectual property rights, and could result in substantial costs and diversion of resources.

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

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. If the Company is unable to obtain these types of licenses, the Company's product development and commercialization efforts may be delayed.

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

The Company may incur substantial costs 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 or federal 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.

Patent Issues Affecting OraQuick

There are factors that will affect the specific countries in which the Company will be able to sell its OraQuick rapid HIV-1/2 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 less than 2% of 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 its OraQuick rapid HIV 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 require the ability 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 generally considered sufficient, 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.

Another factor that may affect the specific countries in which the Company will be able to sell its OraQuick rapid HIV 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 test or its use. The OraQuick rapid HIV test is an analyte-specific lateral flow assay device. There are numerous patents in the United States and other countries which claim lateral flow assay methods and devices that are analyte independent. Some of these patents broadly cover the technology used in the OraQuick assay and are in force in the United States and other countries. The Company would also not be able to make the OraQuick rapid HIV test in the United States and sell it in countries where there is no patent on the device. The Company has licenses under several lateral flow patents and is considering the need for licenses under others. In the event that 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 U.S. and other markets.

History of Losses and Projected Profitability

The Company has not achieved profitability, but expects to be profitable during the second half of 2001 and for the year 2001. The Company incurred net losses of approximately $12.7 million and $4.2 million in 2000 and 1999, respectively, and as of December 31, 2000, the Company had an accumulated deficit of approximately $122.4 million. The Company's limited combined operating history makes it difficult to forecast future operating results. In order to achieve profitability in the estimated time period, the Company's revenue will have to continue to grow at the estimated rates. The Company's ability to reach its estimated revenue growth will be dependent upon a number of factors, including without limitation achieving growth in international markets through the Company's OraQuick rapid HIV test, creating market acceptance for the Intercept drugs of abuse products, and commercially developing, 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 UPT products or its other products, or to the extent other events described in this Section entitled "Risk Factors" occur, the Company's revenue, and consequently profitability, could be lower than estimated.

Loss of Key Personnel

The Company's success will depend to a large extent upon the contributions of its executive officers, management, 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 other 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 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 geologists, biochemists and engineers. 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 technical 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, and in particular scientific 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 plans 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 devote significant resources to increase international sales of its OraQuick and UPT products. However, in the past, it has not had significant direct experience with the governmental regulatory agencies in foreign countries that control sale of products into those countries. In addition to economic and political issues, 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 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 accounts receivable collection may be more difficult;

The Company recently entered into a contract for the manufacture and supply of the OraQuick HIV-1/2 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 or sale. Although the Company has obtained product liability insurance, this insurance may not fully cover potential liabilities. As new products come 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 OraSure Technologies or its strategic partners. If the Company is sued for any injury caused by its products, its liability could exceed its total assets.

Ability to Commercialize UPT

The Company's up-converting phosphor technology is new and is in the early stage of development. Commercial development of UPT may not be successful. Successful products require significant development and investment,

including testing, to demonstrate their cost-effectiveness or other benefits prior to their 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 level of investment for development and commercialization may necessitate involving one or more strategic partners. In particular, the Company's strategy for development and commercialization of UPT and certain other products may entail entering into additional arrangements with corporate partners, universities, research laboratory licensees, and others. If OraSure Technologies is not able to enter into such arrangements, the Company 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 seven issued United States patents, and of one pending U.S. patent application. Corresponding patents and patent applications have been granted or issued 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. Failure by the licensor to prosecute such applications and protect such patent rights could harm the Company's business. 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.

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 on the south side of Bethlehem, Pennsylvania located at 150 Webster Street, 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 33,500 square feet on 3.4 acres of land at 1745 Eaton Avenue 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 believes that its existing facilities are adequate for its current requirements.

**ITEM 3. Legal Proceedings.**

The Company is not a party to any material legal proceedings.

**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 fiscal year covered by this Report.

**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 Merger, 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.

Sales prices per share

| Year ended December 31 | 2000 | | 1999 | |
|---|---|---|---|---|
| | High | Low | High | Low |
| First Quarter | $18.188 | $5.563 | $8.375 | $4.500 |
| Second Quarter | 14.375 | 7.000 | 6.125 | 3.688 |
| Third Quarter | 15.938 | 9.938 | 7.500 | 4.875 |
| Fourth Quarter | 13.500 | 5.563 | 7.219 | 4.375 |

On March 16, 2001, there were 836 holders of record of the Common Stock, and the closing price of the Common Stock was $6.75 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 years ended September 30, 1997 and 1996 include discontinued operations of two of Epitope's former subsidiaries, Agritope, Inc. and Andrew and Williamson Sales, Co. The charge for discontinued operations during these periods 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, 2000 | Three months ended December 31, 1999 | Year ended September 30, 1999 | 1998 | 1997 | 1996 |
|---|---|---|---|---|---|---|
| **Operating Results:** | | | | | | |
| Revenues | $ 28,788 | $ 6,822 | $ 24,046 | $ 20,444 | $ 17,282 | $ 13,211 |
| Costs and expenses | 42,917 | 7,105 | 28,138 | 22,721 | 23,295 | 19,606 |
| Other income (expense), net | 1,407 | (138) | (91) | (98) | 782 | 6,158 |
| Loss from continuing operations before income taxes | (12,722) | (421) | (4,183) | (2,374) | (5,231) | (237) |
| Loss from continuing operations | (12,747) | (471) | (4,233) | (2,374) | (5,231) | (267) |
| Discontinued operations | - | - | - | - | (18,359) | (2,501) |
| Net loss | (12,747) | (471) | (4,233) | (2,374) | (23,590) | (2,768) |
| **Per Share of Common Stock:** | | | | | | |
| Loss from continuing operations | $ (0.36) | $ (0.02) | $ (0.14) | $ (0.09) | $ (0.20) | $ (0.01) |
| Loss from discontinued operations | - | - | - | - | (0.70) | (0.11) |
| Net basic and diluted loss | (0.36) | (0.02) | (0.14) | (0.09) | (0.90) | (0.12) |
| **Shares used in per share calculations:** | 35,002 | 30,887 | 30,597 | 26,180 | 26,055 | 23,253 |
| **Financial position:** | | | | | | |
| Working capital | $ 21,495 | $ 16,314 | $ 16,773 | $ 8,725 | $ 12,470 | $ 30,096 |
| Total assets | 37,736 | 29,626 | 30,251 | 20,783 | 25,978 | 40,242 |
| Long-term debt | 4,644 | 5,820 | 5,820 | 6,001 | 4,026 | 5,077 |
| Accumulated deficit | (122,365) | (109,618) | (109,104) | (104,903) | (96,837) | (73,246) |
| Stockholders' equity | 26,172 | 18,238 | 18,592 | 10,701 | 17,873 | 31,676 |

## 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.*

### Results of Operations – 2000 Compared to 1999

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 valued at $260 million and was accounted for as a "pooling of interests." The Company is reporting its financial results for 2000 on a calendar year basis. 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 fiscal year ending December 31 for financial reporting purposes beginning in 2000. As a result, the Financial Data for 1999 reflects results for the twelve-month periods ended September 30, 1999 and December 31, 1999 for Epitope and STC, respectively. See Note 1 to the Company's Financial Statements for a discussion of the Merger and the change in fiscal year end.

The Merger is expected to leverage the Company's expertise in oral fluid technology, infectious disease testing and substance abuse testing. By building upon the complementary product portfolios, technologies and sales infrastructures of Epitope and STC, the Company intends to open up new markets in the United States and other countries and strengthen its position in key markets such as the rapidly expanding point-of-care market. In particular, the proprietary up-converting phosphor technology contributed by STC has broad applications for oral fluid testing. With the increased sensitivity and accuracy of this technology, the Company believes it can continue to expand the menu of tests available for oral fluid point-of-care testing. This same basic technology is also expected to be of significant benefit to other medical diagnostic manufacturers outside the expertise contributed by Epitope and STC. For many of these additional applications, OraSure Technologies plans to license these other companies to provide an ongoing revenue stream of license fees and royalties.

Comparative results of operations are summarized as follows:

| (In thousands) | Dollars | | Percent Change (%) | Percentage of Total Revenue (%) | |
|---|---|---|---|---|---|
| | 2000 | 1999 | | 2000 | 1999 |
| Revenues | | | | | |
| Product | $ 28,095 | $ 23,148 | 21 | 98 | 96 |
| License and product development | 693 | 898 | (23) | 2 | 4 |
| | 28,788 | 24,046 | 20 | 100 | 100 |
| Cost and expenses | | | | | |
| Cost of products sold | 11,102 | 9,126 | 22 | 39 | 38 |
| Research and development | 10,399 | 5,591 | 86 | 36 | 23 |
| Sales and marketing | 6,932 | 5,697 | 22 | 24 | 24 |
| Acquired in-process technology | - | 1,500 | (100) | - | 6 |
| General and administrative | 6,877 | 6,224 | 10 | 24 | 26 |
| Merger related expenses | 7,607 | - | N/A | 26 | - |
| | 42,917 | 28,138 | 53 | 149 | 117 |
| Operating loss | (14,129) | (4,092) | (245) | (49) | (17) |
| Interest expense | (491) | (545) | (10) | (2) | (2) |
| Interest income | 1,316 | 595 | 122 | 5 | 2 |
| Foreign currency loss | (19) | (141) | (87) | - | (1) |
| Gain on sale of securities | 600 | - | N/A | 2 | - |
| Loss before income taxes | (12,723) | (4,183) | (204) | (44) | (18) |
| Income taxes | 24 | 50 | (52) | - | - |
| Net Loss | $(12,747) | $ (4,233) | (201) | (44) | (18) |

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 products and by license and product development activities.

| | Dollars | | Percent Change (%) | Percentage of Total Revenues (%) | |
|---|---|---|---|---|---|
| | 2000 | 1999 | | 2000 | 1999 |
| Product revenue | | | | | |
| Oral specimen collection devices | $ 11,239 | $ 7,806 | 44 | 39 | 32 |
| OraQuick | 80 | - | N/A | - | - |
| Histofreezer cryosurgical systems | 6,779 | 5,744 | 18 | 24 | 24 |
| Immunoassay tests | 6,726 | 6,158 | 9 | 23 | 26 |
| Western Blot HIV confirmatory tests | 1,897 | 2,133 | (11) | 7 | 9 |
| Other product revenue | 1,374 | 1,307 | 5 | 5 | 5 |
| | 28,095 | 23,148 | 21 | 98 | 96 |
| License and product development | 693 | 898 | (23) | 2 | 4 |
| Total revenues | $ 28,788 | $ 24,046 | 20 | 100 | 100 |

Product revenue increased 21% to approximately $28.1 million in 2000 from approximately $23.1 million in 1999. Sales of the oral specimen collection devices increased approximately 44% to $11.2 million as a result of higher

penetration in the life insurance and public health markets. Sales of the Histofreezer product increased approximately 18% to $6.8 million principally as a result of price and volume increases both domestically and internationally. Immunoassay test sales increased approximately 9% to $6.7 million as a result of increased activity in the life insurance testing market. Sales of the Western Blot products declined 11% to $1.9 million as a result of an overall decline in demand and increased price competition. The Intercept product, which was launched in February 2000, and OraQuick, which began shipping in December 2000, generated approximately $300,000 and $80,000 of revenue, respectively, in 2000. As a percentage of product revenues, international product sales 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.

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 license and product development activities.

| | Dollars | | | Percentage of Total Revenues (%) | |
|---|---|---|---|---|---|
| | 2000 | 1999 | Percent Change (%) | 2000 | 1999 |
| Market sales | | | | | |
| Insurance testing | $ 12,742 | $ 11,177 | 14 | 44 | 46 |
| Public health | 4,705 | 2,914 | 61 | 16 | 12 |
| Physician offices | 6,780 | 5,744 | 18 | 24 | 24 |
| Substance abuse testing | 3,179 | 2,527 | 26 | 11 | 11 |
| Other markets | 689 | 786 | (12) | 3 | 3 |
| | 28,095 | 23,148 | 21 | 98 | 96 |
| License and product development | 693 | 898 | (23) | 2 | 4 |
| Total revenues | $ 28,788 | $ 24,046 | 20 | 100 | 100 |

Sales to the insurance testing market increased by 14% to approximately $12.7 million in 2000 as a result of increased market acceptance of the oral specimen collection device and higher sales of the associated immunoassay tests. Sales to the public health market increased 61% to approximately $4.7 million in 2000 as a result of increased penetration of the Company's higher priced public health HIV kit. Sales to physician offices, which consist solely of the Histofreezer cryosurgical system, increased 18% to approximately $6.8 million in 2000 as a result of price and volume increases both domestically and internationally. Sales to the substance abuse testing market increased 26% to approximately $3.2 million in 2000 as a result of the market introduction of Intercept and increased Q.E.D. and forensic toxicology sales.

License and product development revenue decreased 23% to approximately $693,000 in 2000 from approximately $898,000 in 1999. During 2000, license and product development revenue primarily consisted of income from a collaboration with Lab*One*, Inc. related to the Intercept drugs-of-abuse service, a research agreement with Dräger to develop specific target analytes for UP*link* point-of-care drugs-of-abuse testing, and the first phase of a grant from the National Institutes of Health ("NIH") for the development of an oral fluid, laboratory-based test for syphilis using the OraSure collection device. During 1999, the Company received license 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 service.

During 2001, the Company plans to focus its efforts on the development of license and product development revenue from external research and development contracts. As of December 31, 2000, the Company was performing paid research and development for Dräger, Meridian Bioscience, Lab*One*, and the NIH. In addition, the Company will continue to attempt to develop new relationships with third parties that are expected to generate revenue streams for the Company through research and development and supply agreements. There can be no assurance as to the Company's ability to enter into these types of arrangements or the timing of additional revenues, if any.

Total revenue is expected to increase by 50% to approximately $43 million in 2001, as a result of the expansion of OraQuick HIV-1/2 product sales in international markets, the launch of the first UP*link* products in the second half of 2001, and the continued growth of other product lines. Partially offsetting this sales growth will be the elimination of $1.4 million of annual revenue associated with the suspended Serum Western Blot product line. In February 2001, the Company announced the indefinite suspension of its Serum Western Blot product. This product has historically been unprofitable due to low production yields and the high cost of ensuring the quality of the end product. The Company's ability to achieve the expected level of revenue will depend on a number of factors, including, but limited to, its ability to scale up manufacturing of OraQuick HIV-1/2, complete development of its UP*link* products, and establish distribution channels for these and other products and obtain all required regulatory approvals and clearances (including completing any required clinical trials) in the United States and in other countries.

The Company's gross margin declined slightly to 61% in 2000 from 62% in 1999. The decline is the result of the Company expensing approximately $1.1 million of obsolete inventory, the suspension of the Serum Western Blot product line and manufacturing inefficiencies related to the start up of the OraQuick product line. Without these items, gross margin would have been 65% for the year 2000. Partially offsetting the gross margin reductions in 2000 were favorable changes in product mix and greater revenues compared to the Company's fixed costs.

In February 2001, the Company announced its plans to realign its manufacturing operations, which will include 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 manufacturing capacity in Thailand. This action will provide greatly expanded capacity for production of OraQuick and is expected to result in approximately $1.5 million in annual cost savings to the Company beginning in 2002.

Gross margins are anticipated to improve beginning in 2001 as a result of (1) the consolidation of manufacturing operations in Bethlehem, Pennsylvania, (2) Merger-related efficiencies, and (3) the suspension of the unprofitable Serum Western Blot product line.

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 the development of the OraQuick HIV-1/2 rapid test, development of the UP*link* reader, 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.

Research and development expenses are expected to increase as clinical trials for OraQuick HIV-1/2 and UP*link* research activities continue. In an effort to meet the aggressive development schedule for OraQuick and UP*link*, the Company continues to hire additional personnel and has contracted with several outside consulting firms to supplement the Company's internal resources. The Company expects expenses related to the development of UP*link* to increase over historical levels.

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 to develop and establish foreign markets for OraQuick, which was launched at the XIII International AIDS Conference in Durban, South Africa in July 2000, costs associated with the national market launch of the Intercept drugs-of-abuse service that began in February 2000, and expanded sales activities for the Company's other product lines. Despite the increase in spending, sales and marketing expenses, as a percentage of 2000 revenues, remained constant at 24%.

In connection with the continued expansion of sales and marketing activities for the Company's new products, the Company anticipates an increase in its marketing and sales efforts to create market awareness and demand for these new products. In addition, the Company will focus its efforts on business plan development, market research, and staffing additions for the expected launch of the first UP*link* products in 2001.

In 1999, the Company paid $1.5 million to TPM Europe Holding B.V., its sublicensor (1) 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 (2) to secure a direct research, development, and license arrangement with Leiden University. There were no such expenses in 2000. See "Results of Operations – 1999 Compared to 1998."

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 the facility expansion in Pennsylvania. Despite the increase of spending, general and administrative expenses, as a percentage of 2000 revenues, declined to 24% from 26%.

General and administrative expenses are expected to decline slightly in 2001 as the Company begins to achieve its Merger cost savings as a result of the consolidation of the Accounting, Financing, and Human Resources departments and the continued elimination of duplicative overhead structures. The Company anticipates that the total overhead cost savings will exceed approximately $1 million per year. The Company anticipates additional non-recurring costs resulting from the realignment of manufacturing operations to be approximately $400,000 in the first quarter of 2001.

Merger-related expenses were approximately $7.6 million in 2000. These costs included fees for investment bankers, attorneys and accountants, filing and soliciting proxies, employee severance, and integration costs.

Operating loss increased to approximately $14.1 million in 2000 from approximately $4.1 million in 1999 as a result of expenses associated with the Merger, increased research and development costs, and increased sales and marketing costs. Excluding the non-recurring Merger related expenses, the operating loss would have been approximately $6.5 million.

Interest expense decreased to approximately $491,000 in 2000 from approximately $545,000 in 1999 as a result of principal loan repayments and the refinancing of subordinated debt. Interest expense is expected to decrease in 2001 as a result of the continued repayment of term debt, coupled with the use of cash reserves and internally generated funds for future capital purchases.

Interest income increased to approximately $1.3 million in 2000 from approximately $595,000 in 1999 as a result of higher cash and cash equivalents available for investment as a result of the exercise of stock options and warrants. Interest income is expected to increase slightly in 2001 as a result of higher average cash balances.

Foreign currency loss was approximately $19,000 in 2000 compared to a loss of approximately $141,000 in 1999. Foreign currency fluctuations are not expected to have a material impact in 2001.

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, a provision for income taxes of approximately $24,000 was recorded.

Net loss was approximately $12.7 million in 2000 compared to approximately $4.2 million in 1999. Excluding the non-recurring Merger-related expenses, the net loss would have been approximately $5.1 million.

**Results of Operations – 1999 Compared to 1998**

As a result of the Merger between Epitope and STC on September 29, 2000 and the subsequent change in the Company's fiscal year-end from September 30 to December 31, the Financial Data for 1999 reflects results for the twelve-month periods ended September 30, 1999 and December 31, 1999 for Epitope and STC, respectively, on a consolidated basis. The Financial Data for 1998 reflects results for the twelve-month periods ended September 30, 1998 and December 31, 1998 for Epitope and STC, respectively, on a consolidated basis. See Note 1 to the Company's Financial Statements for a discussion of the Merger and the change in fiscal year end.

Comparative results of operations are summarized as follows:

| (In thousands) | Dollars | | Percent Change (%) | Percentage of Total Revenue (%) | |
|---|---|---|---|---|---|
| | 1999 | 1998 | | 1999 | 1998 |
| Revenues | | | | | |
| Product | $ 23,148 | $ 20,246 | 14 | 96 | 99 |
| License and product development | 898 | 198 | 354 | 4 | 1 |
| | 24,046 | 20,444 | 18 | 100 | 100 |
| Cost and expenses | | | | | |
| Cost of products sold | 9,126 | 8,445 | 8 | 38 | 41 |
| Research and development | 5,591 | 4,455 | 25 | 23 | 22 |
| Sales and marketing | 5,697 | 4,670 | 22 | 24 | 23 |
| Acquired in-process technology | 1,500 | - | N/A | 6 | - |
| General and administrative | 6,224 | 5,151 | 21 | 26 | 25 |
| | 28,138 | 22,721 | 24 | 117 | 111 |
| Operating loss | (4,092) | (2,277) | (80) | (17) | (11) |
| Interest expense | (545) | (570) | (5) | (2) | (3) |
| Interest income | 595 | 468 | 27 | 2 | 2 |
| Foreign currency gain (loss) | (141) | 5 | N/A | (1) | - |
| Loss before income taxes | (4,183) | (2,374) | (76) | (18) | (12) |
| Income taxes | 50 | - | N/A | - | - |
| Net loss | $ (4,233) | $ (2,374) | (78) | (18) | (12) |

Total revenue increased 18% to approximately $24.0 million in 1999 from approximately $20.4 million in 1998.

The table below shows the amount (in thousands) and percentage of the Company's total revenue contributed by each of its principal products and by license and product development activities.

| | Dollars | | | Percentage of Total Revenues (%) | |
|---|---|---|---|---|---|
| | 1999 | 1998 | Percent Change (%) | 1999 | 1998 |
| Product revenue | | | | | |
| Oral specimen collection devices | $ 7,806 | $ 7,195 | 8 | 32 | 36 |
| OraQuick | - | - | - | - | - |
| Histofreezer cryosurgical systems | 5,744 | 4,776 | 20 | 24 | 23 |
| Immunoassay tests | 6,158 | 4,804 | 28 | 26 | 23 |
| Western Blot HIV confirmatory tests | 2,133 | 2,370 | (10) | 9 | 12 |
| Other product revenue | 1,307 | 1,101 | 19 | 5 | 5 |
| | 23,148 | 20,246 | 14 | 96 | 99 |
| License and product development | 898 | 198 | 354 | 4 | 1 |
| Total revenues | $ 24,046 | $ 20,444 | 18 | 100 | 100 |

Product revenue increased 14% to approximately $23.1 million in 1999 from approximately $20.2 million in 1998. This increase was the result of sales of immunoassay tests, which grew 28% to approximately $6.2 million primarily as a result of increased insurance activity, and sales of Histofreezer, which increased 20% to approximately $5.7 million largely due to the acquisition of the worldwide Histofreezer product line in June 1998. Sales of the oral specimen collection devices increased 8% to approximately $7.8 million as a result of higher penetration in the life insurance and public health markets. Sales of the Western Blot product declined 10% to $2.1 million as a result of increasing competition. As a percentage of product revenue, international sales decreased to 12% in 1999 from 13% in 1998.

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 license and product development activities.

| | Dollars | | | Percentage of Total Revenues (%) | |
|---|---|---|---|---|---|
| | 1999 | 1998 | Percent Change (%) | 1999 | 1998 |
| Market sales | | | | | |
| Insurance testing | $ 11,177 | $ 9,311 | 20 | 46 | 46 |
| Public health | 2,914 | 2,944 | (1) | 12 | 14 |
| Physician offices | 5,744 | 4,776 | 20 | 24 | 23 |
| Substance abuse testing | 2,527 | 2,114 | 20 | 11 | 10 |
| Other markets | 786 | 1,101 | (29) | 3 | 6 |
| | 23,148 | 20,246 | 14 | 96 | 99 |
| License and product development | 898 | 198 | 354 | 4 | 1 |
| Total revenues | $ 24,046 | $ 20,444 | 18 | 100 | 100 |

Sales to the insurance testing market increased by 20% to approximately $11.2 million in 1999 as a result of increased market acceptance of the oral specimen collection device, increased testing volume of both urine and oral fluid products, and price increases. Sales to the public health market remained flat at approximately $2.9 million in 1999. Sales to physician offices, which consisted solely of the Histofreezer cryosurgical system, increased 20% to approximately $6.8 million in 1999 as a result of the Histofreezer acquisition in June, 1998. Sales to the substance

abuse testing market increased 20% to approximately $2.5 million in 1999 as a result of increased Q.E.D. and forensic toxicology sales.

Licensing and product development revenues increased 354% to approximately $898,000 in 1999 from approximately $198,000 in 1998. This increase was primarily the result of the Company beginning to secure research projects for the evaluation of UPT for a range of market applications. During 1999, the Company received licensing and product development revenues from 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 partnership with Lab*One* for the Intercept service. During 1998, licensing and product development revenues consisted primarily of fees from outside parties to develop proprietary antibodies and revenues for the development of the Q.E.D. alcohol test.

The Company's gross margin increased to 62% in 1999 from 59% in 1998 primarily as a result of increased sales of high margin reagents and Histofreezer products and improved manufacturing operating processes, partially offset by a decline in gross margins of the Western Blot products.

Research and development expenses increased 25% to approximately $5.6 million in 1999 from approximately $4.5 million in 1998. Research and development efforts were focused on the development of the OraQuick HIV rapid test, UPT development, commercialization of the Intercept service, and FDA regulatory compliance. UPT efforts were focused on the development of a lateral flow device, particle size reduction, feasibility studies for on-site drugs-of-abuse and food borne pathogens testing, and development of the UP*link* reader.

Sales and marketing expenses increased 22% to approximately $5.7 million in 1999 from approximately $4.7 million in 1998. This increase was primarily a result of the Company's preparation for the national market launch of the Intercept drugs-of-abuse service in February 2000, establishment of an international sales office in The Netherlands, and expanded sales activities for existing product lines.

In 1999, the Company paid $1.5 million to TPM Europe Holding B.V., its sublicensor (1) 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 (2) to secure a direct research, development, and license arrangement with Leiden University. The Company accounted for the purchase price as acquired in-process technology expense because, at the date of the transaction, the technology rights acquired by the Company related to UPT had not progressed to a stage where it met technological feasibility and there existed a significant amount of uncertainty as to the Company's ability to complete the development of the technology which would achieve market acceptance within a reasonable timeframe. In addition, the acquired in-process technology did not have an alternative future use to the Company that had reached technological feasibility. There were no such expenses in 1998.

General and administrative expenses increased 21% to approximately $6.2 million in 1999 from approximately $5.2 million in 1998, as a result of the amortization of the patent and product rights associated with the acquisition of worldwide distribution rights to Histofreezer in 1998, implementation of a management bonus plan, and increased staffing.

Operating loss increased to approximately $4.1 million in 1999 from approximately $2.3 million in 1998.

Interest expense decreased to approximately $545,000 in 1999 from $570,000 in 1998 as a result of principal loan repayments.

Interest income increased to approximately $595,000 in 1999 from approximately $468,000 in 1998 as a result of higher cash and cash equivalents.

Foreign currency loss was approximately $141,000 in 1999.

The net loss increased to approximately $4.2 million in 1999 from approximately $2.4 million in 1998.

**Liquidity and Capital Resources**

| (In thousands) | December 31, 2000 | 1999 |
|---|---|---|
| Cash and cash equivalents | $ 5,096 | $ 2,050 |
| Short-term investments | 14,956 | 12,288 |
| Working capital | 21,495 | 16,313 |

The Company's cash and short-term investments position increased $5.7 million to approximately $20.1 million at December 31, 2000, primarily as a result of the receipt of $19.8 million of proceeds from the exercise of stock options and warrants to purchase Common Stock. This increase was largely offset by the continued losses from operations, capital investment into the infrastructure of the Company's facilities, and continued principal term debt repayments. At December 31, 2000, the Company's working capital was approximately $21.5 million.

Liquidity is expected to remain strong for the foreseeable future as a result of anticipated profitability in 2001. However, liquidity will be negatively affected by continued investment in research and development, construction of fully automated lateral flow manufacturing lines, principal loan repayments, and ongoing capital expenditure requirements.

The combination of the Company's current cash position, available borrowings under the Company's credit facilities, and the Company's cash flow from operations is expected to be sufficient to fund the Company's foreseeable operating and capital needs. However, the Company's cash requirements may vary materially from those now planned due to many factors, including, but not limited to, the progress of the Company's research and development programs, the scope and results of clinical testing, changes in existing and potential relationships with strategic partners, the time and cost in obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the ability of the Company to establish development and commercialization capacities or relationships, the costs of manufacturing, market acceptance of new products and other factors.

Net cash used in operating activities was approximately $10.0 million, an increase of approximately $9.2 million over 1999 as a direct result of the 2000 net loss and increased accounts receivable levels as a result of continued sales growth. Partially offsetting these items were lower inventory levels and higher accruals and accounts payable levels. Excluding the non-recurring Merger-related expenses, net cash used in operating activities would have been approximately $2.4 million.

Net cash used in investing activities was approximately $5.6 million, primarily as a result of the Company's investment into tenant fit-out costs, additional laboratory and manufacturing equipment, and information systems equipment, offset by the sale of certain short-term investments.

Net cash provided by financing activities was approximately $18.7 million, primarily as a result of the proceeds received from the exercise of warrants and stock options of approximately $13.9 million and $5.7 million, respectively, partially offset by approximately $1.1 million of term debt repayments.

At December 31, 2000, the Company had a $1.0 million working capital line of credit in place with a bank that accrues interest at LIBOR plus 235 basis points. There were no borrowings under this line of credit at December 31, 2000. This lending facility expires June 30, 2001. The Company anticipates that this facility will be renewed.

At December 31, 2000, the Company had a $1.0 million equipment line of credit in place with a bank. Borrowings under this line of credit will accrue interest at a rate fixed at prime at the time of draw down. There were no

borrowings under this line of credit outstanding at December 31, 2000. The unused portion of this lending facility expires June 30, 2001. The Company anticipates that this facility will be renewed.

The credit facilities require, among other items, the maintenance of minimum financial ratios, and first lien position on all assets.

**Recent Accounting Pronouncements**

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101 "Revenue Recognition in Financial Statements." The bulletin draws on existing accounting rules and provided specific guidance on revenue recognition. The Company has followed such principles in its financial statements.

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 133, as amended by SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities – Deferral of Effective Date of FASB Statement No. 133 – an amendment of FASB Statement No. 133," which had to be adopted by the Company on January 1, 2001, provides a comprehensive and consistent standard for the recognition and measurement of derivatives and hedging activities. The Company does not currently hold derivative instruments or engage in hedging activities, and accordingly, the adoption of this pronouncement did 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 material amounts of derivative financial instruments, other financial instruments, or derivative commodity instruments, and accordingly has no material market risk to report under this Item. See Note 2 to the Consolidated Financial Statements included under Item 14.

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 continues to hold the security to maturity. 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 local currencies to U.S. dollars affects year-to-year comparability of operating results. The Company's foreign operations represented approximately $4.0 million or 14% of the Company's revenues for the year ended December 31, 2000. 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.

On December 18, 2000, the Company dismissed PricewaterhouseCoopers LLP and retained Arthur Andersen LLP as its independent accountants. Disclosure of this action is set forth in the Company's Current Reports on Form 8-K dated December 18, 2000 and March 30, 2001.

## PART III

The Company has omitted from Part III the information that will appear in the Company's Definitive Proxy Statement for its 2001 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 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 September 29, 2000 disclosing the merger of STC Technologies, Inc. and Epitope Inc. into the Company and certain related matters.

2. Current Report on Form 8-K dated December 15, 2000 attaching a press release of the Company announcing the date for the 2001 Annual Meeting of Shareholders and the dates by which certain matters must be submitted by shareholders in order to be included in the Company's Proxy Statement or considered at the meeting.

3. Current Report on Form 8-K dated December 18, 2000 disclosing the dismissal of PricewaterhouseCoopers LLP and the engagement of Arthur Andersen LLP as the Company's independent accountants.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 31, 2001.

ORASURE TECHNOLOGIES, INC.

By: /s/ Robert D. Thompson
Robert D. Thompson
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on March 31, 2001, by the following persons on behalf of the Registrant and in the capacities indicated.

| SIGNATURE | TITLE |
|---|---|
| /s/ Robert D. Thompson<br>Robert D. Thompson | Chief Executive Officer and Director<br>(Principal Executive Officer) |
| /s/ Richard D. Hooper<br>Richard D. Hooper | Vice President – Finance and Chief Financial Officer<br>(Principal Financial Officer) |
| /s/ Mark L. Kuna<br>Mark L. Kuna | Controller<br>(Principal Accounting Officer) |
| /s/ Michael J. Gausling<br>Michael J. Gausling | President, Chief Operating Officer and Director |
| *MICHAEL G. BOLTON<br>Michael G. Bolton | Director |
| *WILLIAM W. CROUSE<br>William W. Crouse | Director |
| *FRANK G. HAUSMANN<br>Frank G. Hausmann | Director |
| *ROGER L. PRINGLE<br>Roger L. Pringle | Director |

* /s/ Robert D. Thompson
Robert D. Thompson
(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, 2000 and 1999, and the related statements of operations, stockholders' equity and cash flows for the year ended December 31, 2000, the three months ended December 31, 1999, and for each of the two years in the period 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 assets of 34 percent at December 31, 1999 and total revenues of 39 percent, 42 percent and 48 percent for the three months ended December 31, 1999 and years ended September 30, 1999 and 1998, 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, 2000 and 1999, and the results of its operations and its cash flows for the year ended December 31, 2000, the three months ended December 31, 1999, and for each of the two years in the period ended September 30, 1999, in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Philadelphia, Pennsylvania,
February 23, 2001

## REPORT OF INDEPENDENT ACCOUNTANTS

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

In our opinion, the consolidated balance sheet and the related 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 financial position of the Company and its subsidiaries at December 31, 1999 and the results of their operations and their cash flows for the three months ended December 31, 1999 and for each of the two years in the period 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, | |
|---|---|---|
| | 2000 | 1999 |
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 5,095,639 | $ 2,049,644 |
| Short-term investments | 14,956,779 | 12,287,795 |
| Accounts receivable, net of allowance for doubtful accounts of $114,685 and $118,954 | 5,276,772 | 3,884,395 |
| Notes receivable from officer | 175,649 | — |
| Inventories | 1,495,604 | 2,405,439 |
| Prepaid expenses and other | 1,189,210 | 742,082 |
| Total current assets | 28,189,653 | 21,369,355 |
| PROPERTY AND EQUIPMENT, net | 6,738,034 | 5,155,815 |
| PATENTS AND PRODUCT RIGHTS, net | 2,402,386 | 2,598,308 |
| OTHER ASSETS | 406,099 | 502,549 |
| | $ 37,736,172 | $ 29,626,027 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Current portion of long-term debt | $ 1,125,138 | $ 1,054,462 |
| Accounts payable | 1,522,295 | 1,213,506 |
| Accrued expenses | 4,047,231 | 2,787,727 |
| Total current liabilities | 6,694,664 | 5,055,695 |
| LONG-TERM DEBT | 4,644,098 | 5,819,980 |
| OTHER LIABILITIES | 225,334 | 512,000 |
| 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, 36,434,004 and 32,632,911 shares issued and outstanding | 36 | 33 |
| Additional paid-in capital | 148,767,789 | 128,115,489 |
| Accumulated other comprehensive loss | (231,247) | (259,218) |
| Accumulated deficit | (122,364,502) | (109,617,952) |
| Total stockholders' equity | 26,172,076 | 18,238,352 |
| | $ 37,736,172 | $ 29,626,027 |

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

| | For the year ended December 31, 2000 | For the three months ended December 31, 1999 | For the year ended September 30, 1999 | For the year ended September 30, 1998 |
|---|---|---|---|---|
| REVENUES: | | | | |
| Product | $ 28,095,408 | $ 6,460,501 | $ 23,147,808 | $ 20,246,374 |
| Licensing and product development | 692,808 | 361,153 | 898,213 | 197,652 |
| | 28,788,216 | 6,821,654 | 24,046,021 | 20,444,026 |
| COSTS AND EXPENSES: | | | | |
| Cost of products sold | 11,102,096 | 2,491,760 | 9,125,995 | 8,444,781 |
| Research and development | 10,399,120 | 1,412,288 | 5,590,807 | 4,455,105 |
| Sales and marketing | 6,932,068 | 1,682,030 | 5,696,673 | 4,669,763 |
| General and administrative | 6,876,516 | 1,518,488 | 6,224,408 | 5,150,913 |
| Acquired in-process technology | — | — | 1,500,000 | — |
| Merger - related | 7,607,158 | — | — | — |
| | 42,916,958 | 7,104,566 | 28,137,883 | 22,720,562 |
| Operating loss | (14,128,742) | (282,912) | (4,091,862) | (2,276,536) |
| INTEREST EXPENSE | (490,415) | (135,357) | (544,643) | (570,083) |
| INTEREST INCOME | 1,315,666 | 183,855 | 594,928 | 467,668 |
| FOREIGN CURRENCY GAIN (LOSS) | (18,696) | (186,873) | (141,687) | 4,805 |
| GAIN ON SALE OF SECURITIES | 600,000 | — | — | — |
| Loss before income taxes | (12,722,187) | (421,287) | (4,183,264) | (2,374,146) |
| INCOME TAXES | 24,363 | 50,000 | 50,000 | — |
| NET LOSS | $ (12,746,550) | $ (471,287) | $ (4,233,264) | $ (2,374,146) |
| BASIC AND DILUTED NET LOSS PER SHARE | $ (0.36) | $ (0.02) | $ (0.14) | $ (0.09) |
| WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING | 35,002,283 | 30,887,007 | 30,596,882 | 26,179,670 |

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY

| | Common Stock | | Additional | Accumulated Other Comprehensive | Accumulated | |
|---|---|---|---|---|---|---|
| | Shares | Amount | Paid-in Capital | Income (Loss) | Deficit | Total |
| **Balance at September 30, 1997** | 26,105,351 | $ 26 | $ 114,709,501 | $ — | $ (96,836,800) | $ 17,872,727 |
| Common stock issued upon exercise of options | 91,278 | — | 411,052 | — | — | 411,052 |
| Common stock issued under Employee Stock Purchase Plan and Savings Plan | 31,711 | — | 135,554 | — | — | 135,554 |
| Compensation expense for stock option grants | — | — | 333,241 | — | — | 333,241 |
| Spin-off of former subsidiary | — | — | — | — | (5,692,017) | (5,692,017) |
| Comprehensive loss: | | | | | | |
| Net loss | — | — | — | — | (2,374,146) | (2,374,146) |
| Currency translation adjustment | — | — | — | 15,042 | — | 15,042 |
| Total comprehensive loss | | | | | | (2,359,104) |
| **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) |
| Unrealized loss on marketable securities | — | — | — | (200,000) | — | (200,000) |
| Total comprehensive loss | | | | | | (4,507,524) |

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, 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) |
| 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) |
| 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 |

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

| | For the year ended December 31, 2000 | For the three months ended December 31, 1999 | For the year ended September 30, 1999 | For the year ended September 30, 1998 |
|---|---|---|---|---|
| OPERATING ACTIVITIES: | | | | |
| Net loss | $ (12,746,550) | $ (471,287) | $ (4,233,264) | $ (2,374,146) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | | | |
| Stock based compensation expense | 792,685 | 87,200 | 321,006 | 333,241 |
| Common stock issued as compensation for services | 62,409 | — | 105,471 | — |
| Amortization of deferred revenue | (143,333) | (40,313) | (107,500) | 80,740 |
| Acquired in - process technology | — | — | 1,500,000 | — |
| Depreciation and amortization | 2,243,001 | 448,654 | 1,855,479 | 1,739,464 |
| Gain on sale of securities | (600,000) | — | — | — |
| (Gain) loss on sale of property and equipment | 10,844 | 42,245 | (36,952) | 31,290 |
| Deferred income taxes | — | 91,497 | — | — |
| Changes in assets and liabilities- | | | | |
| Accounts receivable | (1,853,514) | (261,924) | (985,070) | (731,290) |
| Inventories | 909,835 | 237,956 | (300,882) | 116,840 |
| Prepaid expenses and other | (103,632) | (76,981) | 227,090 | (578,775) |
| Accounts payable | 308,789 | (199,275) | 47,904 | 665,809 |
| Accrued expenses | 1,125,020 | 482,312 | 843,381 | (434,459) |
| Net cash provided by (used in) operating activities | (9,994,446) | 340,084 | (763,337) | (1,151,286) |
| INVESTING ACTIVITIES: | | | | |
| Purchases of property and equipment | (3,071,565) | (626,036) | (1,701,520) | (863,057) |
| Proceeds from the sale of property and equipment | — | 78,250 | 98,250 | 37,629 |
| Purchase of patents and product rights | (619,589) | (18,024) | (1,627,377) | (2,705,753) |
| Purchase of short-term investments | (24,869,468) | (1,250,261) | (37,624,613) | (13,524,782) |
| Proceeds from sale of short-term investments | 22,339,595 | 2,016,757 | 29,383,614 | 16,529,760 |
| Proceeds from sale of securities | 600,000 | — | — | — |
| Investment in affiliated companies | (20,404) | (32,181) | (17,435) | (1,090) |
| Net cash provided by (used in) investing activities | (5,641,431) | 168,505 | (11,489,081) | (527,293) |
| FINANCING ACTIVITIES: | | | | |
| Proceeds from term debt | — | — | 2,219,433 | 6,650,000 |
| Repayment of term debt | (1,054,194) | (250,374) | (1,872,475) | (4,905,166) |
| Net proceeds from issuance of common stock | 19,797,206 | 79,939 | 11,939,624 | 465,866 |
| Capital contribution to former wholly owned subsidiary subsequently spun-off | — | — | — | (2,129,291) |
| Net cash provided by (used in) financing activities | 18,743,012 | (170,435) | 12,286,582 | 81,409 |
| EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH | (61,140) | (38,298) | (74,260) | 15,042 |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | 3,045,995 | 299,856 | (40,096) | (1,582,128) |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 2,049,644 | 1,749,788 | 2,370,469 | 3,952,597 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | $ 5,095,639 | $ 2,049,644 | $ 2,330,373 | $ 2,370,469 |

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, oral fluid assays, proprietary diagnostic products including *in vitro* diagnostic tests, and other medical devices. These products are sold to public and private-sector clients, clinical laboratories, physician offices, hospitals, and for workplace point-of-care testing in the United States and certain foreign countries.

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 (the "Merger Agreement"), by and among Epitope, the Company and STC. The shareholders of STC and Epitope approved the Merger Agreement on September 29, 2000.

As a result of the Merger, each share of STC common stock was converted into five and two hundred ninety-six one thousandths (5.296) shares of the Company's common stock and each share of Epitope common stock was converted into one share of the Company's common stock. Of the 36,434,004 shares of common stock of the Company issued and outstanding at December 31, 2000, 18,373,884 shares were issued to the former stockholders of STC.

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 each of the two years in the period ended September 30, 1999 include Epitope's previous September 30 fiscal year amounts and STC's December 31 calendar year amounts for the corresponding fiscal years of Epitope.

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") precedes the start of the 2000 fiscal year. "1999" and "1998" refer to the respective years ended September 30, and include Epitope's previous September 30 fiscal year amounts and STC's December 31 calendar year amounts for the corresponding fiscal years of Epitope, and "2000" refers to the twelve months ended December 31, 2000. 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.

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

| | Three months ended December 31, 1999 | Year ended September 30, 1999 | 1998 |
|---|---|---|---|
| Revenues: | | | |
| Epitope | $ 2,669,026 | $ 10,031,020 | $ 9,791,582 |
| STC | 4,152,628 | 14,015,001 | 10,652,444 |
| Combined | $ 6,821,654 | $ 24,046,021 | $ 20,444,026 |
| Operating income (loss): | | | |
| Epitope | $ (549,488) | $ (3,515,544) | $ (2,281,834) |
| STC | 266,576 | (576,318) | 5,298 |
| Combined | $ (282,912) | $ (4,091,862) | $ (2,276,536) |
| Net income (loss): | | | |
| Epitope | $ (481,725) | $ (3,237,644) | $ (1,928,008) |
| STC | 10,438 | (995,620) | (446,138) |
| Combined | $ (471,287) | $ (4,233,264) | $ (2,374,146) |

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 Epitope for the Transition Period have been adjusted to reflect the elimination of intercompany transactions between Epitope and STC. Accordingly, these amounts will differ from the results as previously published by Epitope on Form 10-Q for the three months ended December 31, 1999.

In connection with the Merger, the Company recorded merger-related expenses of $7.6 million. The categories of costs incurred, the actual cash payments made in 2000 and the accrued balances at December 31, 2000 are summarized below:

| | Total | Amounts Paid in 2000 | Accrued Balance at December 31, 2000 |
|---|---|---|---|
| Cash costs | | | |
| Transaction costs | $ 5,273,748 | $ 5,273,748 | $ — |
| Employee costs | 1,079,607 | 497,982 | 581,625 |
| Other integration costs | 608,393 | 499,268 | 109,125 |
| | 6,961,748 | $ 6,270,998 | $ 690,750 |
| Non-cash costs | 645,410 | | |
| Total | $ 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. Accrued employee costs at December 31, 2000 will be paid to the employees through the second quarter of 2001. Other integration costs include financial system conversion costs and integration-related travel expenses. The non-cash charge of $645,410 represents the

amount of unamortized deferred compensation on certain nonqualified options granted by Epitope in prior years, which was immediately accelerated upon the closing of the Merger under terms of Epitope's stock option plans.

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, 2000, cash equivalents consisted of certificates of deposit, commercial paper and U.S. government agency obligations.

Short-term Investments

Short-term investments consist of treasury notes, certificates of deposits and other government obligations with original maturities greater than ninety days and less than one year. Such investments are recorded at fair value due to the nature of the maturities.

Supplemental Cash Flow Information

For 2000, the Transition Period, 1999 and 1998, the Company paid interest of $490,410, $135,357, $565,025 and $495,667, respectively.

For 2000, the Transition Period, 1999 and 1998, the Company recorded provisions for bad debts of $0, $0, $8,851, and $17,229, respectively. The Company had deductions of $4,269, $0, $0 and $0 against the allowance for doubtful accounts in 2000, the Transition Period, 1999 and 1998, respectively.

Inventories

Inventories are stated at the lower of cost or market determined on a first-in, first-out basis. The Company currently buys its entire Histofreezer product from a foreign vendor. Purchases are payable in foreign currency. Changes in the exchange rate would 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 3 to 7 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 2000, the Transition Period, 1999 and 1998 was $816,111, $123,366, $482,106 and $372,703, respectively.

Long-term Investments

Included in other assets is an investment in a warrant to purchase 50,000 shares of Lab*One*, Inc. common stock, which is classified 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." Available-for-sale securities are carried at fair value, based on quoted market prices, with unrealized gains and losses reported as a separate component of stockholders' equity. As of December 31, 2000 and 1999, the Company had $250,000 and $200,000 of unrealized losses related to these securities, 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. Up front licensing fees are deferred and recognized ratably over the related license period. Product development revenues are recognized over the period the related product development efforts are performed. Amounts received prior to the performance of product development efforts are recorded as deferred revenues.

In December 1999, the U.S. Securities and Exchange Commission issued 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 license and development fees. The Company has applied the provisions of SAB 101 in the accompanying financial statements.

Significant Customer Concentration

In 2000, 1999, and 1998, one customer accounted for approximately 23 percent, 19 percent, and 20 percent of total revenues, respectively. The same customer accounted for 20 percent and 16 percent of accounts receivable as of December 31, 2000 and 1999, 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 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 using the intrinsic value method in accordance with Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees." 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" and Emerging Issues Task Force 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"), and the Securities and Exchange Commission Staff Accounting Bulletin No. 98. 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 4,677,357, 6,907,212, 7,002,673, and 6,495,506 shares were excluded from the computation of diluted net loss per common share for 2000, the Transition Period, 1999 and 1998, respectively, because they were anti-dilutive due to the Company's losses.

Impairment of Long-Lived Assets

In accordance with SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of," 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 undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the carrying value of the assets to 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, 2000.

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.

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities. SFAS No. 133, as amended by SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities – Deferral of Effective Date of FASB Statement No. 133 – an amendment of FASB Statement No. 133", which had to adopted by the Company on January 1, 2001, provides a comprehensive and consistent standard for the recognition and measurement of derivatives and hedging activities. The Company does not currently hold derivative instruments or engage in hedging activities, and accordingly, the adoption of this pronouncement did not have any impact on the Company's financial position or results of operations.

Gain on Sale of Securities

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.

3. INVENTORIES:

| | December 31, 2000 | December 31, 1999 |
|---|---|---|
| Raw materials | $ 473,575 | $ 581,347 |
| Work in process | 348,819 | 688,168 |
| Finished goods | 673,210 | 1,135,924 |
| | $ 1,495,604 | $ 2,405,439 |

4. PROPERTY AND EQUIPMENT:

| | December 31, 2000 | December 31, 1999 |
|---|---|---|
| Building and leasehold improvements | $ 4,599,859 | $ 3,770,388 |
| Machinery and equipment | 7,778,494 | 7,390,478 |
| Computer equipment | 2,134,411 | 1,734,065 |
| Furniture and fixtures | 1,096,176 | 1,070,720 |
| Vehicles | 70,411 | 108,997 |
| Construction in progress | 942,937 | 415,776 |
| | 16,622,288 | 14,490,424 |
| Less- Accumulated depreciation and amortization | ( 9,884,254) | ( 9,334,609) |
| | $ 6,738,034 | $ 5,155,815 |

Depreciation expense was $1,426,890, $325,288, $1,373,373 and $1,366,761 for 2000, the Transition Period, 1999 and 1998, respectively.

5. ACQUISITION OF PATENTS AND PRODUCT RIGHTS:

On June 9, 1998, the Company acquired the patents and exclusive worldwide distribution rights to the 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 10 years. In connection with the acquisition, the Company also entered into a five-year production agreement with the seller of the Histofreezer product.

6. ACCRUED EXPENSES:

| | December 31, 2000 | December 31, 1999 |
|---|---|---|
| Payroll and related benefits | $ 1,317,774 | $ 920,262 |
| Professional fees | 289,227 | 366,730 |
| Deferred revenue | 475,709 | 166,437 |
| Other | 1,964,521 | 1,334,298 |
| | $ 4,047,231 | $ 2,787,727 |

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 June 30, 2001. There were no borrowings against the line at December 31, 2000 or 1999.

The Company also has a $1,000,000 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, 2000 or 1999. The unused portion of the equipment facility expires on June 30, 2001.

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

8. LONG-TERM DEBT:

| | December 31, | |
|---|---|---|
| | 2000 | 1999 |
| Note payable to bank, interest at 8%, monthly installments of principal and interest of $59,219 through December 2003, and monthly installments of remaining principal and interest based on the prime rate plus 1% through December 2005, secured by certain property and equipment, inventory and intangible assets. | $ 2,927,226 | $ 3,379,663 |
| Note payable to bank, interest at 8%, monthly installments of principal and interest of $8,181 through December 2003, secured by the Company's building. | 928,021 | 949,750 |
| 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. | 491,518 | 539,885 |
| 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. | 864,937 | 1,065,410 |
| 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. | 557,534 | 875,168 |
| Notes payable to bank | — | 64,566 |
| | 5,769,236 | 6,874,442 |
| Less- Current portion | (1,125,138) | (1,054,462) |
| | $ 4,644,098 | $ 5,819,980 |

Long-term debt maturities as of December 31, 2000 are as follows:

| | |
|---|---|
| 2001 | $ 1,125,138 |
| 2002 | 1,057,581 |
| 2003 | 911,069 |
| 2004 | 869,425 |
| 2005 | 783,585 |
| Thereafter | 1,022,438 |
| | $ 5,769,236 |

9. INCOME TAXES:

At December 31, 2000, the Company had a net operating loss carryforwards for federal income tax purposes of approximately $64.4 million that have begun to expire and will continue to expire through 2020. The Tax Reform Act of 1986 contains provisions that may limit the annual amount of net operating loss carryforward 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, 2000.

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 | |
|---|---|---|
| | 2000 | 1999 |
| Deferred tax asset: | | |
| Net operating loss carryforwards | $ 24,901,000 | $ 20,355,000 |
| Stock based compensation | 2,253,000 | 1,945,000 |
| Accruals and reserves currently not deductible | 1,384,000 | 1,267,000 |
| Patent costs | 491,000 | 526,000 |
| Research and development credit carryforwards | 1,677,000 | 1,427,000 |
| Valuation allowance on deferred tax assets | (30,706,000) | (25,520,000) |
| | $ — | $ — |

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 on 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 Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and the related interpretations in accounting for its stock option plans. 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 375,000 options to purchase 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 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 plans. 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 Epitope stock option plans.

Under SFAS No. 123, "Accounting for Stock-Based Compensation," compensation cost related to stock options granted to employees is computed based on the value of the stock option at the date of grant using an option valuation methodology, typically the Black-Scholes pricing model. The Company follows the disclosure requirements of SFAS No. 123, "Accounting for Stock-Based Compensation." Had compensation cost for the Company's common stock option plan been determined based upon the fair value of the options at the date of grant, as prescribed under SFAS No. 123, the Company's net loss for 2000, 1999 and 1998 would have increased as follows:

| | Year ended December 31, 2000 | Year ended September 30, 1999 | 1998 |
|---|---|---|---|
| Net loss: | | | |
| As reported | $ (12,746,550) | $ (4,233,264) | $ (2,374,146) |
| Pro forma | $ (17,611,122) | $ (6,553,202) | $ (5,439,224) |
| Basic and diluted net loss per share: | | | |
| As reported | $ (0.36) | $ (0.14) | $ (0.09) |
| Pro forma | $ (0.50) | $ (0.21) | $ (0.21) |

The weighted average fair value of the options granted during 2000, 1999 and 1998, is estimated at $4.96, $2.44 and $1.62, respectively, per share, using the Black-Scholes option pricing model with the following assumptions: dividend yield of zero; volatility of 64 percent, 55 percent and 50 percent, respectively; weighted average risk-free interest rate of 6.13 percent, 5.31 percent and 5.70 percent, respectively; and an expected life of 7.0, 4.3 and 3.9 years, respectively.

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

| | Shares | Price per Share |
|---|---|---|
| Balance, September 30, 1997 | 3,838,194 | $2.83 – 20.38 |
| Granted | 4,247,748 | 1.29 – 18.17 |
| Exercised | (91,278) | 2.79 – 5.04 |
| Canceled | (4,036,465) | 2.83 – 20.38 |
| 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 |

At December 31, 2000, 1,802,591 shares were available for future grants under the 2000 Plan. The following table summarizes information about stock options outstanding at December 31, 2000:

| | Options outstanding | | | Options exercisable | |
|---|---|---|---|---|---|
| Range of exercise price | Number outstanding | Weighted average remaining life | Weighted average exercise price | Number exercisable | Weighted average exercise price |
| $ 0.80 | 641,647 | 8.4 | $ 0.80 | 214,360 | $ 0.80 |
| $ 1.29 to $3.22 | 455,968 | 7.0 | 2.89 | 414,408 | 2.90 |
| $ 3.51 to $4.17 | 465,675 | 13.9 | 4.09 | 465,675 | 4.09 |
| $ 4.22 to $4.59 | 500,000 | 16.1 | 4.51 | 500,000 | 4.51 |
| $ 4.69 to $5.00 | 205,362 | 8.1 | 4.82 | 205,362 | 4.82 |
| $ 5.04 | 705,686 | 12.2 | 5.04 | 705,686 | 5.04 |
| $ 5.05 to $6.84 | 297,627 | 8.3 | 6.55 | 295,627 | 6.56 |
| $ 7.09 | 1,069,432 | 10.0 | 7.09 | — | — |
| $ 7.30 to $14.81 | 163,960 | 9.3 | 10.62 | 34,500 | 12.61 |
| $ 15.03 | 2,000 | 9.5 | 15.03 | 2,000 | 15.03 |
| | 4,507,357 | 10.70 | $ 4.84 | 2,837,618 | $ 4.40 |

Employee Stock Purchase Plan

In 1993, the shareholders approved Epitope's adoption of the 1993 Employee Stock Purchase Plan ("1993 ESPP"). The plan, as subsequently approved and amended by Epitope's shareholders, covers 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 or 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, 2000, 4,907 shares of common stock were subscribed for through one offering. Shares subscribed for under this 1993 ESPP offering may be purchased over 24 months and had an initial subscription price of $3.96. During the year ended December 31, 2000, 70,253 shares were issued at prices ranging from $2.74 to $4.78 per share under the 1993 ESPP.

As of September 30, 1999, 82,712 shares of common stock were subscribed for through two offerings under the 1993 ESPP. Shares subscribed for under these offerings may be purchased over 24 months and had initial subscription prices of $6.99 and $2.74 per share. The subscription prices for the offering prior to December 30, 1997 were adjusted in fiscal 1998 from $6.99 to $4.20 per share as a result of the spin-off of a former subsidiary of Epitope. During the year ended September 30, 1999, 16,002 shares were issued at prices ranging from $2.74 to $4.78 under the 1993 ESPP.

The weighted average assumptions used for 1993 ESPP rights for 2000, 1999, and 1998 were a risk-free interest rate of 6.0 percent, 5.8 percent, and 5.6 percent, respectively; no expected dividend yield; an expected life of 2.0, 1.0 and 2.0 years, respectively; and an expected volatility of 61 percent, 69 percent, and 69 percent, respectively. The weighted-average fair value of 1993 ESPP rights granted in 2000, 1999, and 1998 were $9,843, $141,397, and $55,066, respectively.

Common Stock Warrants

As of December 31, 2000, 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 | | |

In 2000, warrants to purchase 2,405,907 shares of common stock were exercised for total net proceeds of $13,865,370.

11. COMMITMENTS AND CONTINGENCIES:

Phosphor Agreements

In April 1995, the Company entered into several research, licensing and royalty agreements (collectively the "Phosphor Agreements"), with certain amendments through August 2000. The Phosphor Agreements require, among other things, the Company to make annual license payments and pay royalties on the net sales of related product, research and development fees, and sublicensing revenues.

In July 1999, the Company acquired the patent rights (the "Rights") to such phosphor technology thus amending the Company's requirements to make annual license payments, pay royalties and pay sublicensing fees. The Company paid approximately $1,400,000 for the rights and incurred approximately $100,000 of expenses related to the buyout of the Rights. The Company has accounted for the purchase price of the Rights as acquired in-process technology expenses because, at the date of the transaction, the technology rights acquired by the Company related to UPT had not progressed to a stage where it met technological feasibility and there existed a significant amount of uncertainty

as to the Company's ability to complete the development of the technology which would achieve market acceptance within a reasonable timeframe. In addition, the acquired in-process technology did not have an alternative future use to the Company that had reached technological feasibility. In connection with the buyout, the Company is required to pay royalties of $25,000 per year until the Rights expire. The Company must also pay sponsored research funds of $125,000 per year through July 2002, and $50,000 per year thereafter until the Rights expire.

Leases

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

| | | |
|---|---|---|
| 2001 | $ | 647,028 |
| 2002 | | 654,225 |
| 2003 | | 651,534 |
| 2004 | | 662,514 |
| 2005 and thereafter | | 99,979 |
| | $ | 2,715,280 |

Rent expense for 2000, 1999 and 1998 was $716,748, $461,105 and $459,536, respectively.

Employment Agreements

Under terms of employment agreements with certain executive officers extending through 2003, the Company is required to pay each officer a base salary. The agreements require payments of $1,135,008, $1,022,508 and $487,503 in 2001, 2002 and 2003, respectively.

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:

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 first anniversary date of the Officer Notes. In the event the Officer Notes are not repaid in the period defined, they will bear interest at nine percent per year.

13. RETIREMENT PLANS:

As a result of the Merger, the Company currently maintains two distinct retirement plans covering substantially all of its employees. Both plans permit certain 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 there under. During 2001, the Company intends to combine these two retirement plans into one surviving plan having similar provisions.

During the periods reported, generally all employees of Epitope were eligible to participate in a profit sharing and deferred savings plan. The plan provides 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 $62,409 (5,309 shares), $17,492 (2,691 shares), $75,475 (12,693 shares) and $80,740 (17,260 shares) during 2000, the Transition Period, 1999 and 1998, respectively.

During the periods reported, generally all employees of STC were eligible to participate in a profit sharing plan. The plan provides 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 $122,903, $19,247, $113,708 and $93,607 for 2000, the Transition Period, 1999 and 1998, respectively.

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, 2000 | For the three months ended December 31, 1999 | For the year ended September 30, 1999 | For the year ended September 30, 1998 |
|---|---|---|---|---|
| United States | $ 24,763 | $ 5,912 | $ 21,382 | $ 17,804 |
| Europe | 2,507 | 659 | 1,816 | 1,238 |
| Other regions | 1,518 | 251 | 848 | 1,402 |
| | $ 28,788 | $ 6,822 | $ 24,046 | $ 20,444 |

15. QUARTERLY DATA (Unaudited)

The following tables summarize the quarterly results of operations for each of the quarters in 2000 and 1999, as well as for the Transition Period. 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).

| | Three months ended | | | | |
|---|---|---|---|---|---|
| | March 31, 2000 | June 30, 2000 | September 30, 2000 | December 31, 2000 | 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 | | | | |
|---|---|---|---|---|---|---|
| | Transition Period | December 31, 1998 | March 31, 1999 | June 30, 1999 | September 30, 1999 | 1999 |
| Revenues | $ 6,822 | $ 5,132 | $ 5,500 | $ 6,194 | $ 7,220 | $ 24,046 |
| Costs and expenses | 7,105 | 5,687 | 6,454 | 8,073 | 7,924 | 28,138 |
| Operating loss | (283) | (555) | (954) | (1,879) | (704) | (4,092) |
| Other income (expense), net | (138) | (53) | 47 | 59 | (144) | (91) |
| Loss before income taxes | (421) | (608) | (907) | 1,820 | (848) | (4,183) |
| Income taxes | 50 | — | — | — | 50 | 50 |
| Net loss | $ (471) | $ (608) | $ (907) | $ (1,820) | $ (898) | $ (4,233) |
| Basic and diluted net loss per share | $ (0.02) | $ (0.02) | $ (0.03) | $ (0.06) | $ (0.03) | $ (0.14) |
| Weighted average number of shares outstanding | 30,887 | 26,246 | 28,886 | 30,706 | 30,799 | 30,597 |

## INDEX TO EXHIBITS

| Exhibit Number | Exhibit |
|---|---|
| 2.1 | Agreement and Plan of Merger, dated as of May 6, 2000, by and among Epitope, Inc., the Company and STC Technologies, Inc. ("Merger Agreement"), including the Epitope Stockholders Agreement and the STC Stockholders Agreement attached as Exhibits A and B thereto and the other exhibits attached thereto, is incorporated by reference to Exhibit 2 to the Current Report on Form 8-K of Epitope, Inc. dated May 9, 2000. |
| 3.1 | Certificate of Incorporation of OraSure Technologies is incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-4 (No. 333-39210). |
| 3.1.1 | Certificate of Amendment to Certificate of Incorporation dated May 23, 2000 is incorporated by reference to Exhibit 3.1.1 to the Company's Registration Statement on Form S-4 (No. 333-39210). |
| 3.1.2 | Certificate of Designation of Series A Preferred Stock of OraSure Technologies (filed as Exhibit A to the Rights Agreement referred to in Exhibit 4.2). |
| 3.2 | Amended and Restated Bylaws of OraSure Technologies are incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-4 (No. 333-39210). |
| 4.1 | Specimen certificate representing shares of OraSure Technologies $.000001 par value Common Stock is incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-4 (No. 333-39210). |
| 4.2 | Rights Agreement dated as of May 6, 2000 between OraSure Technologies and ChaseMellon Shareholder Service, L.L.C., as Rights Agent, is incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-4 (No. 333-39210). |
| 4.3 | Stockholders Agreement among STC Technologies, Inc., HealthCare Ventures V, L.P., RHO Management Trust II, Hudson Trust and Pennsylvania Early Stage Partners, L.P., dated March 30, 1999, is incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-4 (No. 333-39210). |
| 4.4 | Amendment to Stockholders Agreement filed is Exhibit 4.3 is incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-4 (No. 333-39210). |
| 10.1 | Form of Indemnification Agreement (and list of parties to such agreement) is incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-4 (No. 333-39210).* |
| 10.2 | Employment Agreement dated as of January 24, 2000 between Epitope, Inc. and Robert D. Thompson.* |
| 10.3 | Employment Agreement dated as of September 29, 2000 between OraSure Technologies and Robert D. Thompson.* |
| 10.4 | Employment Agreement dated as of September 29, 2000 between OraSure Technologies and Michael J. Gausling.* |
| 10.5 | Employment Agreement dated as of September 29, 2000 between OraSure Technologies and William Hinchey.* |

| | |
|---|---|
| 10.6 | Employment Agreement dated as of September 29, 2000 between OraSure Technologies and Dr. R. Sam Niedbala.* |
| 10.7 | Employment Agreement dated as of September 29, 2000 between OraSure Technologies and William D. Block.* |
| 10.8 | Employment Agreement dated as of September 29, 2000 between OraSure Technologies and J. Richard George.* |
| 10.9 | Description of Non-Employee Director Compensation Policy.* |
| 10.10 | Incentive Stock Option Plan of Epitope, Inc. as amended, is incorporated by reference to Exhibit 10.2 to the Epitope, Inc. Annual Report on Form 10-K for 1994.* |
| 10.11 | Amended and Restated Epitope, Inc. 1991 Stock Award Plan is incorporated by reference to Exhibit 10.2 to the Epitope, Inc. Annual Report on Form 10-K for 1997.* |
| 10.12 | OraSure Technologies, Inc. Employee Incentive and Non-Qualified Stock Option Plan, as amended and restated effective September 29, 2000.* |
| 10.13 | OraSure Technologies, Inc. 2000 Stock Award Plan as amended effective as of September 29, 2000.* |
| 10.14 | Nonqualified Stock Option Agreement For Discounted Non-Plan Option between Epitope, Inc. and Robert D. Thompson.* |
| 10.15 | OraSure Technologies Inc. Management Incentive Plan.* |
| 10.16 | Production Agreement with Koninklinjke Utermöhlen, N.V. dated June 9, 1998 is incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-4 (No. 333-39210). |
| 10.17 | Research and License Agreement with SRI International and David Sarnoff Research Center dated April 26, 1995 is incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-4 (No. 333-39210). |
| 10.18 | First Amendment to Research and License Agreement dated September 1, 1995 is incorporated by reference to Exhibit 10.10 of the Company's Registration Statement on Form S-4 (No. 333-39210). |
| 10.19** | Third Amendment to Research and License Agreement dated August 30, 2000 among SRI International, Sarnoff Corporation (formerly David Sarnoff Research Center) and the Company. |
| 10.20 | Commercial Lease between Northampton County New Jobs Corp., as Landlord, and STC Technologies, Inc., as Tenant, dated April 30, 1999, is incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-4 (No 333-39210). |
| 10.21 | Lease dated October 25, 1999 between PS Business Parks, L.P., a California Limited Partnership, and Epitope, Inc., is incorporated by reference to Exhibit 10.6 to the Epitope, Inc. Annual Report on Form 10-K for 1999. |
| 23.1 | Consent of Arthur Andersen LLP. |

| | |
|---|---|
| 23.2 | Consent of PricewaterhouseCoopers LLP. |
| 24 | Powers of Attorney. |

* Management contract or compensatory plan or arrangement.

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