

-----  
-----  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

-----  
FORM 10-K

(Mark one)

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

for the fiscal year ended December 31, 2001.

OR

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

for the transition period from to .

Commission File No. 1-10492

-----  
ORASURE TECHNOLOGIES, INC.  
(Exact Name of Registrant as Specified in Its Charter)

Delaware 36-4370966  
(State or Other Jurisdiction of (I.R.S. Employer  
Incorporation or Organization) Identification No.)

150 Webster Street 18015  
Bethlehem, Pennsylvania (Zip Code)  
(Address of Principal Executive Offices)

(610) 882-1820  
(Registrant's Telephone Number, Including Area Code)

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

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

Common Stock, \$.000001 par value per share  
(Title of Class)

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

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

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

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

Documents Incorporated by Reference:

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

-----  
-----

TABLE OF CONTENTS

	Page
	----
PART I	
ITEM 1. Business.....	1
ITEM 2. Properties.....	26
ITEM 3. Legal Proceedings.....	27
ITEM 4. Submission of Matters to a Vote of Security Holders.....	27
PART II	
ITEM 5. Market for Registrant's Common Equity and Related Stockholder Matters.....	28
ITEM 6. Selected Financial Data.....	28
ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.....	30
ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk....	40
ITEM 8. Financial Statements and Supplementary Data.....	40
ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.....	40
PART III	
ITEM 10. Directors and Executive Officers of the Registrant.....	41
ITEM 11. Executive Compensation.....	41
ITEM 12. Security Ownership of Certain Beneficial Owners and Management.....	41
ITEM 13. Certain Relationships and Related Transactions.....	41
PART IV	
ITEM 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.....	41

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 Epitepe, Inc., an Oregon corporation ("Epitepe"), 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 Epitepe and changing the state of incorporation of Epitepe from Oregon to Delaware. The companies were merged pursuant to an Agreement and Plan of Merger, dated May 6, 2000, by and among Epitepe, STC and the Company. The stockholders of STC and Epitepe approved the Merger Agreement on September 29, 2000.

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

#### General

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

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

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

#### Products

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

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

#### OraSure(R)/Intercept(R) Collection Devices

The Company's OraSure(R) oral fluid collection device is used in conjunction with screening and confirmatory tests for HIV-1 antibodies and other analytes. The device consists of a small, treated cotton-fiber pad on a nylon handle that is placed in a person's mouth for two to five minutes. The device collects oral mucosal transudate ("OMT"), a serum-derived fluid that contains higher concentrations of antibodies and analytes than saliva. As a result, OMT testing is a highly accurate method for detecting HIV-1 infection and other analytes. The Company believes that oral fluid testing has several significant advantages over blood or urine-based testing systems for both health care professionals and individuals being tested, including eliminating the risk of needle-stick accidents, providing a noninvasive collection technique, requiring minimal training to administer, providing rapid and efficient collection in almost any setting, and eliminating the cost of administration by a trained health care professional.

The Company has received approval from the U.S. Food and Drug Administration ("FDA") to sell the OraSure(R) oral fluid collection device for use with a laboratory-based enzyme immunoassay ("EIA") screening test for HIV-1 antibody detection. HIV-1 antibody detection using the OraSure(R) collection device involves three steps: (1) collection of an oral fluid specimen using the OraSure(R) 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(R) Western Blot HIV-1 confirmatory test (described below). A trained health care professional then conveys test results and provides appropriate counseling to the individual who was tested. The Company has also received FDA clearance for use of the OraSure(R) collection device with EIAs to test for cocaine and cotinine (a metabolite of nicotine) in oral fluid specimens.

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

A collection device substantially similar to the OraSure(R) device comprises the Company's Intercept(R) oral fluid drug testing service. The Company has received FDA clearance to use the Intercept(R) collection device with laboratory-based EIAs to test for drugs of abuse commonly identified by the National Institute for Drug Abuse ("NIDA") as the NIDA-5 (i.e., cannabinoids (marijuana), cocaine, opiates, amphetamines, and phencyclidine ("PCP")), and for barbiturates and methadone. The Company also sells, or arranges for a third party vendor to sell, equipment required by its laboratory customers to test oral fluid specimens collected with the Intercept(R) device. Intercept(R) is sold in the workplace testing, public health, criminal justice and drug rehabilitation markets.

The Company believes that the Intercept(R) service has several advantages over certain competing products for drugs-of-abuse testing, including its lower cost, non-invasive nature, safety, mobility and accuracy, the ease of maintaining a chain-of-custody, the treatment of test subjects with greater dignity, no requirement for specially-prepared collection facilities, and difficulty of sample adulteration. The availability of an oral fluid test is intended to allow workplace administrators to test for employee impairment on demand, eliminate scheduling costs, and streamline the testing process.

#### OraQuick(R) Rapid Test

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

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

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

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

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

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

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

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

## UPT(TM) and UPLink(TM)

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

Phosphor particles have been used for decades in television screens and in fluorescent light bulbs. When high energy ultraviolet light strikes the phosphor-coated area in a screen or bulb, it excites the particles and low energy visible colored light is produced. The Company's patented improvements on this base technology employ chemical changes inside the phosphor particles so that low energy infrared light can be used to produce a high energy visible colored signal and is the basis for UPT(TM). 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(TM) overcomes some of the limitations of other diagnostic detection methods and offers features not commercially available today. The fact that UPT(TM) testing produces zero background interference dramatically increases the potential sensitivity of any test system. In addition, UPT(TM) offers the following other key competitive features:

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

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

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

In March 2000, the Company signed a research and development agreement with Drager Safety AG & Co. KGaA (formerly Drager Sicherheitstechnik GmbH) ("Drager"), a European manufacturer and supplier of medical and safety technology products for health care and industrial applications, to develop and optimize an UPlink(TM) system for rapid detection of drugs of abuse in oral fluid. The UPlink(TM) system developed with Drager is expected to be marketed initially to law enforcement officials as a system for rapidly assessing whether an operator or passenger in a motor vehicle is under the influence of one or more drugs of abuse (the "roadside market") and ultimately to certain military, criminal justice, and workplace testing markets. As part of the research and development agreement, the Company received a non-refundable fee and will receive additional fees upon achievement of technical milestones. Upon successful completion of such research and development activities, Drager has the option to become the Company's exclusive distributor of the UPlink(TM) drugs of abuse rapid detection system in Europe and certain other countries in the markets described above.

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

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

#### Histofreezer(R)

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

The Histofreezer(R) product mixes two environmentally friendly cryogenic gases in a small aerosol canister. When released, these gases are delivered to a specially designed foam bud, cooling the bud to -50(degrees) C. The frozen bud is then applied to the lesion for 15 to 40 seconds (depending on the type of lesion) creating localized destruction of the target area. Histofreezer(R) is sold in several canister sizes. Sales of this product have been targeted to primary care physicians such as pediatricians, general and family practitioners, and other physician segments that traditionally referred patients to dermatologists to remove warts. The Company has established a national network of distributors to reach the physician office market in the United States.

## Immunoassay Tests and Reagents

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

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

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

OraSure Technologies currently markets the MICRO-PLATE oral fluid test for use in screening life insurance applicants to test for two of the most important underwriting risk factors: cocaine and cotinine (a metabolite of nicotine). The Company sells the reagents to insurance testing laboratories, which provide the laboratory testing to insurance companies, often in combination with the OraSure(R) oral fluid collection device. AUTO-LYTE(R) 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(R) product line to detect drugs-of-abuse in oral fluid specimens. The Company's toxicology and drugs-of-abuse test products are currently sold in the forensic toxicology, criminal justice, drug rehabilitation, and workplace testing markets.

Whenever possible, the Company enters into multi-year sales agreements with its customers. These agreements generally are entered into with a laboratory which has agreed to purchase a minimum number of tests over a two-to-five-year period. The Company also offers these customers the option of a reagent rental agreement pursuant to which the Company sells the tests at an increased price over a fixed period of time, which includes an additional equipment charge in exchange for providing the customer with the required analytical laboratory equipment.

### Western Blot HIV-1 Confirmatory Test

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

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



## Q.E.D.(R) Saliva Alcohol Test

The Q.E.D.(R) saliva alcohol test is an on-site, cost-effective test device that is an alternative to breath or blood alcohol testing. The test is a quantitative, saliva-based method for the detection of ethanol, and has been cleared for sale by the FDA and the U.S. Department of Transportation ("DOT"). In 1997, the product also received a waiver under the Clinical Laboratory Improvement Act of 1988. Each Q.E.D.(R) 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.(R) device is easy to operate and instrumentation is not required to read the result. The product has a testing range of 0 to 0.145% blood alcohol, and produces results in approximately two minutes.

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

## Products Under Development

### OraSure(R)/Intercept(R) Applications

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

### OraQuick(R) Platform

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

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

### UPT(TM) and UPlink(TM) Development

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

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

#### Western Blot HIV-1 Confirmatory Test

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

#### Research and Development

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

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

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

#### Sales and Marketing

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

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

#### Insurance Risk Assessment

The Company currently markets the OraSure(R) oral fluid collection device for use in screening life insurance applicants in the United States and internationally to test for three of the most important underwriting risk factors: HIV-1, cocaine, and cotinine. The Company sells the devices to insurance testing laboratories, which in turn provide the devices to insurance companies, usually in combination with testing services. The Company also maintains a direct sales force that promotes use of the OraSure(R) device directly to insurance companies. Insurance companies then make their own decision regarding which laboratory to use to supply their collection devices and testing services. The Company's OraSure(R) Western Blot confirmatory test is distributed through BMX and is used to confirm oral fluid specimens that test positive for HIV-1.

Because insurance companies are in various stages of their adoption of the OraSure(R) 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(R) to replace some of their blood and urine-based testing. The Company's sales force continues to encourage additional insurance companies to use OraSure(R) and to extend the use of the product by existing customers. Several companies have expanded use of OraSure(R) to the \$1 million and higher dollar policy amounts. This expansion is attributable to several factors, including increasing acceptance of the reliability of oral fluid testing, the high quality of test results, the low cost of oral fluid testing relative to blood tests, and the ease of use of the OraSure(R) device.

The Company also sells its AUTO-LYTE(R) and MICRO-PLATE assays and reagents in the insurance testing market directly to laboratories, including LabOne, Inc., Heritage Labs, Clinical Reference Laboratory, and the laboratory testing division of Metropolitan Life Insurance Company. AUTO-LYTE(R) 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(R) device for cocaine and cotinine.

#### Infectious Disease Testing

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

#### Substance Abuse Testing

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

#### Physicians' Offices

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

#### International Markets

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

health, and laboratory testing. The Company assists its distributors in registering the products and obtaining required regulatory approvals in each country and provides training and support materials. The Company's international marketing program includes direct assistance to distributors in arranging for laboratory services, cooperation from screening test manufacturers, and performance of Western Blot confirmatory tests when necessary.

#### Significant Products and Customers

Several different products have contributed significantly to the Company's financial performance, accounting for 15% or more of total revenues during the past three years. The Company's OraSure(R) and Intercept(R) oral fluid collection devices, Histofreezer(R), and immunoassay tests and reagents accounted for total revenues of approximately \$13.0 million, \$6.7 million and \$7.4 million in 2001, \$11.2 million, \$6.8 million, and \$6.7 million in 2000, and \$7.8 million, \$5.7 million, and \$6.2 million in 1999, respectively. As new products are developed and commercialized, the Company expects to reduce its dependence on the products referred to above.

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

#### Supply and Manufacturing

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

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

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

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

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

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

Histofreezer(R) is manufactured in The Netherlands by Koninklijke, Utermohlen, N.V. ("Utermohlen"), 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 Utermohlen shall be the exclusive supplier of the Histofreezer(R) product until at least December 31, 2006. The Company believes that additional manufacturers of the Histofreezer(R) product are available on terms no less favorable than the terms of the production agreement with Utermohlen in the event that Utermohlen would be unable or unwilling to continue manufacturing the Histofreezer(R) product.

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

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

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

#### Employees

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

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

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

## Competition

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

A few large corporations produce a wide variety of diagnostic tests and other medical devices and equipment, a larger number of mid-size companies generally compete only in the diagnostic industry, and a significant number of small companies produce only a few diagnostic products. As a result, the diagnostic test industry is fragmented and segmented. The future market for diagnostic tests is expected to be characterized by consolidation, greater cost consciousness, and tighter reimbursement policies. The purchasers of diagnostic products are expected to place increased emphasis on lowering costs, reducing inventory levels, automation, service, and volume discounts. The increased complexity of the market is expected to force many competitors to enter into joint ventures or license certain products or technologies.

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

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

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

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

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

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

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

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

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

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

Q.E.D.(R) has two direct competitors, Roche Diagnostics and Chematics. These companies offer semi-quantitative saliva-based alcohol tests and have received DOT approval. Indirect competitors who offer breath testing equipment include Intoximeters, Drager, 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.(R) test.

The Histofreezer(R) product's delivery system and warmer operating temperature than liquid nitrogen provide the Company with the opportunity to target sales to primary care physicians, such as family practitioners, pediatricians, and podiatrists. The Company does not generally target sales to dermatologists because they have the volume of patients required to support the capital costs associated with a liquid nitrogen delivery system. There is limited competition for convenient cryosurgical products for wart removal in the primary care physician market. Major competitors for the Histofreezer(R) product include CryoSurgery, Inc. and Aurium Pharma Inc. In addition, liquid nitrogen is used by medical professionals to remove warts and other benign skin lesions. Lastly, patients may purchase various over-the-counter products to treat warts at home.

#### Patents and Proprietary Information

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

it with competitive advantages in its selected markets and to accelerate new product introductions. Respecting the patent and intellectual property rights of others, the Company regularly searches for third-party patents in its fields of endeavor to shape its own patent and product commercialization strategies as effectively as possible and to identify licensing opportunities. United States patents generally have a maximum term of 20 years from the date an application is filed.

The Company has ten United States patents and numerous foreign patents for the OraSure(R) and Intercept(R) collection devices and related technology relating to oral fluid collection, containers for oral fluids, methods to test oral fluid, formulations for the manufacture of synthetic oral fluid, and methods to control the volume of oral fluid collected and dispersed. The Company has also applied for additional patents, in both the United States and certain foreign countries, on such products and technology. The Company has one patent for the OraQuick(R) rapid HIV test in the United States and intends to apply for other patents for this product. The Company may need to obtain licenses or other rights under, or enter into distribution or other business arrangements in connection with, certain HIV-2 and lateral flow patents in order to market the OraQuick(R) HIV test in the United States and certain other countries. See the Section entitled, "Risk Factors--Patent Issues Affecting OraQuick(R)," 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(TM). The Company also received non-exclusive worldwide rights under patents and know-how owned by the Sarnoff Corporation (a subsidiary of SRI International formerly called the David Sarnoff Research Center) to develop and market products that involve the use of UPT(TM). The Company has the right to sublicense these rights under the agreements subject to consent from SRI and Sarnoff.

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

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

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

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

The Company has three U.S. patents and numerous foreign patents issued for apparatuses and methods for the topical removal of skin lesions relating to its Histofreezer(R) 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.(R) 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(TM), UPLink(TM), OraSure(R), Intercept(R), OraQuick(R), Histofreezer(R), Q.E.D.(R), and AUTO-LYTE(R). The Company also is the owner of many of these marks and others in several foreign countries. The Company is not aware of any pending claims of infringement or other challenges to the Company's rights to use its marks in the United States or in other countries as currently used by the Company.

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

## Government Regulation

### General

Most of the Company's existing and proposed diagnostic products are regulated by the FDA, certain state and local agencies, and comparable regulatory bodies in other countries. This regulation governs almost all aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and recordkeeping. All of the Company's FDA-regulated products require some form of action by the FDA before they can be marketed in the United States, and, after approval or clearance, the Company must continue to comply with other FDA requirements applicable to marketed products. Both before and after approval or clearance, failure to comply with the FDA's requirements can lead to significant penalties.

### Domestic Regulation

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

There are two review procedures by which medical devices can receive FDA clearance or approval. Some products may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, in which the manufacturer provides a pre-market notification that it intends to begin marketing the product, and shows that the product is substantially equivalent to another legally marketed product (i.e., that it has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness). In some cases, the submission must include data from human clinical studies. Marketing may

commence when the FDA issues a clearance letter finding such substantial equivalence. An applicant must submit a 510(k) application at least 90 days before marketing of the affected product commences. Although FDA clearance may be granted within that 90-day period, in some cases as much as a year or more may be required before clearance is obtained, if at all.

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

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

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

Every company that manufactures biologic products or medical devices distributed in the United States must comply with the FDA's Quality System Regulations ("QSRs"). These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation, and purchasing. Compliance with QSRs is required before the FDA will approve an application, and these requirements also apply to marketed products. Companies are also subject to other post-market and general requirements, including compliance with restrictions imposed on marketed products, compliance with promotional standards, recordkeeping, and reporting of certain adverse reactions. The FDA regularly inspects companies to determine compliance with QSRs and other post-approval requirements. Failure to comply with statutory requirements and the FDA's regulations can lead to substantial penalties, including monetary penalties, injunctions, product recalls, seizure of products, and criminal prosecution.

Products that include electrical or light emitting equipment must also comply with the FDA's safety and performance standards applicable to such equipment. The Company's UPLink(TM) analyzer is a piece of electrical equipment that uses a laser to read the test results and is, therefore, subject to these requirements. In addition, there is an industry safety and performance standard for electrical equipment established by Underwriters Laboratories, Inc., known as UL3101. Although a voluntary standard, compliance with UL3101 will support the Company's 510(k) submission for the UPLink(TM) analyzer. The Company has retained Underwriters Laboratories Inc. to examine and test the UPLink(TM) analyzer and certify that it meets the FDA requirements and UL3101.

The Clinical Laboratory Improvement Act of 1988 ("CLIA") prohibits laboratories from performing in vitro tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the U.S. Department of Health and Human Services applicable to the category of examination or procedure performed. Although a certificate is not required for OraSure Technologies, the Company considers the applicability of the requirements of CLIA in the design and development of its products. In addition, the Company has obtained a waiver of the CLIA requirements for its Q.E.D.(R) alcohol saliva test and may seek similar waivers for certain of its other products. A CLIA waiver will remove certain quality control and other requirements that must be met for certain customers to use the Company's products.

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

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

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

#### International

The Company is also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval from international public health agencies, such as the World Health Organization, in order to sell products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for U.S. governmental approvals. The extent of potentially adverse governmental regulation affecting the Company that might arise from future legislative or administrative action cannot be predicted. The Company will pursue approval only in those countries that have a significant market opportunity.

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

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

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

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

#### Environmental Regulation

Because of the nature of its current and proposed research, development, and manufacturing processes, the Company is subject to stringent federal, state, and local laws, rules, regulations, and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, and handling and disposal of materials and wastes. The Company believes that it has complied with these laws and regulations in all material respects and has not been required to take any action to correct any noncompliance.

#### Forward-Looking Statements

This Report contains certain "forward-looking statements," within the meaning of the Federal securities laws. These may include statements about expected revenues, earnings, expenses or other financial performance, future product performance or development, expected regulatory filings and approvals, planned business transactions, views of future industry or market conditions, other factors that could affect future operations or financial position, and statements that include the words "believes," "expects," "anticipates," "intends," "plans," "estimates," "may," "will," "should," "could," or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors could cause actual performance or results to be materially different from those expressed or implied in these statements. Some of these factors are: ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to obtain and timing of obtaining necessary regulatory approvals; ability to develop product distribution channels; uncertainty relating to patent protection and potential patent infringement claims; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally; loss or impairment of sources of capital; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in the Section entitled, "Risk Factors," and elsewhere in this Report. Although forward-looking statements help to provide complete information about future prospects, they may not be reliable. The forward-looking statements are made as of the date of this Report and Orasure Technologies undertakes no duty to update these statements.

#### Risk Factors

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

#### Competing Products

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

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

#### Ability to Develop New Products

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

During 2001, 2000 and 1999, the Company incurred \$9.4 million, \$10.4 million and \$5.6 million, respectively, in research and development expenses. The Company expects to continue to incur significant costs in its research and development activities. Moreover, there can be no assurance that OraSure Technologies will succeed in its research and development efforts. If the Company fails to develop commercially successful products, or if competitors develop more effective products or a greater number of successful new products, customers may decide to use products developed by the Company's competitors, which would result in a loss of revenues.

#### Market Acceptance of Oral Fluid Testing Products

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

#### Loss or Impairment of Sources of Capital

Although the Company has made significant progress in the past toward controlling expenses and increasing product revenue, historically the Company has depended, to a substantial degree, on capital raised through the sale of equity securities and bank borrowings to fund its operations. The Company's future liquidity and capital requirements will depend on numerous factors, including, but not limited to, the costs and timing of the expansion of manufacturing capacity, the success of product development efforts, the costs and timing of expansion of sales and marketing activities, the timing of commercial launch of new products, the extent to which existing and new products gain market acceptance, competing technological and market developments, and the scope and timing of strategic acquisitions. If additional financing is needed, the Company may seek to raise funds through the sale of equity or other securities or through bank borrowings. There can be no assurance that financing through the sale of securities, bank borrowings or otherwise, will be available to the Company on satisfactory terms, if at all.

#### Ability of the Company to Develop Product Distribution Channels

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

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

#### Obtaining and Maintaining Regulatory Approvals and Clearances

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

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

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

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

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

## Regulatory Compliance

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

## History of Losses and Projected Profitability

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

The Company's limited combined operating history makes it difficult to forecast future operating results. In order to achieve sustainable profitability, the Company's revenues will have to continue to grow at a significant rate. The Company's ability to achieve revenue growth will be dependent upon a number of factors including, without limitation, creating market acceptance for and selling increasing volumes of the OraSure(R) collection device, the Intercept(R) and UPLink(TM) drugs-of-abuse products, and the OraQuick(R) rapid HIV-1 test, achieving growth in international markets with the Company's OraQuick(R) rapid HIV-1 test and other products, obtaining timely FDA approval or clearance for the OraQuick(R) rapid HIV-1 test and UPLink(TM) drugs-of-abuse rapid detection system, and commercially developing, and obtaining regulatory approval and creating market acceptance for, UPT(TM) 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(R) test, the Intercept(R) and UPLink(TM) products, or its other products, or to the extent other events described in this Section occur, the Company's revenue, and consequently profitability, could be lower than estimated. Even if the Company achieves profitability, there is no assurance that such profitability can be sustained in the future.

## Stock Price Volatility

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

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

## Ability to Market New Products

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

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

#### Reliance on Patents and Other Proprietary Rights

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

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

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

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

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

#### Patent Issues Affecting OraQuick(R)

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



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

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

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

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

In the event that it is determined that a license is required and it is not possible to negotiate a license agreement under a necessary patent, the Company may be able to modify the OraQuick(R) rapid HIV test such that a license would not be necessary. However, this alternative could delay introduction of the OraQuick(R) rapid HIV test into the United States and other markets.

#### Loss of Key Personnel

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



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

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

#### International Marketing and Manufacturing

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

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

- . Regulatory requirements (including compliance with applicable customs regulations) may slow, limit, or prevent the offering of products in foreign jurisdictions;
- . Cultural and political differences may make it difficult to effectively market, sell and gain acceptance of products in foreign jurisdictions;
- . Inexperience in international markets may slow or limit the Company's ability to sell products in foreign countries;
- . Exchange rates, currency fluctuations, tariffs and other barriers, extended payment terms and dependence on and difficulties in managing international distributors or representatives may affect the Company's revenues even when product sales occur;
- . The creditworthiness of foreign entities may be less certain and foreign accounts receivable collection may be more difficult;
- . Economic conditions and the absence of available funding sources may slow or limit the Company's ability to sell its products in foreign countries;
- . International markets often have long sales cycles, especially sales to foreign governments, quasi-governmental agencies and international public health agencies, thereby delaying or limiting the Company's ability to sell its products; and
- . The Company may be at a disadvantage if competitors in foreign countries sell competing products at prices at or below such competitors' or the Company's cost.

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

#### Product Liability Exposure

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

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

#### Ability to Fully Commercialize UPT(TM)

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

#### Dependence on Strategic Partners

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

#### Dependence on Third Party Licenses and Rights

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

#### Recent Economic Downturn and Terrorist Attacks

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

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

#### Restructuring of Operations

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

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

#### ITEM 2. Properties.

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

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

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

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

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

ITEM 3. Legal Proceedings.

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

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

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

PART II

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

The Company's Common Stock is listed for trading on the National Market tier of The Nasdaq Stock Market ("NASDAQ") under the symbol OSUR. High and low sales prices reported by NASDAQ during the periods indicated are shown below. Prices for quarters ending prior to the September 29, 2000 Merger with Epitepe and STC, represent the high and low sales prices reported by NASDAQ for the common stock of the Company's predecessor, Epitepe, which traded under the symbol EPTO.

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

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

ITEM 6. Selected Financial Data.

The following table sets forth selected financial data of the Company. See Note 1 to the Company's Financial Statements for a discussion of the Merger with Epitepe and STC and change in the fiscal year end of Epitepe. The data below for the year ended September 30, 1997 includes discontinued operations of two of Epitepe's former subsidiaries, Agritope, Inc. and Andrew and Williamson Sales, Co. The charge for discontinued operations during this period includes the operating losses of these subsidiaries through their disposition dates and final losses on disposal incurred by Epitepe. This information should be read in conjunction with the Financial Statements and notes thereto included in Item 14 and the information set forth in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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

	Year ended December 31,		Three months ended December 31,		Year ended September 30,		
	2001	2000	1999	1998	1999	1998	1997
<b>Operating Results:</b>							
Revenues.....	\$ 32,573	\$ 28,788	\$ 6,822	\$ 5,138	\$ 24,046	\$ 20,444	\$ 17,282
Costs and expenses.....	36,906	42,917	7,105	5,857	28,138	22,721	23,295
Other income (expense), net.....	634	1,407	(138)	(159)	(91)	(98)	782
Loss from continuing operations before income taxes.....	(3,699)	(12,722)	(421)	(878)	(4,183)	(2,374)	(5,231)
Loss from continuing operations.....	(3,728)	(12,747)	(471)	(878)	(4,233)	(2,374)	(5,231)
Discontinued operations.....	--	--	--	--	--	--	(18,359)
Net loss.....	(3,728)	(12,747)	(471)	(878)	(4,233)	(2,374)	(23,590)
<b>Per Share of Common Stock:</b>							
Loss from continuing operations.....	\$ (0.10)	\$ (0.36)	\$ (0.02)	\$ (0.03)	\$ (0.14)	\$ (0.09)	\$ (0.20)
Loss from discontinued operations.....	--	--	--	--	--	--	(0.70)
Basic and diluted net loss.....	(0.10)	(0.36)	(0.02)	(0.03)	(0.14)	(0.09)	(0.90)
Shares used in per share calculations:.....	36,868	35,002	30,887	26,246	30,597	26,180	26,055
<b>Financial position:</b>							
Working capital.....	\$ 19,764	\$ 21,440	\$ 16,314	\$ 8,255	\$ 16,773	\$ 8,725	\$ 12,470
Total assets.....	37,285	37,736	29,626	20,075	30,251	20,783	25,978
Long-term debt.....	3,586	4,644	5,820	6,001	5,820	6,001	4,026
Accumulated deficit.....	(126,092)	(122,365)	(109,618)	(105,603)	(109,104)	(104,903)	(96,837)
Stockholders' equity....	26,541	26,172	18,238	10,264	18,592	10,701	17,873



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

Statements below regarding future events or performance are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The Company's actual results could be quite different from those expressed or implied by the forward-looking statements. Factors that could affect results are discussed more fully under the Sections entitled "Forward-Looking Statements" and "Risk Factors" in Item 1 and elsewhere in this Annual Report on Form 10-K. Although forward-looking statements help to provide complete information about the Company, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements.

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

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

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

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

Results of Operations--2001 Compared to 2000

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

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

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

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

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

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

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

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

Licensing and product development revenues increased 113% to approximately \$1.5 million in 2001 from approximately \$0.7 million in 2000, reflecting a different mix of development work performed in 2001. During 2001, licensing and product development revenues were primarily from the continued development of the ULink(TM) drugs-of-abuse rapid detection system under an agreement with Drager, development of infectious disease applications for ULink(TM) under an agreement with Meridian Bioscience, and the second phase of a grant from the National Institutes of Health ("NIH") for the development of an oral fluid syphilis test. During

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

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

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

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

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

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

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

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

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

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

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

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

#### Results of Operations--2000 Compared to 1999

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### Liquidity and Capital Resources

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

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

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

electronic components for ULink(TM) readers in anticipation of sales growth, and an increase in accounts receivable levels.

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

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

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

The Company believes that it has sufficient cash, cash equivalents, and short-term investments for the foreseeable future. The Company's future liquidity and capital requirements will depend on numerous factors, including, but not limited to, the costs and timing of the expansion of manufacturing capacity, the success of product development efforts, the timing of receipt of regulatory approvals, the costs and timing of expansion of sales and marketing activities, the timing of commercial launch of new products, the extent to which existing and new products gain market acceptance, competing technological and market developments, and the scope and timing of strategic acquisitions. If additional financing is needed, the Company may seek to raise funds through the sale of equity or other securities, bank borrowings or otherwise. There can be no assurance that financing through the sale of securities, bank borrowings or otherwise will be available to the Company on satisfactory terms, if at all.

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

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

- (1) Represents principal repayments required under notes payable to the Company's lenders. See Note 8 to the financial statements included herein.
- (2) \$1,903,211 of the \$2,236,923 represents a note payable which is subject to a call option in December 2003. If the note is not called in December 2003, payments of \$577,542, \$643,829 and \$681,840 would be due in 2003, 2004, and 2005, respectively.
- (3) Represents payments required under the Company's operating leases. See Notes 11 and 12 to the financial statements included herein.
- (4) Represents salary, retention bonus or severance payments payable under the terms of employment agreements executed by the Company. See Note 11 to the financial statements included herein.
- (5) Represents payments required by non-cancelable purchase orders related to capital expenditures. See Note 11 to the financial statements included herein.
- (6) Represents payments required pursuant to certain research, licensing and royalty agreements executed by the Company. See Note 11 to the financial statements included herein.

#### Critical Accounting Policies and Estimates

Management's Discussion and Analysis of Financial Condition and Results of Operations discusses the Company's financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, management evaluates its judgments and estimates, including those related to bad debts, inventories, investments, intangible assets, income taxes, revenue recognition, restructuring costs, contingencies, and litigation. Management bases its judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

**Revenue Recognition.** The Company follows U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). This bulletin draws on existing accounting rules and provides specific guidance on revenue recognition of up-front non-refundable licensing and development fees. The Company licenses certain products or technology to outside third parties, in return for which the



Company receives up-front licensing fees, some of which can be significant. In accordance with SAB 101, the Company is required to defer immediate recognition of these fees as revenue, and instead ratably recognize this revenue over the related license period.

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

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

Allowance for Uncollectible Accounts Receivable. Accounts receivable are reduced by an estimated allowance for amounts that may become uncollectible in the future. On an ongoing basis, management performs credit evaluations of the Company's customers and adjusts credit limits based upon the customer's payment history and creditworthiness, as determined by a review of their current credit information. The Company continuously monitors collections and payments from its customers. Based upon the Company's historical experience and any specific customer collection issues that are identified, management uses its judgment to establish and evaluate the adequacy of the Company's allowance for estimated credit losses. While such credit losses have been within the Company's expectations and the allowance provided, the Company cannot guarantee that it will continue to experience the same credit loss rates as it has in the past. Furthermore, some of the Company's accounts receivable have resulted from sales to distributors located in foreign countries in South Africa and South America. Also, at December 31, 2001, approximately \$1.3 million or 21.4% of the Company's accounts receivable were due from one major customer. Any significant changes in the liquidity or financial position of this customer, or the economies of these foreign nations, could have a material adverse impact on the collectibility of the Company's accounts receivable and its future operating results.

Inventories. The Company's inventories are valued at the lower of cost or market, determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of the Company's inventories are subject to expiration dating. The Company continually evaluates the carrying value of its inventories and when, in the opinion of management, factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off. Management bases these decisions on the level of inventories on hand in relation to the Company's estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. Although the Company makes every effort to ensure the accuracy of its forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of the Company's inventories and its reported operating results.

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

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

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

#### Certain Relationships and Related Transactions

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

The Lease has an initial 10-year term commencing after completion of construction and a base rent starting at \$480,000 and increasing to \$528,000 per year over that term. The base rental rate may be increased after the fifth year of the initial term in order to reflect changes in the interest rate on debt incurred by Tech Partners to finance construction of the leased facilities. The Company has not guaranteed any debt incurred by Tech Partners. The Lease also provides the Company with options to renew the Lease for an additional five years at a rental rate of \$600,000 per year, and to purchase the facility at any time during the initial ten-year term at a fair value. Prior to deciding to enter into the Lease, the Company's Board of Directors retained Imperial Realty Appraisal LLC, an independent commercial real estate appraisal firm, to evaluate the proposed base rental rate under the Lease. Imperial Realty issued an opinion indicating that the annual base rent set forth in the Lease is below the market rental rate the Company could otherwise expect to pay to lease a comparable commercial property in the same general geographic market. The terms of the Lease are otherwise substantially similar to the commercial lease entered into by the Company with a third party for its existing Bethlehem, Pennsylvania headquarters.

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

#### Recent Accounting Pronouncements

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

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

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

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

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

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

The Company does not currently have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. The Company has operations in The Netherlands which are subject to foreign currency fluctuations. As currency rates change, translation of income statements of these operations from Euros to U.S. dollars affects year-to-year comparability of operating results. The Company's operations in The Netherlands represented approximately \$2.0 million or 1% of the Company's revenues for the year ended December 31, 2001. Management does not expect the risk of foreign currency fluctuations to be material.

#### ITEM 8. Financial Statements and Supplementary Data.

Information with respect to this Item is contained in the Company's Financial Statements included in Item 14 of this Annual Report on Form 10-K.

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

None.

### PART III

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

#### ITEM 10. Directors and Executive Officers of the Registrant.

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

#### ITEM 11. Executive Compensation.

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

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

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

#### ITEM 13. Certain Relationships and Related Transactions.

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

### PART IV

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

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

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

(b) Reports on Form 8-K.

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



INDEX TO FINANCIAL STATEMENTS

	Page
	-----
Report of Arthur Andersen LLP--Independent Public Accountants.....	F-2
Report of PricewaterhouseCoopers LLP--Independent Accountants.....	F-3
Balance Sheets.....	F-4
Statements of Operations.....	F-5
Statements of Stockholders' Equity.....	F-6
Statements of Cash Flows.....	F-7
Notes to Financial Statements.....	F-8

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To OraSure Technologies, Inc.:

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

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

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

ARTHUR ANDERSEN LLP

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



REPORT OF INDEPENDENT ACCOUNTANTS

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

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

PricewaterhouseCoopers LLP

Portland, Oregon  
January 15, 2001

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31,	
	2001	2000
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents.....	\$ 2,426,346	\$ 5,095,639
Short-term investments.....	12,764,903	14,956,779
Accounts receivable, net of allowance for doubtful accounts of \$209,492 and \$114,685.....	6,057,927	5,276,772
Notes receivable from officer.....	75,000	175,649
Inventories.....	4,444,772	1,495,604
Prepaid expenses and other.....	1,038,511	1,113,691
	-----	-----
Total current assets.....	26,807,459	28,114,134
PROPERTY AND EQUIPMENT, net.....	7,800,137	6,738,034
PATENTS AND PRODUCT RIGHTS, net.....	2,042,533	2,402,386
OTHER ASSETS.....	634,546	481,618
	-----	-----
	\$ 37,284,675	\$ 37,736,172
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt.....	\$ 1,057,572	\$ 1,125,138
Accounts payable.....	2,874,061	2,120,534
Accrued expenses.....	3,111,886	3,428,862
	-----	-----
Total current liabilities.....	7,043,519	6,674,534
	-----	-----
LONG-TERM DEBT.....	3,586,458	4,644,098
	-----	-----
OTHER LIABILITIES.....	114,025	245,464
	-----	-----
COMMITMENTS AND CONTINGENCIES (Note 11)		
STOCKHOLDERS' EQUITY:		
Preferred stock, par value \$.000001; 25,000,000 shares authorized, none issued.....	--	--
Common stock, par value \$.000001; 120,000,000 shares authorized, 37,403,269 and 36,434,004 shares issued and outstanding.....	37	36
Additional paid-in capital.....	152,758,591	148,767,789
Accumulated other comprehensive loss.....	(125,664)	(231,247)
Accumulated deficit.....	(126,092,291)	(122,364,502)
	-----	-----
Total stockholders' equity.....	26,540,673	26,172,076
	-----	-----
	\$ 37,284,675	\$ 37,736,172
	=====	=====

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

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

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY

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

adjustment.....	--	--	--	(61,140)	--	(61,140)
Net unrealized gain on marketable securities.....	--	--	--	89,111	--	89,111
						-----
Total comprehensive loss.....						(12,718,579)
	-----	-----	-----	-----	-----	-----
Balance at December 31, 2000.....	36,434,004	36	148,767,789	(231,247)	(122,364,502)	26,172,076
Common stock issued upon exercise of options....	968,729	1	3,851,805	--	--	3,851,806
Common stock issued under Employee Stock Purchase Plan and Savings Plan.....	536	--	2,123	--	--	2,123
Compensation expense for stock option grants....	--	--	136,874	--	--	136,874
						-----
Comprehensive loss:						
Net loss.....	--	--	--	--	(3,727,789)	(3,727,789)
Currency translation adjustment.....	--	--	--	(75,670)	--	(75,670)
Net unrealized gain on marketable securities.....	--	--	--	181,253	--	181,253
						-----
Total comprehensive loss.....						(3,622,206)
	-----	-----	-----	-----	-----	-----
Balance at December 31, 2001.....	<u>37,403,269</u>	<u>\$ 37</u>	<u>\$152,758,591</u>	<u>\$(125,664)</u>	<u>\$(126,092,291)</u>	<u>\$ 26,540,673</u>

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

	For the year ended December 31,		For the three months ended December 31,	For the year ended September 30, 1999
	2001	2000	1999	
<b>OPERATING ACTIVITIES:</b>				
Net loss.....	\$ (3,727,789)	\$(12,746,550)	\$ (471,287)	\$ (4,233,264)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Stock based compensation expense.....	136,874	792,685	87,200	321,006
Common stock issued as compensation for services.....	--	62,409	--	105,471
Amortization of deferred revenue.....	(179,167)	(143,334)	(40,313)	(107,500)
Acquired in-process technology.....	--	--	--	1,500,000
Depreciation and amortization.....	2,175,055	2,243,001	448,654	1,855,479
Gain on sale of securities and disposition of investment in affiliated company...	(116,853)	(600,000)	--	--
(Gain) loss on disposition of property and equipment.....	173,975	10,844	42,245	(36,952)
Provision for reserve for excess and obsolete inventories.....	600,000	1,141,351	--	--
Deferred income taxes.....	--	--	91,497	--
Changes in assets and liabilities--				
Accounts receivable..	(1,118,408)	(1,853,514)	(261,924)	(985,070)
Inventories.....	(3,549,168)	(231,516)	237,956	(300,882)
Prepaid expenses and other.....	175,829	(153,631)	(76,981)	31,817
Accounts payable.....	443,050	308,789	(199,275)	47,904
Accrued expenses and other.....	(269,248)	1,125,020	482,312	843,381
Net cash provided by (used in) operating activities.....	(5,255,850)	(10,044,446)	340,084	(958,610)
<b>INVESTING ACTIVITIES:</b>				
Purchases of property and equipment.....	(2,763,639)	(3,071,565)	(626,036)	(1,701,520)
Proceeds from the sale of property and equipment.....	33,231	--	78,250	98,250
Purchase of patents and product rights.....	--	(619,589)	(18,024)	(1,627,377)
Purchase of short-term investments.....	(21,297,303)	(24,869,468)	(1,250,261)	(37,624,613)
Proceeds from sale of short-term investments.....	23,420,432	22,339,595	2,016,757	29,383,614
Proceeds from sale of securities.....	637,500	600,000	--	--
Proceeds from disposition of investment in affiliated company....	106,102	--	--	--

Investment in affiliated companies..	--	(20,404)	(32,181)	(17,435)
(Increase) decrease in other assets.....	(202,819)	50,000	--	195,273
	-----	-----	-----	-----
Net cash provided by (used in) investing activities.....	(66,496)	(5,591,431)	168,505	(11,293,808)
	-----	-----	-----	-----
FINANCING ACTIVITIES:				
Proceeds from term debt.....	--	--	--	2,219,433
Repayment of term debt.....	(1,125,206)	(1,054,194)	(250,374)	(1,872,475)
Net proceeds from issuance of common stock.....	3,853,929	19,797,206	79,939	11,939,624
	-----	-----	-----	-----
Net cash provided by (used in) financing activities.....	2,728,723	18,743,012	(170,435)	12,286,582
	-----	-----	-----	-----
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH.....				
	(75,670)	(61,140)	(38,298)	(74,260)
	-----	-----	-----	-----
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS.....				
	(2,669,293)	3,045,995	299,856	(40,096)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD.....				
	5,095,639	2,049,644	1,749,788	2,370,469
	-----	-----	-----	-----
CASH AND CASH EQUIVALENTS, END OF PERIOD.....				
	\$ 2,426,346	\$ 5,095,639	\$ 2,049,644	\$ 2,330,373
	=====	=====	=====	=====

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

NOTES TO THE FINANCIAL STATEMENTS

1. BACKGROUND:

The Company

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

Merger

On September 29, 2000, STC Technologies, Inc. ("STC") and Epitepe, Inc. ("Epitepe") were merged (the "Merger") into the Company, a newly formed subsidiary of Epitepe incorporated under Delaware law solely for the purposes of combining the two companies and changing the state of incorporation of Epitepe from Oregon to Delaware. The companies were merged pursuant to an Agreement and Plan of Merger, dated May 6, 2000, by and among Epitepe, the Company and STC, which was subsequently approved by both companies' stockholders on September 29, 2000. The Merger was accounted for as a pooling of interests and, accordingly, all prior period financial statements of Epitepe have been restated to include the results of operations, financial position and cash flows of STC. Information concerning common stock, employee stock plans and per share data has been restated on an equivalent share basis. The financial statements as of September 30, 1999 and for the year then ended include Epitepe's previous September 30 fiscal year amounts and STC's December 31, 1999 calendar year amounts.

Change in year-end

On September 29, 2000, the Board of Directors of Epitepe approved a change in the fiscal year-end of Epitepe from September 30 to December 31, effective with the calendar year beginning January 1, 2000. A three-month transition period from October 1, 1999 through December 31, 1999 (the "Transition Period") preceded the start of the 2000 fiscal year. References to "1999" mean the year ended September 30, 1999 and include Epitepe's previous September 30 fiscal year amounts and STC's December 31, 1999 calendar year amounts. References to "2001" and "2000" mean the combined results of the two companies for the years ended December 31, 2001 and 2000, respectively. As a result of the Merger, financial statements for the Transition Period include amounts for Epitepe and STC for the three months ended December 31, 1999. Accordingly, STC's results of operations for the three months ended December 31, 1999 are included in both the financial statements for 1999 and for the Transition Period. Included in the statement of stockholders' equity is a \$152,018 adjustment for the change in fiscal year-end, which represents STC's results of operations for the three months ended December 31, 1999 that is included in both 1999 and the Transition Period.



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

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

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

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

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

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

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of

assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Cash and Cash Equivalents

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

#### Short-term Investments

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

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

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

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

#### Supplemental Cash Flow Information

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

For 2001, 2000, the Transition Period and 1999, the Company recorded provisions for bad debts of \$100,000, \$0, \$0 and \$8,851, respectively. The Company had deductions of \$5,193, \$4,269, \$0 and \$0 against the allowance for doubtful accounts in 2001, 2000, the Transition Period and 1999, respectively.

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

## Inventories

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

## Property and Equipment

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

## Patents and Product Rights

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

## Revenue Recognition

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

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

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

## Significant Customer Concentration

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

## Research and Development

Research and development costs are charged to expense as incurred.

## Income Taxes

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

## Foreign Currency Translation

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

## Stock-Based Compensation

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

## Net Loss Per Common Share

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

## Impairment of Long-Lived Assets

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

## Other Comprehensive Income (Loss)

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

## Restructuring-related Expenses

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

## Recent Accounting Pronouncements

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

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

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

## Gain on Sale of Securities

In December 2001, the Company recognized a gain of \$100,000 on the sale of 50,000 shares of LabOne, Inc. common stock received in connection with a distribution agreement entered into by the Company and LabOne, Inc. in April 1999. The Company's original investment associated with these shares was \$537,500. The Company no longer holds any common shares or warrants of LabOne, Inc.

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

Reclassifications

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

3. INVENTORIES:

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

4. PROPERTY AND EQUIPMENT:

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

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

5. PATENTS AND PRODUCT RIGHTS:

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

6. ACCRUED EXPENSES:

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

7. CREDIT FACILITIES:

The Company has a \$1,000,000 revolving line of credit with a bank which bears interest at LIBOR plus 235 basis points. Borrowings under this line are collateralized by the Company's accounts receivable. The line expires on April

30, 2002. There were no borrowings against the line at December 31, 2001 or 2000.

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

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

8. LONG-TERM DEBT:

	December 31,	
	2001	2000
Note payable to bank, interest at 8%, monthly installments of principal and interest of \$59,219 through December 2003, at which point the remaining principal is subject to a call option by the lender or payable in monthly installments of principal and interest based on the prime rate plus 1% through December 2005, secured by certain property and equipment, inventory and intangible assets.....	\$ 2,435,902	\$ 2,927,226
Note payable to bank, interest at 8%, monthly installments of principal and interest of \$8,181 through December 2003, with remaining monthly installments of principal and interest based on the prime rate plus 1% through December 2018, subject to call options by the lender every five years commencing March 31, 2010, secured by the Company's building.....	904,238	928,021
Note payable to Pennsylvania Industrial Development Authority, interest at 2%, monthly installments of principal and interest of \$4,895 through March 2010, secured by a second lien on the Company's building.....	442,285	491,518
Note payable to bank, interest at 7.8%, monthly installments of principal and interest of \$23,146 through July 2004, secured by certain property and equipment, inventory and intangible assets.....	647,779	864,937
Note payable to bank, interest at 7.75%, monthly installments of principal and interest of \$31,271 through July 2002, secured by certain property and equipment, inventory and intangible assets.....	213,826	557,534
	4,644,030	5,769,236
Less--Current portion.....	(1,057,572)	(1,125,138)
	\$ 3,586,458	\$ 4,644,098
	=====	=====

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

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

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



9. INCOME TAXES:

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

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

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

10. STOCKHOLDERS' EQUITY:

Stock Options

As a result of the Merger, the Epitepe, Inc. 2000 Stock Award Plan was adopted by the Company and renamed the OraSure Technologies, Inc. 2000 Stock Award Plan (the "2000 Plan"). The 2000 Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the 2000 Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards.

Under the terms of the 2000 Plan, qualified incentive stock options for shares of common stock may be granted to eligible employees, including officers of the Company. To date, options have generally been granted with ten-year exercise periods and an exercise price not less than the fair market value on date of grant. Options generally vest over four years, with one quarter of the options vesting one year after grant with the remainder vesting on a monthly basis over the next three years.

The 2000 Plan also provides that nonqualified options may be granted at a price not less than 75 percent of the fair market value of a share of common stock on the date of grant. The option term and vesting schedule of such awards may either be unlimited or have a specified period in which to vest and be exercised. For the discounted nonqualified options issued, the Company amortizes, on a straight-line basis over the vesting period of the options, the difference between the exercise price and the fair market value of a share of stock on the date of grant.

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

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

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

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

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

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

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

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

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

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

#### Employee Stock Purchase Plan

In 1993, Epitope's stockholders approved the adoption of the 1993 Employee Stock Purchase Plan ("1993 ESPP"). The 1993 ESPP, as subsequently amended by Epitope's stockholders, covered a maximum of 500,000 shares of common stock for subscription over established offering periods. As a result of the Merger, the 1993 ESPP was adopted and renamed by the Company. The Compensation Committee of the Board of directors

determines the number of offering periods, the number of shares offered, and the length of each period, provided that no more than three offering periods may be set during each fiscal year of the Company. The purchase price for stock purchased under the 1993 ESPP for each subscription period is the lesser of 85 percent of the fair market value of a share of common stock at the commencement of the subscription period and the fair market value at the close of the subscription period. An employee may also elect to withdraw at any time during the subscription period and receive the amounts paid plus interest at the rate of 6 percent.

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

#### Common Stock Warrants

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

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

#### 11. COMMITMENTS AND CONTINGENCIES:

##### Phosphor Agreements

In April 1995, the Company entered into several research, licensing and royalty agreements (collectively the "Phosphor Agreements"), related to development and commercialization of the Company's up-converting phosphor technology ("UPT(TM)"). Under the terms of the Phosphor Agreements, as amended, the Company is obligated to make an annual license payment of \$50,000 and an annual minimum royalty payment of \$100,000 for usage of patented technology licensed to the Company. Upon the first commercial sale of a UPT(TM)-based product or service, the Company is then obligated to pay royalties based upon a percentage of the net sales of UPT(TM)-based products, research and development fees and sublicensing revenues, for a period equal to the longer of ten years from the date of the first commercial sale of a UPT(TM)-based product or service (which occurred in 2001) or the remaining life of the patents underlying the licensed technology, which expire through 2017. Royalties from the commercial sale of products or services can be credited against the Company's minimum royalty obligation of \$100,000 per year.

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

## Leases

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

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

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

## Capital Expenditures

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

## Employment Agreements

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

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

## Litigation

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

## 12. RELATED-PARTY TRANSACTIONS:

### Officer Notes

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

### Facility Lease

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

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

13. RETIREMENT PLANS:

As a result of the Merger, during 2000 and a portion of 2001, the Company maintained two distinct retirement plans covering substantially all of its employees. Both plans permitted voluntary employee contributions to be excluded from the employees' current taxable income under the provisions of Internal Revenue Code Section 401(k) and the regulations thereunder. During the prior periods reported, generally all employees of Epitope were eligible to participate in a profit sharing and deferred savings plan. The plan provided for a Company matching contribution (either in cash, Company stock, or a combination of both) equal to 50 percent of an employee's contribution, not to exceed 2.5 percent of an employee's compensation. The Company contributed 5,309, 2,691 and 12,693 shares valued at \$62,409, \$17,492 and \$75,475 during 2000, the Transition Period, and 1999, respectively, to this plan. During the prior periods reported, generally all employees of STC were eligible to participate in a profit sharing plan. The plan provided for the Company, subject to the Board of Directors' discretion, to match employee contributions up to \$3,000 or 8% of a participant's salary, whichever is less. Company contributions to the plan were \$75,789, \$122,903, \$19,247, and \$113,708 for 2001, 2000, the Transition Period, and 1999, respectively.

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

14. GEOGRAPHIC INFORMATION:

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

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

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

15. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2001 and 2000, as well as the Transition Period and the comparable three-month period ended December 31, 1998. These quarterly results are unaudited, but in the opinion of management, have been prepared on the same basis as the Company's audited financial information and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information set forth herein (all amounts in thousands, except per share amounts).

2001 Results

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

2000 Results

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

Three months ended  
December 31,

	1999	1998
Revenues.....	\$ 6,822	\$ 5,138
Costs and expenses.....	7,105	5,857
Operating loss.....	(283)	(719)
Other expense.....	(138)	(159)
Loss before income taxes.....	(421)	(878)
Income taxes.....	50	--
Net loss.....	\$ (471)	\$ (878)
Basic and diluted net loss per share.....	\$ (0.02)	\$ (0.03)
Weighted average number		

of shares outstanding..	30,887	26,246
	=====	=====



INDEX TO EXHIBITS

Exhibit Number -----	Exhibit -----
2.1	Agreement and Plan of Merger, dated as of May 6, 2000, by and among Epitope, Inc., the Company and STC Technologies, Inc., including the Epitope Stockholders Agreement and the STC Stockholders Agreement attached as Exhibits A and B thereto and the other exhibits attached thereto, is incorporated by reference to Exhibit 2 to the Current Report on Form 8-K of Epitope, Inc. dated May 9, 2000.
3.1	Certificate of Incorporation of OraSure Technologies is incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-4 (No. 333-39210).
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, effective as of September 27, 2001, are incorporated by reference to Exhibit 3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.
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. (now called Mellon Investor Services LLC), 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).
4.5	Second Amendment to Stockholders' Agreement filed as Exhibit 4.3 is incorporated by reference to Exhibit 4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
10.1	Form of Indemnification Agreement (and list of parties to such agreement) is incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-4 (No. 333-39210).*
10.2	Separation Agreement and Release dated as of February 14, 2002 between OraSure Technologies and Robert D. Thompson.*
10.3	Employment Agreement dated as of September 29, 2000 between OraSure Technologies and Robert D. Thompson is incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*
10.4	Employment Agreement dated as of September 29, 2000 between OraSure Technologies and Michael J. Gausling is incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*
10.5	Employment Agreement dated as of November 1, 2001 between OraSure Technologies and Ronald H. Spair is incorporated by reference to Exhibit 10 to the Company's Quarterly Report on Form 10-Q for the

quarter ended September 30, 2001.\*

Exhibit  
Number  
-----

Exhibit  
-----

- 10.6 Employment Agreement dated as of September 29, 2000 between OraSure Technologies and William Hinchey is incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.\*
- 10.7 Employment Agreement dated as of September 29, 2000 between OraSure Technologies and Dr. R. Sam Niedbala is incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.\*
- 10.8 Employment Agreement dated as of September 29, 2000 between OraSure Technologies and William D. Block is incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.\*
- 10.9 Employment Agreement dated as of September 29, 2000 between OraSure Technologies and J. Richard George is incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.\*
- 10.10 Employment Agreement dated as of September 29, 2000 between OraSure Technologies and P. Michael Formica.\*
- 10.11 Description of Non-Employee Director Compensation Policy is incorporated by reference to Exhibit 10 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.\*
- 10.12 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.\*
- 10.13 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.\*
- 10.14 OraSure Technologies, Inc. Employee Incentive and Non-Qualified Stock Option Plan, as amended and restated effective September 29, 2000, is incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.\*
- 10.15 OraSure Technologies, Inc. 2000 Stock Award Plan, as amended effective as of September 29, 2000, is incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.\*
- 10.16 Nonqualified Stock Option Agreement For Discounted Non-Plan Option between Epitope, Inc. and Robert D. Thompson is incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.\*
- 10.17 Production Agreement with Koninklinjke Utermohlen, 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).
- 10.18 Amendment No. 1 to Production Agreement, dated as of December 11, 2001, between the Company and Koninklijke Utermohlen N.V.
- 10.19 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).
- 10.20 First Amendment to Research and License Agreement among SRI International and David Sarnoff Research Center and the Company dated September 1, 1995 is incorporated by reference to Exhibit 10.10 of the Company's Registration Statement on Form S-4 (No. 333-39210).
- 10.21 Third Amendment to Research and License Agreement dated August 30, 2000 among SRI International, Sarnoff Corporation (formerly David Sarnoff Research Center) and the Company is incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the

year ended December 31, 2000.

Exhibit  
Number

Exhibit

-----

-----

- 10.22 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).
- 10.23 Lease dated October 25, 1999 between PS Business Parks, L.P., a California Limited Partnership, and Epitope, Inc., is incorporated by reference to Exhibit 10.6 to the Epitope, Inc. Annual Report on Form 10-K for 1999.
- 10.24 Commercial Lease between Tech III Partners, LLC and OraSure Technologies, dated March 1, 2002.
- 23.1 Consent of Arthur Andersen LLP.
- 23.2 Consent of PricewaterhouseCoopers LLP.
- 24 Powers of Attorney.
- 99 Letter dated March 28, 2002 from OraSure Technologies to the Securities and Exchange Commission concerning certain representations from Arthur Andersen LLP.

- -----

\* Management contract or compensatory plan or arrangement.

-----

SEPARATION AGREEMENT AND RELEASE

THIS SEPARATION AGREEMENT AND RELEASE (the "Agreement") is entered into on this 14th day of February, 2002 (the "Effective Date"), by and between OraSure Technologies, Inc., a Delaware corporation (the "Company"), and Robert D. Thompson ("Executive").

WHEREAS, Executive is currently employed by the Company as its Chief Executive Officer pursuant to an Employment Agreement dated September 29, 2000 ("Employment Agreement") and a Business Protection Agreement dated January 12, 2000 ("Business Protection Agreement");

WHEREAS, the Employment Agreement and the Business Protection Agreement superseded all prior understandings or agreements between the parties with respect to the subjects covered therein; and

WHEREAS, Executive desires to resign his employment effective January 31, 2002.

NOW THEREFORE, in consideration of these premises and the mutual promises contained herein, and intending to be legally bound hereby, the parties agree as follows:

1. Consideration. After execution of this Agreement and the passage

-----

of the seven-day revocation period referenced in Section 7 below, the Company will provide the following consideration to Executive:

A. The Company will continue to pay Executive's salary until September 29, 2003 ("the severance period"), in accordance with Section 6.5.2 of the Employment Agreement, provided, however, that if Executive fails to comply with the Business Protection Agreement during the severance period, the Company's obligation to continue Executive's salary shall end on the date of non-compliance. Subject to Section 3 hereof, the total amount of severance to be paid is \$456,922.94, less all applicable withholding taxes with respect to all compensation-related benefits. The payments will be made in biweekly installments of \$10,576.92 in accordance with the Company's regular payroll practices.

B. Under COBRA, Executive is eligible for continuing coverage under the Company's health benefit plan for a period of eighteen months from January 31, 2002. If Executive takes the necessary steps to elect COBRA continuation coverage, the Company will reimburse Executive for the cost of his COBRA premiums for the period ending January 31, 2003. For the remaining COBRA period, Executive will be responsible for paying the applicable COBRA premiums.

C. The Company will transfer to Executive ownership of the two Company-provided laptop and desktop computers located in Executive's residence and the Executive's Company-provided cellular phone.

2. Termination of Employment; Resignation from Board. Executive is

-----

terminating his employment pursuant to Section 6.2 of the Employment Agreement. However,

subject to the execution of this Agreement and compliance with all of the conditions set forth herein, the parties agree to treat the termination as a termination without cause by the Company under the first sentence of Section 6.4 of the Employment Agreement. Executive acknowledges that, pursuant to Section 2 of this Agreement, he has received written notice, as required by Section 6.4 of the Employment Agreement. Executive affirms that he has resigned from his position as a member of the Company's Board of Directors, effective January 31, 2002.

3. Loan Repayment. The parties agree that the Executive's interest-

-----

free loan in the amount of \$75,000 from the Company is due to be repaid on April 17, 2002. The parties agree that the loan will be repaid by deductions from the continuing salary payments set forth in Section 1 in the following manner. Beginning with the first salary payment due after April 17, the amount of the loan will be offset from the net portion of that salary payment and of the following salary payments until the loan is fully repaid. Executive will not be charged interest on the loan payments. Executive agrees that he shall be responsible for paying all applicable federal, state, or local taxes due with respect to the loan to the extent not withheld by the Company.

4. Directors' and Officers' Liability Insurance. To the extent the

-----

Company maintains liability insurance coverage for its directors and officers, the Company agrees to make reasonable efforts to continue to maintain coverage for the Executive under such policy or policies through January 31, 2005, in accordance with its or their terms, to the maximum extent of the coverage provided under such policy or policies in effect for any other director or officer of the Company.

5. Release. As contemplated by Section 6.5.2. of the Employment

-----

Agreement, in exchange for the consideration referenced in Section 1 and the other consideration set forth in this Agreement, Executive hereby generally releases and discharges the Company, together with each and every of its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates, divisions and related entities, directors, officers, Executives and agents, whether present or former (collectively the "Releasees"), from any and all suits, causes of action, complaints, obligations, demands, or claims of any kind, whether in law or in equity, direct or indirect, known or unknown, suspected or unsuspected (hereinafter "claims"), which the Executive ever had or now has arising out of or relating to any matter, thing or event occurring up to and including the date of this Agreement. Except as otherwise expressly provided in this Agreement, Executive's release specifically includes, but is not limited to:

A. any and all claims for wages and benefits including, without limitation, salary, stock, options, commissions, royalties, license fees, health and welfare benefits, severance pay, vacation pay, incentives, and bonuses;

B. any and all claims for wrongful discharge, breach of contract (whether express or implied), or for breach of the implied covenant of good faith and fair dealing;

C. any and all claims for alleged employment discrimination on the basis of age, race, color, religion, sex, national origin, veteran status, disability and/or handicap and any and all other claims in violation of any federal, state or local statute, ordinance, judicial

precedent or executive order, including but not limited to claims under the following statutes: Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. (S)2000e et seq., the Civil Rights Act of 1866, 42 U.S.C. (S)1981, the

-----  
Age Discrimination in Employment Act, 29 U.S.C. (S)621 et seq., the Older

-----  
Workers Benefit Protection Act, 29 U.S.C. (S)626(f), the Americans with Disabilities Act, 42 U.S.C. (S)12101 et seq., the Family and Medical Leave Act

-----  
of 1993, the Fair Labor Standards Act, the Employee Retirement Income Security Act of 1974, or any comparable statute of any other state, country, or locality except as required by law, but excluding claims for vested benefits under the Company's pension plans;

D. any and all claims under any federal, state or local statute or law;

E. any and all claims in tort (including but not limited to any claims for misrepresentation, defamation, interference with contract or prospective economic advantage, intentional or negligent infliction of emotional distress, duress, loss of consortium, invasion of privacy and negligence);

F. any and all claims for attorneys' fees and costs;

G. any and all other claims for damages of any kind; and

H. any and all claims relating to or arising out of the Employment Agreement.

Notwithstanding the foregoing, nothing contained in this Section 5 shall apply to, or shall release the Company from, (i) any obligation of the Company under this Agreement; (ii) any accrued or vested benefit of the Executive pursuant to any employee benefit plan of the Company, (iii) any obligation of the Company under the Non-Qualified Stock Option Agreement for Discounted Non-Plan Options dated January 5, 2000 and the Employee Incentive and Non-Qualified Stock Option Agreement dated December 13, 2000, or (iv) the Executive's rights to indemnification and contribution related to his service as an officer or director of the Company under the Indemnification Agreement between the Company and the Executive, dated September 29, 2000, or pursuant to the Company's Certificate of Incorporation or Bylaws.

In procuring the forgoing release from the Executive, the Company acknowledges and affirms to the Executive that the executive officers of the Company have no present actual knowledge of any claim, demand or cause of action against the Executive arising out of or related to his past or present employment with the Company. The Company further agrees that in the event the Company shall hereinafter assert a claim against the Executive arising out of or related to his past or present employment, the foregoing release shall not prevent the Executive from asserting any defense to such claim in any proceeding relating thereto.

6. Acknowledgment. Executive understands that his release extends

-----  
to all of the aforementioned claims and potential claims which arose on or before the date of this Release, whether now known or unknown, suspected or unsuspected, and that this constitutes an essential term of this Release. Executive further understands and acknowledges the significance and consequence of this Release and of each specific release and waiver, and expressly consents that this Release shall be given full force and effect according to each and all of its express terms and provisions, including those relating to unknown and unsuspected claims, demands, obligations,



and causes of action, if any, as well as those relating to any other claims, demands, obligations or causes of action herein above-specified.

7. Advice of Counsel; Revocation Period. Executive is hereby

-----  
advised to seek the advice of counsel. Executive acknowledges that he has, in fact, sought the advice of counsel, and is acting of his own free will, that the Executive has been afforded a reasonable time to read and review the terms of the Release, and that the Executive is voluntarily entering into this Release with full knowledge of its provisions and effects. Executive intends that this Release shall not be subject to any claim for duress. Executive further acknowledges that the Executive has been given at least twenty-one (21) days within which to consider this Release and that if the Executive decides to execute this Release before the twenty-one day period has expired, the Executive does so voluntarily and waives the opportunity to use the full review period. Executive also acknowledges that he has seven (7) days following his execution of this Release to revoke acceptance of the Release of age discrimination claims, with the Release of age discrimination claims not becoming effective until the revocation period has expired. If Executive chooses to revoke his acceptance of this Release, he should provide written notice to:

Jeffrey P. Libson, Esquire  
Pepper Hamilton LLP  
899 Cassatt Road  
400 Berwyn Park  
Berwyn, PA 19312

8. No Admissions. Neither the execution of this Agreement nor the

-----  
terms hereof constitute an admission by the Company of liability to Executive.

9. No Disparagement. Executive agrees to refrain from making

-----  
disparaging comments about the Company, and further agrees not to disrupt the Company's business activities in any manner whatsoever, and not to take any action that might affect adversely the professional or business reputation of the Company. The Company agrees not to disparage the Executive.

10. Confidentiality. Except to the extent otherwise required by law,

-----  
rule or regulation, the parties hereto will not disclose, in whole or in part, the existence, negotiation, or any of the terms of this Agreement. However, the parties may disclose the terms of this Agreement to their legal and financial advisors (and Executive may disclose the terms of this Agreement to his spouse), provided that the parties take all reasonable measures to assure that those individuals do not disclose the terms of this Agreement to a third party except as otherwise required by law.

11. Business Protection Agreement. Executive acknowledges that he

-----  
continues to be bound by the provisions of the Business Protection Agreement and that the provisions of that agreement continue in full force and effect in accordance with its terms.

12. Return of Property. On or before January 31, 2002, Executive

-----  
shall return to the Company in good working order all Company property within his possession, custody and control, except for the property transferred to the Executive pursuant to Section 1.C. Such

property includes, but is not limited to keys, software, calculators, equipment, credit cards, forms, files, documents, manuals, correspondence, business cards, personnel data, lists of or other information regarding customers, contacts and/or employees, contracts, contract information, agreements, leases, plans, financial data or documents, brochures, catalogues, training materials, computer tapes and diskettes or other portable media.

13. Miscellaneous.

A. Successors and Assigns. This Agreement shall inure to the

-----  
benefit of and be binding upon the Company and Executive and their respective successors, executors, administrators, heirs and/or permitted assigns; provided, however, that neither Executive nor the Company may make any assignments of this Agreement or any interest herein, by operation of law or otherwise, without the prior written consent of the other party, except that, without such consent, the Company may assign this Agreement to any successor to all or substantially all of its assets and business by means of liquidation, dissolution, merger, consolidation, transfer of assets, or otherwise. The Company shall cause any successor to all or substantially all of its assets to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no succession had taken place.

B. Notice. Any notice or communication required or permitted

-----  
under this Agreement shall be made in writing and (a) sent by overnight courier, (b) mailed by certified or registered mail, return receipt requested or (c) sent by telecopier, addressed as follows:

If to Executive:

Robert Thompson  
2130 Augusta Drive  
Center Valley, PA 18034  
Fax: (610) 317-9495

If to Company:

OraSure Technologies, Inc.  
150 Webster Street  
Bethlehem, PA 18015  
Fax: (610) 882-1830

with a copy to:

Pepper Hamilton LLP  
899 Cassatt Road  
400 Berwyn Park  
Berwyn, PA 19312  
Attn: Jeffrey Libson, Esquire  
Fax: 610-640-7835

or to such other address as either party may from time to time duly specify by notice given to the other party in the manner specified above.

C. Entire Agreement; Amendments. This Agreement contains the entire

-----  
agreement and understanding of the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating to the employment of Executive by the Company, except the agreements referred to in the second to last paragraph of Section 5 above. This Agreement may not be changed or modified, except by an Agreement in writing signed by each of the parties hereto.

D. Waiver. Any waiver by either party of any breach of any term or

-----  
condition in this Agreement shall not operate as a waiver of any other breach of such term or condition or of any other term or condition, nor shall any failure to enforce any provision hereof operate as a waiver of such provision or of any other provision hereof or constitute or be deemed a waiver or release of any other rights, in law or in equity.

E. Governing Law. This Agreement shall be governed by, and enforced

-----  
in accordance with, the laws of the Commonwealth of Pennsylvania without regard to the application of the principles of conflicts of laws.

F. Severability. Whenever possible, each provision of this Agreement

-----  
will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or the effectiveness or validity of any provision in any other jurisdiction, and this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had never been contained herein.

G. Section Headings. The section headings in this Agreement are for

-----  
convenience only; they form no part of this Agreement and shall not affect its interpretation.

H. Consent to Suit. Any legal proceeding arising out of or relating

-----  
to this Agreement shall be instituted in the United States District Court for the Eastern District of Pennsylvania, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in the county in Pennsylvania in which the Company maintains its principal place of business, and Executive and the Company hereby consent to the personal and exclusive jurisdiction of such court and hereby waive any objection that Executive or the Company may have to personal jurisdiction, venue, and any claim or defense of inconvenient forum.

I. Counterparts and Facsimiles. This Agreement may be executed,

-----  
including execution by facsimile signature, in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized officer, and Executive has executed this Agreement, in each case on the date first above written.

OraSure Technologies, Inc.

By: /s/ Michael J. Gausling

-----

Name: Michael J. Gausling

-----

Title: President and Chief Executive Officer

-----

/s/ Robert D. Thompson

-----

Robert D. Thompson

EMPLOYMENT AGREEMENT

This Employment Agreement is entered into as of September 29, 2000, between Phillip Michael Formica ("Employee") and OraSure Technologies, Inc., a Delaware corporation (the "Company").

1. SERVICES.

1.1 Employment. The Company agrees to employ Employee as Vice President of Operations of the Company, and Employee hereby accepts such employment in accordance with the terms and conditions of this Agreement.

1.2 Duties. Employee shall have the position named in Section 1.1 with such powers and duties appropriate to that office (a) as may be provided by the bylaws of the Company, (b) as otherwise set forth in Exhibit A attached to this Agreement, and (c) as determined by the board of directors from time to time. Subject to the provisions of Section 6.4 hereof, Employee's position and duties may be changed from time to time during the term of this Agreement. Employee's place of work shall be the Company's headquarters, at its present location or as it may be relocated.

1.3 Outside Activities. Employee shall obtain the consent of the board of directors before he engages, either directly or indirectly, in any other professional or business activities that may require an appreciable portion of Employee's time or effort to the detriment of the Company's business.

1.4 Direction of Services. Employee shall at all times discharge his duties in consultation with and under the supervision and direction of the Chief Operating Officer of the Company or such other person as the Chief Executive Officer or board of directors may designate.

2. Term. The initial term of this Agreement shall begin as of the date first written above and end on the second anniversary of that date, unless sooner terminated in accordance with Section 6 below. Thereafter, this Agreement shall automatically renew from year to year for successive one-year terms (a) unless either party gives the other party written notice of that party's intent not to renew this Agreement at least 180 days before the expiration of its current term or (b) the Agreement is terminated in accordance with Section 6 below.

3. COMPENSATION AND EXPENSES.

3.1 Salary. As compensation for services under this Agreement, the Company shall pay to Employee a regular salary of \$12,500 per month. Subject to the provisions of Section 6.4 hereof, such salary may be adjusted from time to time in the discretion of the board of directors. Payment shall be made on a bi-weekly basis, less all amounts required by law or authorized by Employee to be withheld or deducted.

3.2 Bonus. The Company shall establish an executive bonus plan, on such terms as may be approved by the board of directors or its executive compensation committee. In addition to the salary described in Section 3.1 above, Employee shall be entitled to participate in the executive bonus plan.

3.3 Long-Term Incentive. To the extent otherwise eligible, Employee shall be entitled to participate in accordance with the terms of the plan in any long-term incentive plan that may from time to time be adopted by the board of directors or its executive compensation committee, in its sole discretion.

3.4 Additional Employee Benefits. To the extent otherwise eligible, Employee shall be entitled to receive or participate in any additional benefits, including without limitation medical and dental insurance programs, profit sharing or pension plans, and medical reimbursement plans, which may from time to time be made available by the Company to corporate officers. The Company may change or discontinue such benefits at any time in its sole discretion.

3.5 Expenses. The Company shall reimburse Employee for all reasonable and necessary expenses incurred in carrying out his duties under this Agreement, subject to compliance with the Company's reasonable policies relating to expense reimbursement.

3.6 Fees. All compensation earned by Employee, other than pursuant to this Agreement, as a result of services performed on behalf of the Company or as a result of or arising out of any work done by Employee in any way related to the scientific or business activities of the Company shall belong to the Company. Employee shall pay or deliver such compensation to the Company promptly upon receipt. For the purposes of this provision, "compensation" shall include, but is not limited to, all professional and nonprofessional fees, lecture fees, expert testimony fees, publishing fees, royalties, and any related income, earnings, or other things of value; and "scientific or business activities of the Company" shall include, but not be limited to, any project or projects in which the Company is involved and any subject matter that is directly or indirectly researched, tested, developed, promoted, or marketed by the Company.

4. Stock Options. Employee shall be entitled to participate in the Company stock option plan. The number of stock options that are granted to Employee under the plan shall be determined by the board of directors or its executive compensation committee.

5. Business Protection Agreement. In consideration of the stock option grant described in Section 4, and other good and valuable consideration, Employee and the Company are concurrently entering a Business Protection Agreement. Employee's compliance with the terms of the Business Protection Agreement, including without limitation the noncompetition provisions of the Business Protection Agreement, is a material requirement of this Agreement. Employee acknowledges that employment on the terms stated in this Agreement constitutes a bona fide advancement.

## 6. TERMINATION.

6.1 Termination Upon Death. This Agreement shall terminate immediately upon Employee's death.

6.2 Termination by Employee. Employee may terminate his employment under this Agreement by 60 days' written notice to the Company.

6.3 Termination by the Company for Cause. Employee's employment under this Agreement may be terminated by the Company at any time for cause. Only the following actions, failures, or events by or affecting Employee shall constitute "cause" for termination of Employee by the Company: (i) willful and continued failure by Employee to substantially perform his duties provided herein after a written demand for substantial performance is delivered to Employee by the chairman of the board of the Company, which demand identifies with reasonable specificity the manner in which Employee has not substantially performed his duties, and Employee's failure to comply with such demand within a reasonable time; (ii) the engaging by Employee in gross misconduct or gross negligence materially injurious to the Company; (iii) the commission of any act in direct competition with or materially detrimental to the best interests of the Company; or (iv) Employee's conviction of having committed a felony. Notwithstanding the foregoing, Employee shall not be deemed to have been terminated by the Company for cause unless and until there shall have been delivered to him a copy of a resolution duly adopted by the affirmative vote of not less than a majority of the entire membership of the board of directors of the Company finding that, in the good faith opinion of the board of directors, the Company has cause for the termination of the employment of Employee as set forth in any of clauses (i) through (iv) above and specifying the particulars thereof in reasonable detail. The findings of the board of directors shall not be binding on the arbitrators or other finders of fact in connection with any litigation or dispute arising out of this Agreement.

6.4 Termination by the Company Without Cause. The Company may terminate Employee's employment under this Agreement without cause by written notice to Employee. Employee may (but shall not be required to) elect to treat any of the following events as a termination without cause, provided Employee acts within 60 days of the event:

6.4.1 A material breach of this Agreement by the Company and a failure by the Company to cure the breach within 30 days after Employee has given written notice of the breach to the board of directors.

6.4.2 A reduction in Employee's salary below the amount stated in Section 3.1 (except as part of and in proportion to a reduction in all executive officers' salaries) or a change in Employee's title or a substantial diminution in Employee's duties below those stated in this Agreement.

6.4.3 A "Change of Control" of the Company. For purposes of this Agreement, a "Change of Control" shall mean a change of control of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A as in effect on the date hereof pursuant to the Securities Exchange Act of 1934 (the "Exchange Act");

provided that, without limitation, such a change of control shall be deemed to have occurred at such time as (i) any Acquiring Person hereafter becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 30 percent or more of the combined voting power of Voting Securities; (ii) during any period of 12 consecutive calendar months, individuals who at the beginning of such period constitute the board of directors cease for any reason to constitute at least a majority thereof unless the election, or the nomination for election, by the Company's shareholders of each new director was approved by a vote of at least a majority of the directors then still in office who were directors at the beginning of the period; (iii) there shall be consummated (a) any consolidation or merger of the Company in which the Company is not the continuing or surviving corporation or pursuant to which Voting Securities would be converted into cash, securities, or other property, other than a merger of the Company in which the holders of Voting Securities immediately prior to the merger have the same, or substantially the same, proportionate ownership of common stock of the surviving corporation immediately after the merger, or (b) any sale, lease, exchange, or other transfer (in one transaction or a series of related transactions) of all, or substantially all, of the assets of the Company; or (iv) approval by the shareholders of the Company of any plan or proposal for the liquidation or dissolution of the Company. For purposes of this Agreement, "Acquiring Person" means any person or related persons which constitute a "group" for purposes of Section 13(d) and Rule 13d-5 under the Exchange Act, as such Section and Rule are in effect as of the date of this Agreement; provided, however, that the term Acquiring Person shall not include: (i) the Company or any of its subsidiaries; (ii) any employee benefit plan of the Company or any of its subsidiaries; (iii) any entity holding voting capital stock of the Company for or pursuant to the terms of any such employee benefit plan; or (iv) any person or group solely because such person or group has voting power with respect to capital stock of the Company arising from a revocable proxy or consent given in response to a public proxy or consent solicitation made pursuant to the Exchange Act. For purposes of this Agreement, "Voting Securities" means the Company's issued and outstanding securities ordinarily having the right to vote at elections for the Company's board of directors.

#### 6.5 Compensation Upon Termination.

6.5.1 Termination Under Sections 6.1, 6.2, or 6.3. In the event of a termination of Employee's employment under Sections 6.1, 6.2, or 6.3, Employee's regular compensation pursuant to Section 3.1 shall be prorated and payable until the date of termination and Employee shall be paid any bonus that has been approved but not yet paid.

6.5.2 Termination Under Section 6.4. In the event of a termination of Employee's employment by the Company without cause as provided in Section 6.4, Employee shall continue to be paid the salary provided in Section 3.1 for the greater of (a) 12 months, (b) the remaining term of this Agreement, or (c) 24 months if Employee elects to treat an event described in Section 6.4.3 as a termination without cause, from the date of notice of such termination of employment or the date of such event, in the manner and at the times at which regular compensation was paid to Employee during the term of his employment under this Agreement, except that if Employee elects to treat an event described in Sections 6.4.1, 6.4.2, or 6.4.3 as a termination without cause but continues to work for the Company or any of its subsidiaries, then any amounts Employee receives as compensation following the event shall be credited against the amounts payable to Employee under this section. In no other respect



shall the amount of any payment provided for in this section be reduced by any compensation or benefits earned by employee as a result of employment after his termination. As a condition to receipt of the compensation described in the first sentence of this Section 6.5.2, Employee shall sign and deliver a release agreement, in form and substance satisfactory to the Company and Employee, releasing all claims related to Employee's employment. The Company's obligation to pay the amounts stated in this section shall terminate if Employee fails to comply with the Business Protection Agreement within the applicable time period stated in the first sentence of this section.

7. Remedies. The respective rights and duties of the Company and Employee under this Agreement are in addition to, and not in lieu of, those rights and duties afforded to and imposed upon them by law or at equity.

8. Severability of Provisions. The provisions of this Agreement are severable, and if any provision hereof is held invalid or unenforceable, it shall be enforced to the maximum extent permissible, and the remaining provisions of the Agreement shall continue in full force and effect.

9. Nonwaiver. Failure by either party at any time to require performance of any provision of this Agreement shall not limit the right of the party failing to require performance to enforce the provision. No provision of this Agreement may be waived by either party except by a writing signed by that party. A waiver of any breach of a provision of this Agreement shall be construed narrowly and shall not be deemed to be a waiver of any succeeding breach of that provision or a waiver of that provision itself or of any other provision.

#### 10. Arbitration.

10.1 Claims Covered. All claims or controversies, except for those excluded by Section 10.2 ("claims"), whether or not arising out of Employee's employment (or its termination), that the Company may have against the Employee or that Employee may have against the Company or against its officers, directors, employees or agents, in their capacity as such or otherwise, shall be resolved as provided in this Section 10. Claims covered by this Section 10 include, but are not limited to, claims for wages or other compensation due; claims for breach of any contract or covenant (express or implied); tort claims; claims for discrimination (including, but not limited to, race, sex, sexual orientation, religion, national origin, age, marital status, or disability); claims for benefits (except where an employee benefit or pension plan specifies that its claims procedure shall culminate in an arbitration procedure different from this one), and claims for violation of any federal, state, or other governmental law, statute, regulation, or ordinance, except as provided in Section 10.2.

10.2 Non-Covered Claims. Claims arising out of the Business Protection Agreement and workers' compensation or unemployment compensation benefits are not covered by this Section 10. Non-covered claims include but are not limited to claims by the Company for injunctive and/or other equitable relief for unfair competition and/or the use and/or unauthorized disclosure of trade secrets or confidential information, as to which Employee understands and agrees that the Company may seek and obtain relief from a court of competent jurisdiction.

10.3 Required Notice of All Claims and Statute of Limitations.

Company and Employee agree that the aggrieved party must give written notice of any claim to the other party within one year of the date the aggrieved party first has knowledge of the event giving rise to the claim; otherwise the claim shall be void and deemed waived even if there is a federal or state statute of limitations which would have given more time to pursue the claim. The written notice shall identify and describe the nature of all claims asserted and the facts upon which such claims are based.

10.4 Arbitration Procedures. Any arbitration shall be conducted in accordance with the then-current Model Employment Arbitration Procedures of the American Arbitration Association ("AAA"), modified to substitute for AAA actions, the United States Arbitration and Mediation Service ("USA&MS"), before an arbitrator who is licensed to practice law in the state of Pennsylvania (the "Arbitrator"). The arbitration shall take place in or near Bethlehem, Pennsylvania.

10.4.1 Selection of Arbitrator. The USA&MS shall give each party a list of 11 arbitrators drawn from its panel of labor-management dispute arbitrators. Each party may strike all names on the list it deems unacceptable. If only one common name remains on the lists of all parties, that individual shall be designated as the Arbitrator. If more than one common name remains on the lists of all parties, the parties shall strike names alternately until only one remains. The party who did not initiate the claim shall strike first. If no common name remains on the lists of all parties, the USA&MS shall furnish an additional list or lists until an Arbitrator is selected.

10.4.2 Applicable Law. The Arbitrator shall apply the substantive law (and the law of remedies, if applicable) specified in this Agreement or federal law, or both, as applicable to the claim(s) asserted. The Arbitrator, and not any federal, state, or local court or agency, shall have exclusive authority to resolve any dispute relating to the interpretation, applicability, enforceability or formation of this Agreement, including but not limited to any claim that all or any part of this Agreement is void or voidable. The arbitration shall be final and binding upon the parties, except as provided in this Agreement.

10.4.3 Authority. The Arbitrator shall have jurisdiction to hear and rule on pre-hearing disputes and is authorized to hold pre-hearing conferences by telephone or in person as the Arbitrator deems necessary. The Arbitrator shall have the authority to entertain a motion to dismiss and/or a motion for summary judgment by any party and shall apply the standards governing such motions under the Federal Rules of Civil Procedure. The Arbitrator shall render an award and opinion in the form typically rendered in labor arbitrations.

10.4.4 Representation. Any party may be represented by an attorney or other representative selected by the party.

10.4.5 Discovery. Each party shall have the right to take the deposition of one individual and any expert witness designated by another party. Each party also shall have the right to make requests for production of documents to any party. The subpoena right specified below shall be applicable to discovery pursuant to this paragraph. Additional discovery may be had only where the Arbitrator selected pursuant to this Agreement so orders,

upon a showing of substantial need. At least 30 days before the arbitration, the parties must exchange lists of witnesses, including any experts, and copies of all exhibits intended to be used at the arbitration. Each party shall have the right to subpoena witnesses and documents for the arbitration.

10.4.6 Reporter. Either party, at its expense, may arrange for and pay the cost of a court reporter to provide a stenographic record of proceedings.

10.4.7 Post-Hearing Briefs. Either party, upon request at the close of hearing, shall be given leave to file a post-hearing brief. The time for filing such a brief shall be set by the Arbitrator.

10.5 Enforcement. Either party may bring an action in any court of competent jurisdiction to compel arbitration under this Agreement and to enforce an arbitration award. Except as otherwise provided in this Agreement, both the Company and Employee agree that neither shall initiate or prosecute any lawsuit (other than for a non-covered claim) in any way related to any claim covered by this Agreement. A party opposing enforcement of an award may not do so in an enforcement proceeding, but must bring a separate action in any court of competent jurisdiction to set aside the award, where the standard of review will be the same as that applied by an appellate court reviewing a decision of a trial court sitting without a jury.

10.6 Arbitration Fees and Costs. Company and Employee shall equally share the fees and costs of the Arbitrator. Each party will deposit funds or post other appropriate security for its share of the Arbitrator's fee, in an amount and manner determined by the Arbitrator, 10 days before the first day of hearing. Each party shall pay for its own costs and attorneys' fees, if any, provided that the Arbitrator, in its sole discretion, may award reasonable fees to the prevailing party in a proceeding.

11. General Terms and Conditions. This Agreement constitutes the entire understanding of the parties relating to the employment of Employee by the Company, and supersedes and replaces all written and oral agreements heretofore made or existing by and between the parties relating thereto. This Agreement shall be construed in accordance with the laws of the state of Pennsylvania, without regard to any contrary conflicts of laws rules thereof. This Agreement shall inure to the benefit of any successors or assigns of the Company. All captions used herein are intended solely for convenience of reference and shall in no way limit any of the provisions of this Agreement. Employee acknowledges that he signed this Agreement upon his initial employment with the Company.

The parties have executed this Employment Agreement as of the date stated above.

ORASURE TECHNOLOGIES, INC.

/s/ Phillip Michael Formica  
-----  
Phillip Michael Formica

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

EXHIBIT A TO EMPLOYMENT AGREEMENT

SPECIFIC DUTIES OF EMPLOYEE AS PRESIDENT AND CHIEF OPERATING OFFICER

Employee as the President and Chief Operating Officer of the Company shall be responsible for \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_.

AMENDMENT NO. 1 TO PRODUCTION AGREEMENT

This Amendment No. 1 to Production Agreement (this "Amendment") is made and entered into this 11th day of December, 2001 by and between OraSure Technologies, Inc., a Delaware corporation and successor to STC Technologies, Inc., with its registered offices at Bethlehem, Pennsylvania 18015 U.S.A. (the "Purchaser"), and Koninklijke Utermohlen N.V., a limited liability company organized under the laws of the Netherlands, with its registered offices at Wolvega, the Netherlands (the "Seller"). Seller and Purchaser are each referred to herein as a "Party" and collectively as the "Parties."

BACKGROUND

Seller and Purchaser are parties to a Production Agreement, dated June 8, 1998 (the "Original Agreement"), pursuant to which Seller agreed to produce certain products related to the Histofreezer Business for the Purchaser. The Parties desire to amend the Original Agreement to, among other things, provide for the production of new products by Seller for Purchaser and to extend the term of the Original Agreement, as more fully set forth in this Amendment.

AGREEMENT

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

1. Definitions.

- 1.1 Capitalized terms not otherwise defined in this Amendment shall have the meanings set forth in the Original Agreement.
- 1.2 The definition of the term "Specifications" set forth in Article 1 of the Original Agreement is hereby amended and restated as follows:

"The term "Specifications" shall mean the technical file set forth in Exhibit 3.1 to this Agreement as the same shall be amended from time to time pursuant to Section 3.1 of this Agreement, together with current ISO 9002/46002 standards, CE standards, all relevant laws, all relevant regulations, all relevant directives, best manufacturing practices and procedures, principles of good workmanship, acknowledged standards and specific (but reasonable) instructions of the Purchaser in the relevant order for any Product(s)."

2. Products. Exhibit 1 to the Original Agreement is hereby amended

and restated in its entirety as set forth in Exhibit 1 to this Amendment.

3. Specifications and Quality Control.  
-----

3.1 Exhibit 3.1 to the Original Agreement is hereby amended and restated in its entirety as set forth in Exhibit 3.1 to this Amendment.

3.2 Section 3.4 of the Original Agreement is hereby amended and restated in its entirety as follows:

"The Seller shall produce the Products in accordance with the then current ISO 9002/46002 and CE standards. Copies of all relevant documents related to the production of the Products, including, but not limited to, those documents required to maintain compliance with the Specifications, will be provided by the Seller to the Purchaser upon request. The parties acknowledge that the Purchaser has obtained CE registration for the Products in its name. The Seller shall maintain all CE mark files in accordance with good practice for all Products purchased prior to the Purchaser obtaining CE registration in its name. The Purchaser shall, subject to the Seller's obligation to provide documents under this Article 3.4, be responsible for maintaining the CE mark files for all Products purchased on or after the Purchaser's receipt of the CE registration in its name. The Purchaser shall supply the Seller with copies of all additions or changes to the CE file relating to the production of the Products. The Seller shall not modify any method, process or document relating to the production of the Products, including, without limitation, the quality control aspects of production, without first obtaining the Purchaser's prior written consent, which may be granted or withheld in the Purchaser's sole discretion."

4. Purchase Price.  
-----

4.1 Exhibit 4.1 to the Original Agreement is hereby amended and restated in its entirety as set forth in Exhibit 4.1 to this Amendment. The prices set forth in Exhibit 4.1 to this Amendment shall apply to all Products purchased on or after the date of this Amendment.

4.2 The reference to "30%" set forth in Article 4.2 of the Original Agreement is hereby changed to "10%."

4.3 All payments required by either Party under the Original Agreement, as amended by this Amendment, shall be made in Euros.

5. Delivery. The references to "Incoterms 1990 of the International  
-----

Chamber of Commerce" in Sections 5.2 and 5.3 of the Original Agreement are hereby changed to "Incoterms 2000 of the International Chamber of Commerce."

6. Penalty Clause.  
-----

6.1 Article 10.1(i) of the Original Agreement is hereby amended and restated in its entirety as follows:

"Articles 7, 9 and 16.7 of this Agreement and Article 11 of the Asset Purchase Agreement shall be considered by the Parties hereto as an event of gross default ("Gross Default"); and"

6.2 The references to "NGL 250,000", "NGL 10,000" and "NGL 500,000" set forth in Article 10.2 are hereby changed to "EUR 113,446," "EUR 4,538," and "EUR 226,891," respectively.

7. Replacement and Recall of Products. The reference to "5 Working  
-----

Days" in Article 11.1 of the Original Agreement is hereby changed to "10 Working Days."

8. Duration and Termination.  
-----

8.1 The first sentence of Article 13.1 of the Original Agreement is hereby amended and restated as follows:

"This Agreement shall be in force commencing on June 1, 1998 and terminating on the later of (i) December 31, 2006 and (ii) the date on which the Purchaser shall have ordered and the Seller shall have supplied Products having an aggregate of 30,000,000 treatment applications."

The date specified in clause (ii), above, shall be determined only by reference to the Products ordered and purchased on or after December 11, 2001. The number of treatment applications shall be determined by reference to the number of treatment applicators sold with aerosol canisters to the Purchaser.

8.2 Article 13.3(a) is hereby amended and restated in its entirety as follows:

"if there are changes in the direct or indirect control or ownership (the shares in the capital or otherwise) of the Seller and the Purchaser does not provide its written consent for the same prior to such change, which consent may be granted or withheld in the Purchaser's sole discretion; or"

9. Notices. The notice information for the Purchaser set forth in

-----

Article 14.1 of the Original Agreement is hereby amended and restated as follows:

"If to the Purchaser:

OraSure Technologies, Inc.  
150 Webster Street  
Bethlehem, Pennsylvania 18015  
U.S.A.

To the attention of: President"

10. Assignment. Article 16.7 of the Original Agreement is hereby

-----

amended and restated in its entirety as follows:

"None of the rights or obligations under this Agreement may be assigned or transferred by the Seller without the prior written consent of the Purchaser, which consent may be granted or withheld in the Purchaser's sole discretion. The Seller and the Purchaser can, without obtaining the prior consent of the other, fully assign and transfer any ("cessie") or all ("contractsoverneming") of its respective rights and obligations under this Agreement to an affiliated company. An affiliated company of a party shall mean a company or entity which controls, is controlled by or is under common control with such party. Notwithstanding the foregoing, a change in ownership or control of the Seller shall be deemed to be a transfer of the Agreement by the Seller requiring the Purchaser's prior written consent, which consent may be granted or withheld in the Purchaser's sole discretion. The Purchaser may, without the consent of the Seller, freely assign any ("cessie") or all ("contractsoverneming") of its rights and obligations under this Agreement to any third party. To the extent either the Seller or the Purchaser assigns or transfers its rights and obligations under this Agreement to any party in accordance with this Article 16.7, the assignee of the Seller shall be deemed to be the "Seller", and the assignee of the Purchaser shall be deemed to be the "Purchaser", for purposes of this Agreement."

11. Party References. All references to the Purchaser in the Original

-----

Agreement are hereby deemed to mean OraSure Technologies, Inc., as successor by merger to STC Technologies, Inc.

12. No Other Changes. Except as set forth in this Amendment, the

-----

Original Agreement remains in full force and effect without any other changes. The Original Agreement, together with this Amendment, constitute the entire agreement between the Seller and the Purchaser with respect to the subject matter hereof and thereof and supersede and cancel all previous negotiations, agreements, and commitments, whether



oral or in writing, with respect to such subject matter. All references to the Agreement shall be deemed to mean the Agreement as amended by this Amendment.

13. Counterparts. This Amendment may be executed in two or more

-----  
counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. A facsimile transmission of a signed original shall be deemed to be the same as delivery of a signed original.

14. Governing Law. This Amendment and any controversy, claim or

-----  
dispute arising under this Amendment shall be governed by, and construed in accordance with, the laws of the Netherlands.

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

ORASURE TECHNOLOGIES, INC.

KONINKLIJKE UTERMÖHLEN N.V.

By: /s/ Michael J. Gausling

By: /s/ Don T. van der Vat

-----  
Name: Michael J. Gausling  
Title: President and  
Chief Executive Officer

-----  
Name: Don T. van der Vat  
Title: Managing Director

EXHIBIT 1

THE PRODUCTS

-----

Art.nr.	Description
- - - - -	-----
123070	Histofreezer Dutch/French 5mm (40 applicators)
123082	Histofreezer English 5mm (40 applicators)
123086	Histofreezer English 2mm (50 applicators)
123080	Histofreezer DPC Norway 5mm (40 applicators)
123079	Histofreezer Uhlmann 5mm (40 applicators)
122010	Histofreezer Uhlmann 2mm (50 applicators)
F78040	Histofreezer Askina French 5mm (40 applicators)
F78050	Histofreezer Askina French 2mm (50 applicators)
321059	Histofreezer Askina Spanish 5mm (40 applicators)
325897	Histofreezer Askina Spanish 2mm (50 applicators)
09381007	Histofreezer Askina German 5mm (40 applicators)
09381015	Histofreezer Askina German 2mm (50 applicators)
002556	Histofreezer Paladin Mix (50 applicators)
H-60	Histofreezer OraSure USA Mix (60 applicators)
H-135	Histofreezer United Medical Mix (50 applicators)
H-140	Histofreezer Mexico Mix (50 applicators)
H-150	Histofreezer English Mix (50 applicators)
H-155	Histofreezer Uhlmann Mix (50 applicators)
H-505	Histofreezer OraSure USA 5mm (50 applicators)
H-105	Histofreezer Sample Mix (5 applicators)
H-110	Histofreezer (Glaxo) Mix (10 applicators)
H-109	Supplementary Applicators 20 x 2mm
H-119	Supplementary Applicators 20 x 5mm

EXHIBIT 3.1

SPECIFICATIONS

-----

-7-

EXHIBIT 4.1

COMMERCIAL LEASE  
BETWEEN  
TECH III PARTNERS, LLC,  
AS LANDLORD,  
AND  
ORASURE TECHNOLOGIES, INC.,  
AS TENANT,  
DATED  
March 1, 2002  
PREMISES:  
48,000 SQUARE FEET  
BETHLEHEM TECHNOLOGY CENTER III  
BETHLEHEM, PENNSYLVANIA

COMMERCIAL LEASE

-----

This Commercial Lease (hereinafter referred to as this "Lease") is made as of the 1st day of March, 2002, by and between TECH III PARTNERS, LLC, a Pennsylvania limited liability company, having an office at 1512 Colesville Road, Bethlehem, Pennsylvania 18015 ("Landlord") and ORASURE TECHNOLOGIES, INC., a Delaware corporation, having its principal offices at 150 Webster Street, Bethlehem, Pennsylvania 18015 ("Tenant").

NOW, THEREFORE, in consideration of the premises and mutual covenants herein, and intending to be legally bound, the parties hereto covenant and agree as follows:

Section 1. PREMISES; PROJECT BUDGET

(a) Landlord does hereby lease, demise and let unto Tenant a building with an aggregate square footage of approximately 48,000 square feet which includes certain Common Areas (as defined below) in such building ("Building"), as shown on the Floor Plans of the Building and the Leased Premises annexed as Exhibit A hereto, which Building is situated on

-----  
approximately 3.7 acres of land situate in the City of Bethlehem, Northampton County, Pennsylvania ("Land"), together with the right to use the Common Areas (defined below) (the Building, Land and Common Areas are referred to, collectively, as the "Leased Premises"). As used herein, "square feet" or "square footage" means the usable area measured from the middle of the demising walls outlining the Building set forth in Exhibit A. It is agreed that the

-----  
design plans and drawings of the proposed Building are incorporated herein by reference and that no changes will be made to said design plans and drawings without the consent of Tenant.

(b) Attached hereto as Exhibit B is a Project Budget which

-----  
sets forth Landlord's best estimate, as of the date of this Lease, of the total costs expected to be incurred in acquiring the Land and constructing the Building and Common Areas (exclusive of any Tenant Finish Work), the Tenant finish Work Allocation Amount (as defined below), and the amounts expected to be contributed by Landlord as equity contribution ("Landlord Equity Contribution") and the amounts expected to be financed by Landlord through loans or other borrowings ("Landlord Borrowing Amount"). The parties agree that Landlord shall expend \$4 million in total in acquiring the Land, constructing the Building and Common Areas and paying the Tenant Finish Work Allocation.

(c) On or prior to March 31, 2002, Landlord shall provide Tenant with a not-to-exceed budget ("Final Construction Budget") for the construction of the Building and Common Areas (exclusive of any Tenant Finish Work) and an explanation, in reasonable detail, of any differences from the costs set forth in such budget and the estimated costs set forth in Exhibit B hereto. The Final Construction Budget shall be subject to review and approval by Landlord and Tenant. No later than thirty (30) days prior to the Commencement Date, Landlord shall provide Tenant with any changes to the Landlord Equity Contribution and Landlord Borrowing Amount

shown on Exhibit B hereto that are required to reflect Landlord's final financing plans and an explanation, in reasonable detail, of the reasons for such changes.

(d) Landlord and Tenant shall revise Exhibit B (the "Revised Exhibit B") in order to reflect the Final Construction Budget approved by the parties in accordance with Subparagraph (c) above and the changes, if any, to the Landlord Equity Contribution and Landlord Borrowing Amount. Once the Revised Exhibit B has been prepared and agreed to by the parties, Landlord and Tenant shall execute and deliver a Lease Amendment, in the form set forth in Exhibit C hereto, to confirm the Revised Exhibit B, and as such Revised Exhibit B shall replace and supercede the Project Budget originally attached to this Lease as Exhibit B.

Section 2. TERM. The term of this Lease shall be for ten (10) years, commencing on the date ("Commencement Date") which is the latest to occur of (i) June 1, 2002, and (ii) the date the Building and Tenant Finish Work are Substantially Complete (defined below) and a verbal occupancy permit has been received; and expiring on the last day ("Expiration Date") of the tenth (10th) Lease Year (defined below), unless renewed or sooner terminated as hereinafter provided. Landlord and Tenant anticipate that the term of this Lease will commence on or about June 1 2002.

As used in this Lease, "Lease Year" means each consecutive twelve calendar month period beginning with the Commencement Date, except that if the Commencement Date does not occur on the first day of a calendar month, then the first Lease Year shall also include the number of days from the Commencement Date until the last day of the first month of Tenant's occupancy and the term of this Lease shall be ten (10) years plus said number of days and shall expire on the last day of the one hundred twentieth (120th) full month of the term.

When the Commencement Date and Expiration Date have finally been determined, Landlord and Tenant shall execute and deliver a Lease amendment, in the form of the Lease Commencement Date Amendment annexed as Exhibit D hereto, -----  
to confirm said dates.

Section 3. RENT.

(a) Beginning on the Commencement Date and continuing thereafter during the entire initial term of this Lease, Tenant shall pay to Landlord, as yearly rent, the following sums ("Base Rent"), in equal monthly installments, in advance on the first day of each calendar month, without demand or notice:

Lease Month	Rentable Sq. Feet	Annualized Base Rent	Monthly Base Rent	Base Rent Rate/SF
1-60	48,000	\$480,000	\$40,000	\$10.00 sq. ft.
61-72	48,000	\$489,600	\$40,800	\$10.20 sq. ft.
73-84	48,000	\$499,200	\$41,600	\$10.40 sq. ft.
85-96	48,000	\$508,800	\$42,400	\$10.60 sq. ft.
97-108	48,000	\$518,400	\$43,200	\$10.80 sq. ft.
109-120	48,000	\$528,000	\$44,000	\$11.00 sq. ft.

The parties acknowledge that the foregoing Base Rent is based on an assumed annual interest rate on the Landlord Borrowing Amount of 7% per year. If the interest rate on the Landlord Borrowing Amount is different than 7% for any Lease Year after the fifth Lease Year, the parties will adjust the foregoing Base Rent for each Lease Year after the fifth Lease Year to reflect such change and execute an amendment to this Lease reflecting such adjusted Base Rent amounts.

(b) In the event that the Commencement Date occurs on a day other than the first day of a calendar month, Tenant shall pay to Landlord a pro rata portion of the monthly installment of Base Rent for such partial month, computed at the Base Rent rate of \$40,000 per month.

(c) Whenever under the terms of this Lease any sum of money is required to be paid by Tenant in addition to the Base Rent herein reserved, and said additional sum is not designated as "Additional Rent," then if not paid when due, said sum shall nevertheless be deemed "Additional Rent" and be collectible as such with any installment of Base Rent thereafter falling due hereunder, but nothing herein contained shall be deemed to suspend or delay the payment of any such sum at the time the same became due and payable hereunder, or limit any other remedy of Landlord.

(d) All payments of Base Rent and Additional Rent shall be paid when due at 1512 Colesville Road, Bethlehem, Pennsylvania 18015, or at such other place as Landlord may from time to time direct by written notice to Tenant. All checks shall be made payable to the order of Landlord.

Section 4. ADDITIONAL RENT. Tenant shall pay to or on behalf of Landlord, as Additional Rent, the following:

(a) Utilities: Tenant shall pay directly to the applicable utility all normal and customary electric and gas charges for and with respect to the Leased Premises as shown on a separate meter exclusively for the Leased Premises.

(b) Other Expenses: Tenant shall pay to the Landlord the following listed expenses as incurred multiplied by the Tenant's Space Ratio. Tenant's Space Ratio (hereinafter "Tenant's Space Ratio") is that percentage determined by dividing the square footage of the Building leased by Tenant hereunder, as the numerator, by the total aggregate square footage of rentable space in the Building, as the denominator. Tenant's current Space Ratio is 100%. Tenant's Space Ratio shall be revised in the event of any change in the amount of square footage leased by Tenant in the Building or in the event Landlord constructs an additional building on the Land.

(1) Real estate taxes assessed upon the Land and Building of which the Leased Property is a part.

(2) Fire and liability insurance premiums pertaining to the Land and Building. At Tenant's option, Tenant may purchase fire and liability insurance coverage pertaining to the Land and Building, in such amounts and with such companies as may be reasonably acceptable to the Landlord. Such insurance shall name the Landlord as an additional insured and



shall provide that the Landlord shall receive at least ten (10) days' written notice in the event the insurance coverage is materially changed or terminated for any reason. In the event that Tenant purchases insurance as permitted under this Section 4.(b)(2), the Tenant shall be solely responsible for paying all premiums for such insurance and shall not be required to pay the Landlord Additional Rent in respect of any such insurance purchased by Landlord.

(3) Water and sewer charges and fees made by the City of Bethlehem for water used at the Building. This contemplates the ordinary use of water for cafeteria, toilet, washroom and drinking facilities. In the event Tenant uses greater amounts of water for operational reasons, Tenant shall be charged, and Tenant hereby agrees to pay, for this increased use in addition to the percentage set forth in this paragraph.

(4) Common Area expenses which include, but are not limited to, expenses of metered utilities (electric and gas) and routine cleaning, repairs, and similar expenses associated exclusively with the Common Areas. Landlord agrees that there shall be a competitive bidding procedure to contract for expenses related to the Common Area.

(5) Landscaping maintenance, snow removal, and similar expenses related to servicing the 3.7 acres associated with the Building.

(6) Each and every other expense reasonably incurred in connection with the ordinary operation of the Leased Premises, including, but not limited to, elevator maintenance, window cleaning and janitorial services.

(c) Trash Removal: Tenant shall pay as Additional Rent a trash removal fee based on the actual cost for removing trash and recyclable material from the Building based on the Tenant's Space Ratio. This Additional Rent will be reimbursed to the Landlord quarterly. Tenant shall separately and directly contract for any removal of medical and/or hazardous waste.

(d) Life Safety Inspections and Expenses: Tenant shall pay, as Additional Rent, Tenant's proportionate share (based on Tenant's Space Ratio), of all costs of the annual inspection of the fire alarm and sprinkler system plus costs associated with fire extinguisher recharging and replacement, battery replacements, and other minor repairs to the systems.

(e) Heating, Ventilation and Air Conditioning ("HVAC"): Tenant shall pay as Additional Rent all costs related to the repair and maintenance of the HVAC system(s) serving the Building based on the Tenant's Space Ratio.

All sums due under this Section shall be appropriately apportioned and prorated for any portion of a Lease Year, so that Tenant shall not be obligated to pay any costs of operation that accrue either prior to the Commencement Date or following the Expiration Date of the term of this Lease.

Section 5. LATE PAYMENT. In the event that Tenant shall fail to pay Base Rent or any Additional Rent within ten (10) days after its due date, Tenant shall pay an automatic

late charge to Landlord of \$.05 for each dollar overdue. Such late charge shall be deemed Additional Rent for all purposes under this Lease.

Section 6. USE OF LEASED PREMISES; INDEMNIFICATION.

(a) Tenant shall use and occupy the Leased Premises as a commercial office, and manufacturing, research, development, and light industrial facility, together with all appurtenant and incidental uses relating thereto (but only to the extent permitted by applicable zoning and similar ordinances and regulations). Tenant shall not use or occupy the Leased Premises for any other purpose or business, without the prior written consent of Landlord. Tenant shall observe and comply with (i) the Rules and Regulations annexed as Exhibit E hereto, as amended, modified and supplemented from time to

-----  
time by Landlord, provided such change does not conflict with any express provision of this Lease ("Rules and Regulations"); (ii) the Restrictive Covenants on the Land attached hereto as Exhibit F; and (iii) the Deed

-----  
restrictions set forth in Exhibit G. The Rules and Regulations applicable to

-----  
Tenant shall not be more restrictive than those applicable to other tenants, if any, of the Building and their respective employees, agents, licensees, invitees, subtenants and contractors.

(b) With respect to the Leased Premises, in addition to and not in limitation of the foregoing, during the term of this Lease, Tenant, its subtenants, licensees, invitees, agents, contractors, subcontractors, and employees shall conduct its business on and occupy the Leased Premises in strict compliance with all federal, state, and local statutes, ordinances, regulations, rules, standards, and requirements of the common law, whether now in force or as amended or enacted in the future, concerning or relating to industrial hygiene and the protection of health and the environment (collectively, the "Environmental Laws"). Tenant shall also cause its subtenants, licensees, invitees, agents, contractors, subcontractors and employees to comply with all Environmental Laws. Except as provided below, Tenant shall, at its own expense, obtain, maintain, and comply with all terms and conditions in any and all permits, licenses, registrations, authorizations, and other governmental and regulatory approvals required for Tenant's use and occupancy of the Leased Premises. Tenant shall insure that any materials or wastes discharged into the sanitary sewer systems are appropriately treated, if necessary, are discharged in accordance with the City of Bethlehem's Industrial User Wastewater Discharge Policies, as established by Bethlehem's approved pre-treatment program, applicable pre-treatment regulations found at 40 C.F.R. Part 403, and Section 307 of the Clean Water Act, 33 U.S.C [sec]1317 and pay any surcharges or extra-strength charges assessed in relation thereto. If necessary, Tenant shall, at its own expense, obtain a license from the Nuclear Regulatory Commission. Tenant shall insure that its importation, receipt, acquisition, possession, use, storage, transfer, delivery and disposal of by-product, source and/or nuclear material is performed in strict accordance with any such license.

With respect to the Leased Premises, it shall be Tenant's sole responsibility to receive, acquire, use, handle, manage, generate, process, treat, store, deliver, transfer, and dispose of all hazardous substances in strict compliance with the Environmental Laws and prudent industry standards. Upon expiration or earlier termination of the Term of this Lease, Tenant shall cause all Hazardous Substances brought upon the Leased Premises by its agents, employees, contractors, or

invitees, or generated by its operation, to be removed from the Leased Premises and transported for use, storage, treatment or disposal in accordance with the Laws. Tenant shall, at its own expense, develop and maintain any appropriate spill plan with respect to all Hazardous Substances brought onto the Leased Premises. To the extent that Tenant is required to complete and file EPA Form R (40 C.F.R. Part 372), Tenant shall, as soon as is practicable, provide Landlord with a copy of the same. Tenant shall not cause or permit any condition on the Leased Premises which might give rise to liability, the imposition of a statutory lien or require "Response," "Removal" and "Remedial Action" as defined herein, under any Environmental Laws. As used in this Lease, the terms "Response," "Removal" and "Remedial Action" shall be defined with reference to Sections 101(23) - 101(25) of the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA") as amended by the Superfund Amendments and Reauthorization Act, 42 U.S.C. [sec][sec]9601 (23)-9601(25).

With respect to the Leased Premises, Tenant shall have the sole responsibility of complying with the requirements of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRTKA), 41 U.S.C. [sec][sec] 11001-11050, the Occupational Safety and Health Act of 1970 (OSHA), 29 U.S.C. [sec][sec] 651-678, as amended, and the Pennsylvania Worker and Community Right-to-Know Act, PA Stat. Ann. tit. 35 [sec][sec]7301-7320 (Purdon 1989). Tenant shall submit to Landlord on an annual basis a list of the Hazardous Substances, hazardous mixtures, or hazardous chemicals for which it is required to maintain Material Safety Data Sheets (MSDS). Tenant shall also provide Landlord copies of all required contingency plans including, without limitation, plans for spills of Hazardous Substances, fire and other potential emergencies.

With respect to the Leased Premises, as used in this Lease, the term "Hazardous Substances" shall mean any substance regulated under any of the Environmental Laws including, without limitation, any substance which is: (i) petroleum, explosives, radioactive materials, asbestos or material containing asbestos, polychlorinated biphenyls or related or similar materials; (ii) defined, designated or listed as a "Hazardous Substance" pursuant to Sections 307 and 311 of the Clean Water Act or Section 103 of the Pennsylvania Hazardous Sites Clean-Up Act, PA Stat. Ann. tit. 35 [sec] 6020.103; (iii) defined, designated or listed as a "Hazardous Waste" under Section 1004(5) of the Resource Conservation and Recovery Act, 42 U.S.C. [sec] 9603(5) or Section 103 of the Pennsylvania Solid Waste Management Act, PA Stat. Ann. tit. 35 [sec] 6018.103; (iv) regulated under the Pennsylvania Clean Streams Law, PA Stat. Ann. tit. 35 [sec][sec]691.1-691.1001; (v) listed in the United States Department of Transportation Hazardous Materials Table, 49 C.F.R. [sec] 172.101; (vi) defined, designated or listed as a "byproduct, source and/or special nuclear material" under the Atomic Energy Act of 1954, as amended by the Energy Reorganization Act of 1974 (Public Law 93-438), 42 U.S.C. [sec] 2011-2296 and 10 C.F.R. Parts 30, 31, 32, 22, 34, 35, 40 and 70; and (vii) defined, designated or listed as a "Hazardous Material" under Section 103 of the Hazardous Material Emergency Planning Response Act, PA Stat. Ann. tit. 35 [sec] 6022-103; and (viii) any element, compound or material which can pose a threat to the public health or the environment when released into the environment; and (ix) any other substance designated by any of the Environmental Laws or a federal, state, or local agency as detrimental to public health, safety and the environment.

With respect to the Leased Premises, Tenant shall immediately notify Landlord, in writing, upon discovering any condition on the Leased Premises which might require Tenant to

notify any governmental or regulatory agency or which might give rise to liability, imposition of a statutory lien, or require Response, Removal or Remedial Action under any of the Environmental Laws. In addition, Tenant shall immediately notify Landlord, in writing, of Tenant's receipt, knowledge, or discovery of: (i) the presence of any Hazardous Substance on, about, beneath, or arising from any portion of the Leased Premises in violation of any of the Environmental Laws; (ii) any enforcement, Response, Removal, Remedial Action, or other governmental or regulatory actions instituted or threatened against Tenant or the Leased Premises pursuant to any of the Environmental Laws; (iii) any claim made or threatened by any person against Tenant or the Leased Premises relating to any form of damage, loss or injury resulting from or claimed to result from any Hazardous Substance or any violation of the Environmental Laws; and (iv) any communication received from any governmental or regulatory agency arising out of or in connection with Hazardous Substances on, about, beneath, arising from, or generated at the Leased Premises including, without limitation, any notice of violation, citation, complaint, order, directive, request for information, notice letter, or compliance schedule. Tenant shall supply to Landlord as promptly as possible and in any event within five (5) business days after Tenant receives or sends the same, copies of all reports required to be filed under any of the Environmental Laws, responses to any requests for information, and any claim, complaint, notice of violation, citation, order, directive, compliance schedule, notice letter, or other communications relating in any way to the Leased Premises, Tenant's use thereof of Hazardous Substances on, about, beneath, arising from or generated at the Leased Premises. Tenant shall also promptly deliver to Landlord copies of any hazardous waste manifests listing the Leased Premises as the facility and the Tenant as generator and reflecting legal and proper disposal of all Hazardous Substances removed from the Leased Premises.

With respect to the Leased Premises, except in case of emergency or as otherwise required by the Environmental Laws, Tenant shall not take any Response, Removal, or Remedial Action or notify any governmental or regulatory agency in response to the presence of Hazardous Substances on, about, beneath, or arising from the Leased Premises, or enter into any settlement agreement, consent degree, administrative consent order or other compromise with respect to any claim relating to any Hazardous Substances in any way connected with the Leased Premises without first notifying Landlord of Tenant's intention to do so and affording Landlord an ample opportunity to appear, intervene, or appropriately assert and protect Landlord's interest with respect thereto.

(c) With respect to the Leased Premises, Tenant, its subtenants, licensees, invitees, agents, contractors, subcontractors and employees shall not dispose, release, spill, pump, pour, emit, empty, dump or otherwise discharge or allow to escape Hazardous Materials into the environment, and Tenant shall take all action necessary to remedy the results of any such disposal, release, spillage, pumping, pouring, emission, emptying, dumping, discharge, or escape.

(d) Tenant shall, as soon as is practicable, supply Landlord with copies of any written communication between Tenant and any governmental agency or instrumentality concerning or relating to violations or alleged violations of Environmental Laws with respect to the Leased Premises.

(e) Tenant shall indemnify, defend (by counsel reasonably acceptable to Landlord) and hold harmless Landlord, its directors, officers, employees, affiliated entities, members, predecessors, successors and assigns, from and against any and all claims, liabilities, penalties, fines, judgments, forfeitures, losses (including, without limitation, diminution in the value of the Leased Premises or damages for any loss or restriction on the use of rentable or usable space of any amenity of the Leased Premises), costs, and expenses (including reasonable attorneys fees, consultant, and expert fees) in any way arising from or relating to: (i) the presence of any Hazardous Substance on, about, beneath or arising from the Leased Premises excluding any Hazardous Substances which pre-exist the term of this Lease or any Hazardous Substances discharged by Landlord or any third party not in any way connected with Tenant's occupancy, (ii) Tenant's use, handling, generation, processing, treatment, manufacture, storage, transportation, disposal, release, or discharge of Hazardous Substances on, about, beneath, or arising from the Leased Premises; (iii) Tenant's failure to comply with any of the Environmental Laws; and (iv) Tenant's breach of any of the Environmental Covenants contained herein. Tenant's indemnity and defense obligations under this paragraph shall include, without limitation, whether foreseeable or unforeseeable, any and all costs incurred in connection with any investigation of site conditions on, about, beneath, or arising from the Leased Premises, and any and all costs of any required Response, Removal or Remedial Actions, and the preparation and implementation of any closure, remedial action, or other required plans or reports in connection therewith. The Tenant's obligations under this paragraph shall survive the expiration or earlier termination of the terms of this Lease.

Section 7. COMMON AREAS. All parking areas, walkways, stairs, elevators, driveways, public corridors, rest rooms, loading areas, and fire escapes, and other areas, facilities and improvements now or hereafter existing in or outside the Building or on the Land ("Common Areas") which may be provided by Landlord from time to time for the general use, in common, of Tenant and other tenants, if any, of the Building, their employees, agents, invitees and licensees, shall at all times be subject to the control and management of Landlord. Landlord shall have the right from time to time to establish, modify and enforce reasonable rules and regulations with respect to the Common Areas, provided such rules and regulations do not adversely affect Tenant's use of the Leased Premises.

Section 8. ALTERATIONS AND TRADE FIXTURES, REMOVAL.

(a) Except as set forth in Section 27 with respect to the initial Tenant Finish Work, during the term of this Lease, Tenant shall not make any structural or material alterations or additions to the Leased Premises or the Building without the prior written consent of Landlord, which consent shall not be unreasonably withheld or delayed. All such alterations and additions shall be performed (i) at Tenant's sole cost and expense, (ii) in accordance with the specifications prepared by and at the expense of Tenant and reasonably approved by Landlord, (iii) by contractors, subcontractors and materialmen reasonably approved by Landlord, and (iv) in conformity with all applicable laws, codes and regulations. During the course of performance of said work, Tenant will carry or cause to be carried Comprehensive General Liability insurance, in the minimum limit of \$1,000,000 naming Landlord as additional insured and further providing such insurance cannot be cancelled without at least thirty (30) days' prior written notice to Landlord.

(b) Any consent by Landlord permitting Tenant to do any or cause any work to be done in or about the Building, and right of Tenant to perform such work, shall be and hereby is conditioned upon Tenant's work being performed by workmen and mechanics working in harmony and not interfering with labor employed by Landlord, Landlord's mechanics or contractors or any other tenant or their contractors.

(c) All alterations, interior decorations, improvements or additions made to the Leased Premises by Tenant, except for movable furniture, equipment and trade fixtures, shall immediately become Landlord's property. Upon termination of this Lease, Tenant shall remove all movable furniture, equipment and trade fixtures installed by Tenant in the Leased Premises ("Tenant's Property"), and repair any damage caused to the Leased Premises by said removal. All of Tenant's Property remaining on the Leased Premises after the Expiration Date, or after any sooner termination date due to any default of Tenant, shall at the option of Landlord be deemed to be abandoned property and shall become the property of Landlord.

Section 9. MECHANICS' LIENS. Prior to Tenant performing, or permitting performance of, any construction or other work in or about the Leased Premises for which a lien could be filed against the Leased Premises or the Building, Tenant shall have its contractor execute a Waiver of Mechanics' Lien satisfactory to Landlord, and provide Landlord with a copy thereof. Notwithstanding the foregoing, if any mechanics' or other lien shall be filed against the Leased Premises or the Building purporting to be for labor or materials furnished or to be furnished at the request of Tenant, then at its expense, Tenant shall cause such lien to be removed of record by payment, bond or otherwise, within thirty (30) days after the filing thereof. If Tenant shall fail to cause such lien to be removed of record within such thirty (30) day period, Landlord may cause such lien to be removed of record by payment, bond or otherwise, without investigation as to the validity thereof or as to any offsets or defenses thereto, in which event such payment(s) shall be deemed and collectible as Additional Rent and Tenant shall reimburse Landlord in the amount paid by Landlord, including expenses, within ten (10) days after Landlord's billing therefor. Tenant shall indemnify and hold Landlord harmless from and against any and all claims, costs, damages, liabilities and expenses (including reasonable attorney fees) which may be brought or imposed against or incurred by Landlord by reason of any such, lien or removal of record. The provisions of this Section 9 shall survive the expiration or sooner termination of this Lease.

Section 10. BUILDING SERVICES. Landlord shall provide the following services, systems and facilities for the Building and Common Areas within the Building ("Building Services"), and for the Common Areas outside the Building ("Common Area Services"), subject to Tenant's payment of Additional Rent as set forth in paragraph 4 above;

(a) Basic HVAC for the Leased Premises. Tenant shall be responsible for utility charges related to the HVAC systems(s) serving the Building based on the Tenant's Space Ratio. Landlord further shall perform necessary repairs and maintenance on the HVAC system(s) and shall be reimbursed by Tenant for the actual costs to Landlord of said repairs and maintenance based on the Tenant's Space Ratio. Tenant shall also be solely responsible, at Tenant's cost, for all major repairs and any replacement of the HVAC system(s);

(b) Electrical service for office, manufacturing, research and development and light industrial use, including office, manufacturing, research and development and light industrial equipment, in the Leased Premises, subject to payment by Tenant of all utility charges;

(c) Life safety support systems for the Building including sprinkler and fire extinguisher inspections subject to reimbursement by Tenant for the cost of same; however, Landlord shall be responsible, at Landlord's cost, for major repairs and any replacement of the sprinkler system;

(d) Structural systems for the Building;

(e) Water and sewer system for Tenant's use at the Leased Premises and a plumbing system for the Building, subject to payment by Tenant of all fees and charges related thereto;

(f) Cleaning and maintenance of Common Areas in or relating to the Building, including bathroom facilities, if any, subject to payment by Tenant of a proportionate share of the Common Area expenses based on the Tenant's Space Ratio;

(g) Landscaping and snow and ice removal; provided Landlord shall not be obligated to remove snow more frequently than once in any 24-hour period, and Tenant shall be responsible for a proportionate share of the expenses related thereto based on the Tenants Space Ratio; and

(h) Tenant shall have the continuing right during the term of this Lease to utilize, in common, on a pro-rata basis calculated upon each such tenant's space ratio, with other tenants within the Building, if any, the parking area for the Building.

Landlord does not warrant that Building Services or Common Area Services shall be free from any temporary slowdown, interruption or stoppage caused by the maintenance, repair, replacement or improvement of any of the equipment involved in the furnishing of any such services, or caused by strikes, lockouts, fuel shortages, accidents, acts of God or the elements or any other cause beyond the control of Landlord. Landlord agrees to use its best efforts to resume the service upon any such slowdown, interruption or stoppage as soon as reasonably possible.

#### Section 11. ASSIGNMENT AND SUBLETTING.

(a) Tenant shall not assign or hypothecate this Lease or any interest therein or sublet the Leased Premises or any part thereof without the prior written consent of Landlord, which consent shall not be unreasonably withheld or delayed. For purposes of this Lease, a transfer of all or substantially all of the businesses or assets of Tenant, by merger, consolidation, sale, operation of law or otherwise shall constitute an assignment.

(b) No sublease or assignment shall be valid and no subtenant or assignee shall take possession of the premises subleased or assigned until an executed counterpart of such sublease or assignment of this Lease has been delivered to Landlord.

(c) Regardless of Landlord's consent, no subletting or assignment shall release Tenant of Tenant's obligations or alter the primary liability of Tenant to pay the Base Rent and Additional Rent and to perform all other obligations to be performed by Tenant under this Lease. The acceptance of rent by Landlord from any other person shall not be deemed to be a waiver by Landlord of any provision hereof. Consent to one assignment or subletting shall not be deemed consent to any subsequent assignment or subletting. In the event of default by any assignee of Tenant or any successor of Tenant in the performance of any of the terms of this Lease, Landlord may proceed directly against Tenant without the necessity of exhausting remedies against such assignee or successor.

(d) In the event that the Leased Premises or any part thereof have been sublet by Tenant and Tenant is in default under this Lease then Landlord may collect rent from the subtenant and apply the amount collected to the Base Rent and Additional Rent herein reserved, but no such collection shall be deemed a waiver of the provisions of this Section with respect to subletting or the acceptance of such subtenant as Tenant hereunder or a release of Tenant under the Lease, or an election by Landlord of its remedies.

Section 12. ACCESS TO LEASED PREMISES. Landlord, its employees and agents shall have the right to enter the Leased Premises at all reasonable times during Tenant's normal business hours and at anytime in case of an emergency for the purpose of examining or inspecting the Leased Premises, showing the Leased Premises to prospective purchasers, mortgagees and (during the last year of the Lease term only) tenants of the Building, and making such alterations, repairs, improvements or additions to the Leased Premises or to the Building as permitted or required under Section 13, below. If representatives of Tenant shall not be present to open any entrance into the Leased Premises at any time when such entry by Landlord is necessary or permitted hereunder, Landlord may enter by means of a master key (or forcibly in the event of an emergency) without liability to Tenant and without such entry constituting an eviction of Tenant or termination of this Lease. Landlord shall use reasonable efforts not to interfere with the conduct of Tenant's business when entering the Leased premises. Except in the case of an emergency, Landlord shall notify Tenant (which notice may be oral) of Landlord's intended entry of the Leased Premises at least 24 hours advance, and obtain consent of the Tenant, which consent shall not be unreasonably withheld.

Section 13. MAINTENANCE AND REPAIRS.

(a) Subject to the terms hereof, Landlord shall promptly make all repairs and replacements necessary, in Landlord's discretion, to maintain or promptly restore (i) all building systems including plumbing, heating, ventilating, air conditioning and electrical systems (including the light fixtures of Tenant); (ii) roof, interior and exterior walls, windows, floors (except carpeting) and all other structural portions of the Building (whether or not including the Leased Premises), in good repair and operating condition and in order and appearance appropriate for a building of similar



type. Landlord shall also be responsible for the maintenance of all Common Areas. In no event shall Landlord be obligated under this paragraph to repair damage caused by (1) any act, omission, accident or negligence of Tenant or its employees, agents, invitees, licensees, subtenants, or contractors or (2) any alterations or additions to the Leased Premises or the Building made by Tenant without the prior written consent of Landlord (which consent shall be deemed given with respect to all of the initial Tenant Finish Work).

(b) Tenant shall, at its sole cost and expense, provide customary routine maintenance for the Leased Premises and the fixtures therein and keep them in neat and orderly condition, wear and tear and damage by fire or other casualty excepted. Tenant shall otherwise maintain the Leased Premises except to the extent provided in paragraph (a) above.

(c) Landlord shall not be liable for any interference with Tenant's business arising from the making of any repairs in the Leased Premises under paragraph (a) above. Landlord shall use its best efforts not to interfere with the operation of Tenant's business when making repairs in the Leased Premises. There shall be no abatement of Base Rent or Additional Rent because of such repairs.

#### Section 14. INDEMNIFICATION AND LIABILITY INSURANCE.

(a) Tenant shall indemnify, defend and hold Landlord, its members, employees, representatives, contractors, servants and agents, harmless from and against any and all costs, expenses (including reasonable counsel fees), liabilities, losses, damages, suits, actions, fines, penalties, claims or demands of any kind and asserted by or on behalf of any person or governmental authority, arising out of or in any way connected with, and Landlord, its members, employees, representatives, contractors, servants and agents, shall not be liable to Tenant on account of, (i) any failure by Tenant to perform any of the agreements, terms, covenants or conditions of this Lease required to be performed by Tenant, (ii) any failure by Tenant to comply with any statutes, ordinances, regulations or orders of any governmental authority applicable to Tenant or its use and occupancy of the Leased Premises (except for requirements applicable to the Building in general and its occupancy, which shall be Landlord's sole responsibility), or (iii) any accident, death or personal injury, or damage to or loss or theft of property, which shall occur in or about the Leased Premises. In no event shall Tenant be obligated under this paragraph to indemnify, defend or hold harmless Landlord, its members, employees, representatives, contractors, servants and agents, from and against damages, claims or demands of any kind arising out of the willful or negligent conduct of Landlord, its members, employees, representatives, contractors, servants or agents. In no event shall Landlord, its members, employees, representatives, contractors, servants or agents, be responsible for inspecting or monitoring the Leased Premises for workplace safety arising out of or with respect to Tenant's equipment and operations.

(b) During the term of this Lease and any renewal thereof, Tenant shall obtain and promptly pay all premiums for Comprehensive General Liability Insurance with broad form extended coverage, including Contractual Liability, covering claims for bodily injury (including death resulting therefrom) and property loss or damage occurring upon, in or about the Leased

Premises, with a minimum combined single limit of at least \$5,000,000. All such policies and renewals thereof shall name Landlord as an additional insured and shall otherwise be in form and substance, and from insurers, satisfactory to Landlord. All policies of insurance shall provide (i) that no material change or cancellation of said policies shall be made without at least thirty (30) days' prior written notice to Landlord and Tenant, and (ii) that any loss shall be payable notwithstanding any act or negligence of Tenant or Landlord which might otherwise result in the forfeiture of said insurance. Upon request of Landlord, Tenant shall promptly forward copies of all insurance policies maintained pursuant to this paragraph indicating compliance with the terms hereof. In addition, not less than fifteen (15) days prior to the expiration dates of said policy or policies, Tenant shall furnish Landlord with renewal certificates of the policies of insurance required under this paragraph. The aforesaid insurance limits may be reasonably increased by Landlord from time to time during the term of this Lease.

(c) Landlord shall indemnify, defend and hold Tenant, its subtenants, shareholders, affiliates, directors, employees, representatives, contractors, servants and agents, harmless from and against any and all costs, expenses (including reasonable counsel fees), liabilities, losses, damages, suits, actions, fines, penalties, claims or demands of any kind and asserted by or on behalf of any person or governmental authority, arising out of or in any way connected with, and Tenant, its subtenants, shareholders, affiliates, directors, employees, representatives, contractors, servants and agents, shall not be liable to Landlord on account of, (i) any failure by Landlord to perform any of the agreements, terms, covenants or conditions of this Lease required to be performed by Landlord, (ii) any failure by Landlord to comply with any statutes, ordinances, regulations or orders of any governmental authority applicable to Landlord, or (iii) any accident, death or personal injury, or damage to or loss or theft of property, which shall occur in or about the Common Areas or Land as a result of the negligence and/or willful conduct of Landlord. In no event shall Landlord be obligated under this paragraph to indemnify, defend or hold harmless Tenant, its subtenants, shareholders, affiliates, directors, employees, representatives, contractors, servants or agents, from and against damages, claims or demands of any kind arising out of the willful or negligent conduct of Tenant, its subtenants, shareholders, affiliates, directors, employees, representatives, contractors, servants or agents.

Section 15. QUIET ENJOYMENT. Landlord covenants and agrees with Tenant that upon Tenant paying the Base Rent and Additional Rent and observing and performing all the terms, covenants and conditions, on Tenant's part to be observed and performed under Lease, Tenant may peaceably and quietly enjoy the Leased Premises hereby demised, subject, nevertheless, to the terms and conditions of this Lease, and subject to the mortgages hereinafter mentioned.

Section 16. NEGATIVE COVENANTS OF TENANT. Tenant agrees that it will not do or suffer to be done, any act, matter or thing objectionable under any generally applicable fire insurance or any other insurance now in force or hereafter placed on the Leased Premises or any part thereof or on the Building by Landlord which shall cause such Policy to become void or suspended. In case of a breach of this covenant, in addition to all other remedies hereunder, Tenant agrees to pay to Landlord, as Additional Rent, any and all increases in premiums on insurance carried

by Landlord on the Leased Premises or any part thereof or on the Building caused in any way by the occupancy of Tenant.

Section 17. FIRE OR OTHER CASUALTY.

(a) Subject to the provisions of paragraphs (b) and (c) below, if the Leased Premises and/or any portion(s) or component(s) of the Building or the Common Areas outside the Building that are reasonably necessary to provide Tenant with normal access to and from the Building or Leased Premises or which provide Building Services or Common Area Services to the Leased Premises (the "Significant Building Components") are damaged by fire or other insured casualty, Tenant shall give prompt notice of such event to Landlord and, provided Landlord's mortgagees permit insurance proceeds to be made available for the repair and restoration of the Leased Premises, the damages shall be repaired by and at the expense of Landlord and restore to substantially the condition that existed immediately prior to such damage. Landlord agrees to repair such damage in an expeditious manner after receipt from Tenant of written notice of such damage, subject to any delays caused by Acts of God or other events beyond Landlord's control relating to the actual construction (including receipt of insurance proceeds) which Landlord has used best efforts to avoid or overcome. Landlord shall not be liable for any inconvenience or annoyance to Tenant or injury to the business of Tenant resulting in any way from such damage or the repair thereof, provided, however, that if the fire and/or damage was not caused by the negligence or misconduct of Tenant, its subtenants, shareholders, directors, employees, representatives, contractors, servants or agents, Tenant shall be entitled to an abatement of the rent in proportion to the unusable amount of square feet to the total square feet in the Building from the date of the casualty until the space is again useable. Tenant acknowledges notice that (i) Landlord shall not obtain insurance of any kind in Tenant's furniture or furnishings, equipment, fixtures, alterations, improvements and additions, (ii) it is Tenant's obligation to obtain such insurance at Tenant's sole expense, and (iii) Landlord shall not be obligated to repair any damage thereto or replace the same, unless such damage is caused by the negligence or misconduct of Landlord, its agents, servants or employees.

(b) If (i) the Leased Premises are rendered substantially untenable or any Significant Building Component is rendered substantially unusable or inoperable by reason of such fire or other casualty, or (ii) sixty percent (60%) or more of the Leased Premises is damaged by said fire or other casualty, and, in either case, Landlord's engineer or architect reasonably estimates that it will take more than three (3) months to substantially complete the required repairs and restoration, Landlord or Tenant shall have the right, upon written notice to the other within fifteen days after determination by such architect, in the case of Landlord to elect not to repair and restore the Leased Premises or Significant Building Component, and in the case of Tenant (except with respect to a fire or other casualty caused by the negligence or willful misconduct of Tenant, its subtenants, shareholders, directors, employees, representatives, contractors, servants or agents,) to terminate this Lease, and in such event, this Lease and the tenancy hereby created shall cease as of the date of said occurrence, the Base Rent and Additional Rent to be adjusted and apportioned as of said date.

(c) If the Building shall be damaged by fire or other casualty and any of Landlord's lenders refuse to permit available insurance proceeds to be used by Landlord to restore the Building and the Leased Premises to substantially the condition that existed immediately prior to the occurrence of the fire or other casualty, Landlord shall have the right, upon written notice to Tenant within fifteen days after notice from such lenders, to terminate this Lease, and in such event, this Lease and the tenancy hereby created shall cease and the Base Rent and Additional Rent shall be adjusted and apportioned as of the date of said termination unless terminated as of the date of said occurrence in accordance with paragraph (b) above.

#### Section 18. SUBORDINATION.

(a) Subject to the provisions of paragraph 18(b) below, this Lease shall be subject and subordinate at all times to the lien of any and all mortgages now placed on the Land or the Building without the necessity of any further instrument or act on the part of the Tenant to effectuate such subordination.

(b) Landlord covenants and agrees to use Landlord's best efforts to obtain and furnish to Tenant, simultaneously with Tenant's execution of this Lease, an agreement reasonably acceptable to Tenant ("Non-Disturbance Agreement") executed and acknowledged from holder(s) of any mortgage now encumbering the Building or the Leased Premises ("Existing Holder") whereby each Existing Holder agrees to not disturb Tenant in its rights, use and possession of the Leased Premises and Building under this Lease or to terminate this Lease, except to the extent permitted to Landlord by the terms of this Lease, notwithstanding the foreclosure or the enforcement of the mortgage or termination or other enforcement of an underlying lease or installment purchase agreement. Tenant covenants and agrees to execute and deliver the Non-Disturbance Agreement(s).

(c) Tenant further agrees that this Lease shall be subject and subordinate to the lien of any mortgages hereafter placed upon the Land or the Building and that Tenant shall execute such additional documents to confirm same, provided that the holder thereof shall have entered into a Non-Disturbance Agreement with Tenant as described in paragraph (b) above, which Non-Disturbance Agreement shall be in form reasonably acceptable to the mortgagee and also may provide for the subordination of this Lease and Tenant's agreement to attorn as part of its terms.

#### Section 19. CONDEMNATION.

(a) If any of the Leased Premises or a portion of the Building or the Common Areas that contains a Significant Building Component shall be condemned or taken permanently for any public or quasi-public use or purpose, under any statute or by right of eminent domain, or by private purchase in lieu thereof (and, as a result, Tenant's use and enjoyment of the Leased Premises is substantially impaired), then in that event, at the option of either Landlord or Tenant exercised by notice to the other within thirty (30) days after the date when possession is taken, the term of this Lease shall cease and terminate as of the date when possession is taken pursuant to such proceeding or purchase. The Base Rent and Additional Rent shall be adjusted apportioned as of the time of such termination and any Base Rent and Additional Rent paid for a period thereafter shall be refunded. In the event a material portion only of the Building shall be so

taken (even though the Leased Premises may not have been affected by the taking of a portion of the Building), Landlord may, within such 30-day period, elect to terminate this Lease as of the date when possession is taken pursuant to such proceeding or purchase or Landlord may elect to repair and restore the portion not taken at its own expense, and thereafter the Base Rent and Additional Rent shall be reduced proportionately to reflect the portion of the Leased Premises or Building not taken.

(b) In the event of any total or partial taking of the Building, Landlord shall be entitled to receive the entire award in any such proceeding and Tenant hereby assigns any and all right, title and interest of Tenant now or hereafter arising in or to any such award or any part thereof and Tenant hereby waives all rights against Landlord and the condemning authority except that Tenant shall have the right to claim and prove in any such proceeding and to receive any award which may be made to Tenant, if any, specifically for damages for loss of movable trade fixtures, equipment and moving expenses.

Section 20. ESTOPPEL CERTIFICATE. At any time and from time to time and within ten (10) days after written request by Landlord, Tenant shall execute, acknowledge and deliver to Landlord a statement in writing duly executed by Tenant, certifying that (i) this Lease is in full force and effect without modification or amendment (or, if there have been any modifications or amendments, that this Lease is in full force and effect as modified and amended and setting forth the dates of the modifications and amendments); (ii) the dates to which annual Base Rent and Additional Rent have been paid; (iii) to the knowledge of the certifying party, no default exists under this Lease or specifying each such default; and (iv) such other matters as Landlord may reasonably request; it being the intention and agreement of Landlord and Tenant that any such statement by Tenant may be relied upon by a prospective purchaser or a prospective mortgagee of the Building, or by others, in any matter affecting the Leased Premises.

Section 21. DEFAULT. The occurrence of any of the following shall constitute an event of default ("Event of Default") and a material breach of this Lease by Tenant:

(a) The failure of Tenant to take possession of the Leased Premises within sixty (60) days after the Commencement Date of this Lease;

(b) A failure by Tenant to pay, when due, any installment of Base Rent required to be paid by Tenant under this Lease, and such failure continues for more than fifteen (15) days after written notice, provided that such grace period shall not be applicable more than two times in any twelve (12) consecutive month period;

(c) A failure by Tenant to pay, when due, any installment of Additional Rent or any other sum required to be paid by Tenant under this Lease and such failure continues for more than fifteen (15) days after Tenant has received written notice of the delinquent payment from Landlord, provided that such grace period shall not be applicable more than two times in any twelve (12) consecutive month period;

(d) A failure by Tenant to observe and perform any other provision or covenant of this Lease to be observed or performed by Tenant, and such failure continues for thirty

(30)days after Tenant receives written notice thereof from Landlord; provided, however, that if the nature of the default is such that the same cannot reasonably be cured within such thirty (30)day period but is subject to cure within an additional sixty (60) days after the end of the thirty (30)day period, Tenant shall not be deemed to be in default if Tenant shall commence and diligently pursue the cure of the default within such thirty (30)day period and cures such failure within such additional sixty (60)day period; and

(e) The filing of a petition by or against Tenant for adjudication as a bankrupt or insolvent or for its reorganization or for the appointment of a receiver or trustee of Tenant's property pursuant to any local, state or federal bankruptcy or insolvency law; or an assignment by Tenant for the benefit of creditors; or the taking possession of the property of Tenant by any local, state or federal governmental officer or agency or court-appointed official for the dissolution or liquidation of Tenant or for the operating, either temporary or permanent, of Tenant's business, provided, however, that if any such action is commenced against Tenant the same shall not constitute a default if Tenant causes the same to be dismissed within sixty (60) days after the filing thereof.

Section 22. REMEDIES. Upon the occurrence of any Event of Default then, in addition to all rights and remedies provided by law or equity, or provided for elsewhere in this Lease, Landlord shall have all of the rights and remedies specified in the following paragraphs, without any further notice or demand whatsoever

(a) Landlord may perform for the account of Tenant the cure of any such default of Tenant and immediately recover as additional rent any expenditures made and the amount of any obligations incurred in connection therewith, plus interest accrued at a rate per annum equal to the prime rate announced by Citibank, N.A., from time to time ("Prime Rate"), plus four percent (4%), from the date of any such expenditures;

(b) Landlord may immediately proceed to collect or bring action for the rent as well as for liquidated damages provided for hereinafter, as being rent in arrears, or may file a Proof of Claim in any bankruptcy or insolvency proceeding for such rent, or Landlord may institute any other proceedings, whether similar to the foregoing or not, to enforce payment thereof, the requirement of a Notice to Quit being hereby expressly waived;

(c) Landlord may re-enter and repossess the Leased Premises breaking open locked doors, if necessary, and may use as much force as necessary to effect such entrance. Landlord may remove all of Tenant's goods and property from the Building and store same, at Tenant's sole cost and expense,

(d) At any time after the occurrence of any Event of Default, Landlord may re-enter and repossess the Leased Premises or any part thereof and attempt to relet all or any part of the Leased Premises for and upon such terms and to such persons, firms or corporations and for such period or periods as Landlord, in its sole discretion, shall determine, including a term beyond the termination of this Lease. Landlord shall consider any tenant offered by Tenant in connection with such reletting. For the purpose of such reletting, Landlord may decorate or make reasonable

repairs, changes, alterations or additions in or to the Building and Leased Premises to the extent reasonably deemed necessary by Landlord; and the cost of such changes, alterations or additions shall be charged to and be payable by Tenant as Additional Rent hereunder, as well as any reasonable brokerage and legal fees expended by Landlord. Any sums collected by Landlord from any new tenant during the remaining term of the Lease shall be credited against the balance of the Base Rent and Additional Rent due hereunder as aforesaid. Tenant shall pay to Landlord monthly, on the days when the Base Rent and Additional Rent would have been payable under this Lease, the amount due hereunder less the net amount obtained by Landlord from such new tenant. Landlord shall use reasonable efforts to re-let the Leased Premises;

(e) At its option, Landlord may serve notice upon Tenant that this Lease and the unexpired term hereof shall cease and expire and become absolutely void on the date specified in such notice, to be not less than fifteen (15) days after the date of such notice, without any right on the part of Tenant to save the forfeiture by payment of any sum due or by performance of any term, provision, covenant, agreement or condition broken; and, thereupon and at the expiration of the time limit in such notice, this Lease and the term hereof granted, as well as the entire right, title and interest of Tenant hereunder, shall wholly cease and expire and become void in the same manner and with the same force and effect (except as to Tenant's liability) as if the date fixed in such notice were the expiration date of the term of this Lease. Thereupon, Tenant shall immediately quit and surrender the Leased Premises to Landlord and Landlord may enter into and repossess the Leased Premises by summary proceedings, detainer, ejectment or otherwise and remove all occupants thereof and, at Landlord's option, any property therein, without being liable to indictment, prosecution or damages therefor;

(f) At Landlord's option, Tenant shall pay to Landlord on demand all Base Rent, Additional Rent and other charges payable hereunder due and unpaid to the date of demand (allowing Tenant a credit for any sums collected by Landlord from any new tenant to the extent provided in paragraph (d) above), together with liquidated damages in an amount equal to twenty five percent (25%) of the Base Rent, Additional Rent and other charges required to be paid under this Lease from the date of said demand to the Expiration Date of the term of this Lease, as if the same had not or will not be terminated, together with interest thereon from the date of demand to the date paid at a rate equal to the Prime Rate plus four percent (4%) per annum. The amount of liquidated damages attributable to Tenant's Space Ratio of operating costs shall equal the amount of such costs paid as Additional Rent by Tenant for the entire Lease Year immediately prior to such default multiplied by the number of Lease Years (or portions thereof) remaining through the Expiration Date. Landlord and Tenant acknowledge that the damages to which Landlord is entitled in the event of a default under this Lease and, if applicable, termination by Landlord, are not easily computed and are subject to many variable factors. Therefore, Landlord and Tenant have agreed to the liquidated damages as herein provided in order to avoid extended litigation in the event of default by Tenant, and if applicable, termination of this Lease.

In the event Landlord exercises the remedy under this paragraph and Tenant pays Landlord the entire amount of the liquidated damages, Landlord shall be deemed to have made an election of remedies and except for regaining possession of the Leased Premises and termination of

this Lease, Landlord shall not be entitled to exercise any further remedy under this Section; it being expressly agreed by the parties that the payment of the liquidated damages shall not entitle Tenant to continue this Lease and possession of the Leased Premises, which Landlord may terminate at any time under an Event of Default hereunder.

(g) If an Event of Default shall arise as a result of Tenant's failure to pay any Base Rent, Additional Rent or other charges hereunder (for the purposes of this sub-section, "Charges"), Tenant hereby empowers any Prothonotary, Clerk of Court or attorney of any Court of Record to appear for Tenant in any and all actions which may be brought for such Charges and to sign for Tenant a warrant of attorney for the recovery of such Charges subject to the limitations as set forth in Section 22(f) hereof, and in said warrant or suit to CONFESS JUDGMENT against Tenant for same, and for interest at the rate of one and one half percent (1 1/2%) per month from the date of delinquency or such lower rate required by applicable law. Such authority shall not be exhausted by one exercise thereof, but judgment may be confessed as aforesaid from time to time in the event of subsequent Events of Default during the original or any extension term hereof, and such powers may be exercised as well after the expiration of the original term and/or during any extension or renewal of this Lease. Interest at the above stated rate shall continue to accrue on any and all outstanding sums due to Landlord notwithstanding the entry of judgment.

When this Lease shall be terminated as a result of an Event of Default, either during the original Term of this Lease or any renewal or extension thereof, and also when and as soon as the Term hereby created or any extension thereof shall have expired, it shall be lawful for any attorney as attorney for Tenant to CONFESS JUDGMENT in EJECTMENT against Tenant and all persons claiming under Tenant for the recovery by Landlord of possession of the herein Leased Premises, for which this Lease shall be its sufficient warrant, whereupon, if Landlord so desires, a writ of Execution or of Possession may issue forthwith, without any prior writ or proceedings whatsoever subject, however, to the applicable Rules of Civil Procedure for the Commonwealth of Pennsylvania, as amended, and provided that if for any reason after such action shall have been commenced the same shall be determined and the possession of the Leased Premises hereby demised remain in or be restored to Tenant, Landlord shall have the right upon any subsequent Event or Events of Default, or upon the termination of this Lease as hereinbefore set forth, to enter successive judgments to recover possession of the said Leased Premises, the ability to CONFESS JUDGMENT in EJECTMENT contained herein not being exhausted by the single or multiple use thereof.

Tenant expressly waives the benefits of all laws, now or hereafter in force, exempting any goods on the Leased Premises, or elsewhere from distraint, levy or sale in any legal proceedings taken by the Landlord to enforce any rights under this Lease. Tenant further waives the right of inquisition on any real estate that may be levied upon to collect any amount which may become due under the terms and conditions of this Lease, and does hereby voluntarily condemn the same and authorizes the Prothonotary or Clerk of Court to issue a Writ of Execution or other process upon Tenant's voluntary condemnation, and further agrees that the said real estate may be sold on a Writ of Execution or other process. If proceedings shall be commenced by Landlord to recover possession under the Acts of Assembly, either at the end of the term or sooner termination of this Lease, or for nonpayment of rent or any other reason to the extent applicable, if at all, Tenant specifically waives



the right to the three months' notice and/or the fifteen or thirty days' notice required by the Act of April 6, 1951, P.L. 69, and any and all amendments thereto. Tenant also expressly agrees to pay for all of Landlord's costs and expenses, including but not limited to attorney's fees, incurred by Landlord in the enforcement of any or all of his rights hereunder. No reference to any specific right or remedy shall preclude Landlord from exercising any other right or from having any other remedy or from maintaining any action to which it may otherwise be entitled at law or in equity.

(h) The rights and remedies given to Landlord in this Lease are distinct, separate and cumulative remedies, and no one of them, whether or not exercised by Landlord, shall be deemed to be in exclusion of any of the others.

Section 23. REQUIREMENT OF STRICT PERFORMANCE. The failure or delay on the part of Landlord to enforce or exercise at any time any of the provisions, rights or remedies in the Lease shall in no way be construed to be a waiver thereof, or in any way to affect the validity of this Lease or any part thereof, or the right of Landlord to thereafter enforce each and every such provision, right or remedy. No waiver of any breach of this Lease shall be held to be a waiver of any other or subsequent breach. The receipt by Landlord of Base Rent or Additional Rent at a time when the Tenant is in default in the payment of Base Rent or Additional Rent under this Lease shall not be construed as waiver of such default. The receipt by Landlord of a lesser amount than the Base Rent or Additional Rent due shall not be construed to be other than a payment on account of the Base Rent or Additional Rent then due, and any statement on Tenant's check or any letter accompanying Tenant's check to the contrary shall not be deemed an accord and satisfaction, and Landlord may accept such payment without prejudice to Landlord's right to recover the balance of the Base Rent or Additional Rent due or to pursue any other remedies provided in this Lease. No act or thing done by Landlord or Landlord's agents or employees during the term of this Lease shall be deemed an acceptance of a surrender of the Leased Premises and no agreement to accept such a surrender shall be valid unless in writing and signed by Landlord.

Section 24. SURRENDER OF LEASED PREMISES; HOLDING OVER.

(a) The Lease shall terminate and Tenant shall deliver up and surrender possession of the Leased Premises to Landlord at 11:59 P.M. local time on the last day of the term hereof, and Tenant hereby waives the right to any notice of termination or notice to quit. Upon the expiration or sooner termination of this Lease, Tenant covenants to deliver up and surrender possession of the Leased Premises in the same condition in which Tenant has agreed to maintain and keep the same during the term of this Lease in accordance with the provisions of this Lease, normal wear and tear excepted.

(b) Upon the failure of Tenant to surrender possession of the Leased Premises to Landlord upon the expiration or sooner termination of this Lease, Tenant shall pay to Landlord, as liquidated damages, an amount equal to 150% of the then current Base Rent and Additional Rent required to be paid by Tenant under this Lease, applied to the first thirty (30) days Tenant shall remain in possession after the expiration or sooner termination of this Lease, and 200% of the then current Base Rent and Additional Rent required to be paid by Tenant under this Lease,

applied to the holdover period from and after the 31st day Tenant shall remain in possession after the expiration or sooner termination of this Lease. Acceptance by Landlord of Base Rent or Additional Rent after such expiration or earlier termination shall not constitute a consent to a holdover hereunder or result in a renewal. The foregoing provisions of this paragraph are in addition to and do not affect Landlord's right of reentry or any other rights of Landlord hereunder or otherwise provided by law.

Section 25. COMPLIANCE WITH LAWS AND ORDINANCES. At its sole cost and expense, Tenant shall promptly fulfill and comply with all laws, ordinances, regulations and requirements of the Federal, state and local governments and any and all departments thereof having jurisdiction over the Building applicable to Tenant's use and occupancy of the Leased Premises (but not those applicable to the Building generally or its occupancy, which, subject to the terms hereof, shall be Landlord's sole responsibility), and the National Board of Fire Underwriters or any other similar body now or hereafter constituted, affecting Tenant's occupancy of the Leased Premises or the business conducted therein.

Section 26. TENANT DESIGN PROCESS.

(a) Landlord shall retain, at Landlord's cost and expense, the services of a qualified and experienced tenant finish architect ("Tenant Finish Architect") and other consultants, to be approved by Tenant, as shall be reasonably necessary for the purposes of planning, designing and construction of the Leased Premises for Tenant's occupancy acceptable to Tenant in scope and detail ("Tenant Finish Work"), it being understood that Landlord's required "Tenant Finish Work" shall be limited to amounts determined in Landlord's discretion to be normal tenant finish work and that Landlord's financial contribution to said work shall in no event exceed the Tenant Finish Work Allowance Amount (as defined below). It is agreed that the design and installation of the HVAC system in the Building shall be included in the Tenant Finish Work. The cost of the Tenant Finish Architect shall be included in the Tenant Finish Work Allowance Amount provided by Landlord. The Tenant Finish Architect shall be responsible for the development, completion and submission of certain design and construction documentation for Tenant's and Landlord's review and approval as set forth herein. Tenant hereby approves Lee Architectural Associates as the Tenant Finish Architect.

(b) The Tenant Finish Architect shall meet with Tenant to determine Tenant's space requirement program. Tenant's space requirement program shall include a determination of Tenant's general space requirements, Tenant's specific functional and organizational space requirements, special lighting, electrical and security requirements, preferred locations and configurations of offices, work rooms, manufacturing requirements, conference rooms, reception areas, file rooms and other rooms, and a determination of any other specialized Tenant requirements.

(c) The Tenant Finish Architect shall complete the plans, drawings, and specifications ("Tenant Construction Documents") necessary and required to implement the Tenant Finish Work. Tenant Construction Documents shall be in compliance with and contain all information necessary to obtain the permits and licenses required to perform the Tenant Finish Work.

Section 27. TENANT FINISH WORK.

(a) Tenant hereby approves and Landlord consents to the use of Boyle Associates, or such other contractor as may be approved by Tenant, as the Tenant Finish Work contractor. Within two weeks after receiving the Tenant Construction Documents, Boyle Associates will develop a not-to-exceed construction cost for the entire Tenant Finish Work.

(b) Landlord shall pay the Tenant Finish Work Allowance Amount towards the cost of the Tenant Finish Work for the Leased Premises. Tenant shall pay for the balance of the cost of the Tenant Finish Work for the Leased Premises. Such amounts shall be payable as follows:

(1) Upon receipt and approval by Landlord and Tenant of the not-to-exceed figure for the Tenant Finish Work for the Leased Premises, Landlord and Tenant shall open a joint checking account requiring the signatures of both Landlord and Tenant on checks. Landlord shall deposit the Tenant Finish Work Allowance Amount into said account, and Tenant will deposit an amount equal to the not-to-exceed figure less Tenant Finish Work Allowance Amount, in each case within ten (10) days of the acceptance of the not-to-exceed figure except as otherwise mutually agreed by Landlord and Tenant.

(2) All invoices for the Tenant Finish Work, upon approval by Boyle Associates and Lee Architectural Associates, shall be delivered to Landlord for review with Tenant and approval by both Landlord and Tenant.

(3) Upon approval of the invoices, Landlord and Tenant shall jointly execute a check and deliver the same for payment of such invoices.

(4) Tenant shall be responsible for the cost of any Tenant Finish Work in excess of Tenant Finish Work Allowance Amount regardless of the reason for such overage. In the event the total cost of the Tenant Finish Work is in excess of Tenant Finish Work Allowance Amount but less than the total amount deposited in the joint account, the balance remaining in the account upon completion of the Tenant Finish Work shall be delivered to Tenant. In the event the total cost of the Tenant Finish Work is less than the Tenant Finish Work Allowance Amount, an amount equal to Tenant Finish Work Allowance Amount less the total cost shall be refunded to Landlord and the balance remaining in the account, if any, shall be delivered to Tenant. The provisions of this Section 27(b)(4) shall survive the expiration or earlier termination of this Lease.

(c) The term "Tenant Finish Work Allowance Amount" shall mean the excess, if any, of \$4 million over the total amount of the Final Construction Budget approved by the parties in accordance with Section 1(c) of this Lease and shall be set forth in the Revised Exhibit B adopted pursuant to Section 1(d) of this Lease.

(d) Landlord shall cause all Tenant Finish Work to be done in a good and workmanlike manner. Subject to force majeure, Landlord shall cause the Tenant Finish Work to be

carried forward expeditiously and with adequate work forces so as to achieve Substantial Completion of the Leased Premises on or before the Anticipated Commencement Date.

(e) Landlord shall leave the Leased Premises, upon completion of all construction, in a broom-swept and fully serviceable fashion.

(f) If, within one (1) year after the date of Substantial Completion of the Tenant Finish Work, any of Tenant's Finish Work is reasonably found by Tenant to be not in substantial accordance with the requirements of the Tenant Construction Documents, Landlord shall cause it to be corrected promptly after receipt of written notice from Tenant to do so, provided however, that Landlord's financial contribution toward the Tenant Finish Work shall not exceed the Tenant Finish Work Allowance Amount. Landlord's obligation under this paragraph shall survive Tenant's occupancy of the Leased Premises upon Substantial Completion. Tenant shall give Landlord notice promptly after discovery of the condition.

(g) Changes in the Tenant Finish Work may be accomplished only by change order signed by Landlord and Tenant ("Change Order"). Changes in the Tenant Finish Work shall be performed in conformity with the provisions of this section and the provisions of the Change Order.

Tenant shall have the right to request changes in the Tenant Finish Work by making a written request to Landlord describing the requested change, provided that Landlord shall not be obliged to execute the requested change unless a Change Order is issued with respect thereto.

A Change Order is a written instrument prepared by the Tenant Finish Contractor and signed by Landlord and Tenant stating their agreement upon all of the following: (a) a change in the Tenant Finish Work; (b) the extent of the adjustment in the cost of the Tenant Finish Work, and which party shall pay; and (c) the extent of the adjustment in the date of Substantial Completion of the Tenant Finish Work, if any.

Section 28. TENANT'S SEPARATE CONTRACTORS. At Tenant's sole cost and expense, Tenant may perform work with separate contractors, prior to the Commencement Date, subject to the following requirements:

(a) The work shall be limited to computer, network installation, telephone installations, process gas line installation, DI water system installation, and furniture, carpet, and equipment installations.

(b) Tenant shall obtain Landlord's prior written approval of the contractor and of the specified work to be performed, which approval will not be unreasonably withheld or delayed, and shall furnish Landlord with adequate design documentation of such work.

(c) As soon as practicable, Tenant shall furnish to Landlord, in writing, the names of the persons or entities proposed to perform Tenant's separate work. Tenant shall not contract with any person or entity with whom Landlord has reasonable objection.

(d) The entry by Tenant and Tenant's contractors, workmen and mechanics into the Leased Premises shall be deemed to be under all of the terms, covenants, conditions and provisions of this Lease, except the covenant to pay Base Rent and Additional Rent.

(e) Landlord shall not be liable to Tenant in any way for any injury or death to any person or persons, loss or damage to any of the leasehold improvements or installations made in the Leased Premises or loss or damage to property placed therein or thereabout, the same being at Tenant's sole risk, except for any injury or damage caused in whole or in part by the negligence or willful misconduct of Landlord, its employees, agents or independent contractors. In addition to any other conditions or limitations on such license to enter the Leased Premises prior to the Commencement Date, Tenant expressly agrees that none of its agents, contractors, workmen, mechanics, suppliers or invitees shall enter the Leased Premises prior to the Commencement Date unless and until each of them shall furnish Landlord with satisfactory evidence of Comprehensive General Liability insurance coverage and financial responsibility.

(f) Landlord shall endeavor to afford Tenant's separate contractors reasonable access to work areas at reasonable times consistent with the restrictions herein, provided, however, that the reasonable decision of Landlord as to such access shall be final.

#### Section 29. SUBSTANTIAL COMPLETION.

(a) As used herein, the Leased Premises shall be considered "Substantially Complete" as of the date when construction of the Building, Common Areas and Tenant Finish Work has been substantially completed in conformity with the Floor Plans of the Building and the Leased Premises annexed as Exhibit A hereto and the Tenant Construction Documents, in all aspects necessary to permit Tenant to occupy and utilize the Leased Premises for the uses permitted by this Lease, subject to minor punch list items.

(b) Immediately prior to occupancy of the Leased Premises by Tenant, Tenant and Landlord jointly shall inspect the Building and the Leased Premises in order to determine and record their condition and to prepare a comprehensive list of items that have not been completed (or which have not been correctly or properly completed) in conformity with the building plans and specifications set forth in Exhibit A and Tenant's Construction Documents ("Punch List Item"). Thereafter Landlord shall proceed promptly to complete and correct all Punch List Items.

Section 30. TENANT DELAYS DEFINED. A "Tenant Delay" is any delay in the completion of Tenant's Construction Documents or in preparation of the Leased Premises for occupancy, caused by an act or omission of Tenant, including, without limitation, the following:

(a) Tenant's failure to submit in a timely manner as provided herein approved Tenant's Construction Documents.

(b) Delay caused by revisions to approved Tenant's Construction Documents requested by Tenant after submission to Landlord.

(c) Delay in the commencement of Tenant Finish Work resulting from Tenant's failure to authorize the award of the Tenant Construction Contracts in a timely manner as provided herein.

(d) Delay caused by the performance or nonperformance of any work or activity by Tenant or any of its employees, agents or separate contractors or consultants, provided Landlord gives Tenant written notice of such delay as promptly as possible, but in any event within (30) days following any such delay.

(e) Delay caused by Tenant requested changes in the Tenant Finish Work as established by written Change Order signed by Landlord and Tenant.

Section 31. DELAY IN POSSESSION. In the event that Substantial Completion of the Leased Premises is delayed by any Tenant Delay, then for purposes of determining the Commencement Date as provided in Section 2 hereof, the date of Substantial Completion shall be adjusted by subtracting one (1) day from the actual date of Substantial Completion of the Leased Premises for each day of Tenant Delay.

Section 32. OPTIONS TO RENEW; ADDITIONAL SPACE; RIGHT OF FIRST REFUSAL.

(a) Landlord hereby grants Tenant one (1) option to renew the term of the Lease, upon the following terms and conditions:

(1) The renewal term shall be for five (5) years, commencing on the day following the expiration date of the initial term;

(2) Tenant must exercise the option, if at all, upon at least ninety (90) days' written notice to Landlord, prior to the expiration date of the initial term, as the case may be;

(3) At the time Tenant delivers its notice of election to renew to Landlord, this Lease shall be in full force and effect and Tenant shall not then be in default under any of the material terms and conditions of the Lease beyond any applicable cure period;

(4) The renewal term shall be upon the same terms, covenants and conditions contained in this Lease, except that the annual Base Rent for the renewal term shall be the rent set forth in Exhibit H attached hereto;

(5) Tenant shall continue to pay Tenant's Space Ratio of all costs and expenses of operation as set forth in Section 4 above;

(6) In the event that Tenant assigns this Lease at any time prior to the end of the tenth (10th) Lease Year, there shall be no further right or privilege to renew the term of this Lease; and

(7) If Tenant exercises the option to renew, Landlord and Tenant shall execute and deliver an amendment to this Lease confirming the commencement and expiration dates of the renewal term, the Base Rent payable by Tenant during the renewal term, and any other relevant terms and conditions agreed upon by Landlord and Tenant applicable during the renewal term.

(b) (1) If, during the period commencing after the date hereof and through to the end of the term or any renewal term, Landlord shall construct additional space and or buildings upon the Land that are not part of the Building and Landlord shall have received a bona fide offer or request for proposal from a third party (other than Landlord or any person or entity affiliated with Landlord) to lease any such additional space, other than the space then (or at any prior time) under lease to Tenant (or any affiliate or subtenant of Tenant) pursuant to this Lease or otherwise (the additional space is referred to herein as "Additional Space"), or Landlord shall make an offer to such third party to lease the Additional Space, provided that there has been no Event of Default (or event or condition which, with the passage of time or giving of notice, or both, would constitute an Event of Default) that has occurred and is continuing at such time, Landlord shall notify Tenant that it has made an offer or received an offer or request for proposal for such space. In the event Landlord and such third party agree on the terms for leasing the Additional Space, then promptly following such agreement (which shall be subject to Tenant's rights under this Section 32(b)(1)), Landlord shall notify Tenant of such occurrence, in writing (the "Expansion Notice"), including the proposed rental rate, lease term, renewal(s) and other material terms, if any, contained in such agreement with the third party for leasing the Additional Space. The Expansion Notice shall also contain the terms upon which Landlord will be willing to lease the portion of the Additional Space subject to such agreement, to Tenant (the "Offered Terms"), including, without limitation, the term, any renewal term and rental rate (it being understood that the Offered Terms will be fair market terms, but may be different than but in no event less favorable to Tenant than the terms applicable to the third party). Tenant shall have thirty (30) days from receipt of Landlord's Expansion Notice to exercise its option to lease the portion of the Additional Space subject to such offer (on the Offered Terms), by written notice to Landlord. The parties further agree that once any space in the Additional Space is leased to any person or entity other than Landlord or any person or entity affiliated with Landlord (any such tenant being referred to herein as the "New Tenant" and such portion of the Additional Space leased to the New Tenant being referred to as the "New Tenant Space"), and provided that Landlord has complied with the provisions in this Section 32 (b)(1) with respect to such space and the terms under which the New Tenant Space is leased are no more favorable to the New Tenant than the Offered Terms, Tenant's rights described in this Section 32(b)(1) with respect to the New Tenant Space shall expire, and Landlord shall have no further obligations to Tenant with respect to the New Tenant Space, except as expressly provided in Section 32(b)(2) hereof.

(2) If, during the period commencing after the date hereof and through to the end of the term or renewal term any New Tenant provides written notice to Landlord that it is vacating any New Tenant Space and ending its lease of such space (and is not subleasing or assigning such space to another entity) or the lease of such space otherwise terminates or expires, and provided that there has been no Event of Default (or event or condition which, with the passage of

time or giving of notice, or both, would constitute an Event of Default) that has occurred and is continuing at such time, Landlord shall notify Tenant of the same, and the terms upon which Landlord will be willing to lease the New Tenant Space to Tenant (the "Offered Lease Terms"), including, without limitation, the term, any renewal term and the rental rate (it being understood that the Offered Lease Terms will be fair market terms and in no event less favorable to Tenant than the terms applicable to the New Tenant), and that Tenant may elect to lease the New Tenant Space on such terms when such space becomes available. Tenant shall have thirty (30) days from receipt of Landlord's notice to exercise its option to lease such New Tenant Space (on the Offered Lease Terms), by written notice to Landlord. In the event that Tenant does not exercise its right with respect to such New Tenant Space, Tenant's rights described in this Section 32(b)(2) with respect to such New Tenant Space shall expire, and Landlord shall have no further obligations to Tenant with respect to such New Tenant Space; provided that Landlord has complied with this Section 36(b)(2) and does not thereafter lease the New Tenant Space to a third party on terms more favorable than the Offered Lease Terms.

(3) If requested in writing by Tenant, Landlord shall, promptly following its receipt of such request, provide Tenant with the then current tenants at the Leased Premises and the scheduled expiration dates of their respective leases.

(4) Notwithstanding anything contained in this Lease, the parties agree that the provisions of Sections 32(b)(1) and 32(b)(2) hereof shall not be applicable, and shall be of no force or effect, if Tenant (and/or any affiliate of Tenant) at any time is leasing the entire portion of the Leased Premises and all leasable portions of any Additional Space pursuant to this Lease or otherwise.

(c) If, during the period commencing after the date hereof and through to the end of the term or the renewal term, Landlord shall have made a bona fide offer to or received a bona fide offer or request for proposal from a third party (other than Landlord or any entity or person affiliated with Landlord) to sell the Leased Premises, the Additional Space or any part thereof, Landlord shall notify Tenant of such occurrence. In the event Landlord and such third party reach agreement on the terms of such sale (which agreement shall be subject to Tenant's rights under this Section 32(c)), then promptly following the reaching of such agreement, Landlord shall notify Tenant of such occurrence, in writing (the "Sale Notice"), including the proposed terms of such sale. The Sale Notice shall also contain the essential terms upon which Landlord will be willing to sell the Lease Premises, the Additional Space or the portion thereof, as the case may be, to Tenant (the "Offered Sale Terms") (it being understood that the Offered Sale Terms shall be fair market terms and in no event less favorable to Tenant than the terms of sale agreed to with such third party). Tenant shall have thirty (30) days from receipt of Landlord's Sale Notice to exercise its right of first refusal (on the Offered Sale Terms), by written notice to Landlord. The parties further agree that once any sale to any person or entity other than Landlord or any person or entity affiliated with Landlord (any such purchaser being referred to herein as the "New Owner") has occurred, Tenant's rights described in this Section 32(c) with respect to the right of first refusal shall expire; provided



that Landlord has complied with the provisions in this Section 32(c) with respect to such sale and Landlord does not sell to the New Owner on terms more favorable than the Offered Sale Terms.

Section 33. PURCHASE OPTION. At any time on or prior to the end of the tenth (10th) Lease Year, Tenant shall have the right, privilege and option (the "Option"), upon the terms and conditions hereinafter set forth, to purchase the Leased Premises. The Option shall be exercised by Tenant giving Landlord written notice of its intent to exercise the Option (the "Option Notice"). The following terms and conditions shall apply to a sale made pursuant to exercise of the Option:

(a) Closing on the sale of the Leased Premises pursuant to the Option (the "Closing") shall be made by Landlord and Tenant within ninety (90) days after the Option Notice is given to Landlord, on such date as Tenant shall specify as the date of the Closing (the "Closing Date"). The Closing shall occur at such place in Bethlehem, Pennsylvania, as Tenant shall specify in writing to Landlord.

(b) The purchase price shall be paid at the Closing by certified check, cashier's check or title insurance company check. The purchase price for the Leased Premises shall be calculated as follows: (i) as of the Closing Date, the aggregate of (A) the Equity Return (as defined below), plus

-----  
(B) the then current unpaid principal balance of all Landlord's loan(s) or other borrowings incurred for the purpose of acquiring the Leased Premises and constructing, improving, renovating and maintaining the Building and Common Areas plus accrued but unpaid interest, pre-payment penalties, fees, costs and

-----  
similar expenses of and from Landlord's lender(s); then (ii) the sum of subparagraph (i) shall be reduced by the amount of the security deposit then  
-----  
held by Landlord pursuant to Section 47 of the Lease.

(c) For purposes hereof, the term "Equity Return" shall be determined pursuant to the following formula:

$$ER = LEC \times (1.5 + (0.05 \times LY))$$

"ER" means the Equity Return payable in connection with the exercise of the Option.

"LEC" means the final Landlord Equity Contribution as set forth in the Revised Exhibit B to this Lease.

"LY" means the Lease Year in which the Option is exercised by Tenant, provided that LY shall in no event exceed 10.

(d) Within sixty (60) days after the Commencement Date and thereafter within sixty (60) days after the end of each calendar year, Landlord shall deliver to Tenant an amortization

schedule showing the then current balance of its loan(s) then secured by mortgage(s) on the Leased Premises plus accrued interest, if any. Landlord shall give Tenant at least thirty (30) days advance written notice of any refinancing of any of the loans or borrowings referred to in Section 33(b)(i)(B). If Tenant delivers an Option Notice to Landlord during that thirty (30) day period, Landlord agrees not to refinance such loans or borrowings.

(e) Conveyance of the Leased Premises shall be by special warranty deed to Tenant, together with an assignment of all other existing tenant leases, if any, on any portion of the Leased Premises. Title shall be a good and marketable fee simple title, free and clear of all liens and encumbrances, and shall be insurable as such at regular rates by a title insurance company maintaining an office in Allentown or Bethlehem, Pennsylvania.

In the event that a good and marketable title, as provided in the previous paragraph, cannot be given by Landlord to Tenant, the Tenant may accept the title without insurance or subject to exceptions or Tenant may, by written notice to Landlord, rescind its exercise of the Option.

Real estate taxes shall be apportioned between the parties as of the Closing Date on a fiscal year basis. All rent under the Lease and any other tenant leases, and all sewer rent, water rent and other utility charges shall be apportioned as of the Closing Date on the basis of the then current term. Municipal assessments shall be the responsibility of the Tenant.

(f) The costs and expenses of sale and conveyance shall be borne by the parties as follows:

(i) Landlord shall pay for the preparation of and acknowledgment of the deed.

(ii) Tenant shall pay all Pennsylvania and local real estate transfer taxes.

(iii) All other expenses of conveyance shall be paid by the party incurring them.

(g) Provided the Closing occurs, Tenant shall be responsible for the costs of any work done or ordered to be done by notice from any duly constituted authority upon or about the Leased premises after the date of the exercise of the Option.

(h) In the event that Tenant assigns this Lease at any time prior to the end of the tenth (10<sup>th</sup>) Lease Year, there shall be no further right or privilege to exercise the Option to purchase the Leased Premises in accordance with this Section 33 unless Landlord agrees in writing that the Option shall be exercisable by the assignee.

(i) The parties hereto shall execute and Tenant shall record, at its sole cost and expense, a Memorandum of Lease substantially in the form as attached hereto as Exhibit I.

Section 34. PROJECT NAME AND SIGNAGE. During the term of this Lease, Tenant shall have the right to display its name highest on a "monument sign" located near the entrance to Land (to the extent permitted by applicable zoning ordinances and regulations). No other signage shall be permitted on the Leased Premises without the prior written approval of Landlord.

Section 35. ARBITRATION. Any controversy or claim arising out of or related to this Lease (other than arising under paragraphs 21 and 22 hereof) shall be settled by arbitration in Northampton County, Pennsylvania, in accordance with the Rules of the American Arbitration Association, and the arbitrator's award shall be binding on the parties and judgment upon such award may be entered in any court having jurisdiction thereof. If Landlord and Tenant are unable to agree on the resolution of a controversy or claim, either party may five (5) days thereafter, by written notice to the other and to the American Arbitration Association, submit the dispute to arbitration for conclusive and final determination. No arbitration shall include, by consolidation or joinder or in any other manner, parties other than the Landlord and the Tenant, including Tenant's assigns and subtenants.

Section 36. NOTICES. All notices or demands under this Lease shall be in writing and shall be given or served by either Landlord or Tenant to or upon the other, either personally or by Registered or Certified Mail, Return Receipt Requested, postage prepaid, or by Federal Express or any other national overnight delivery service, and addressed as follows:

(a) To Landlord:

Tech III Partners, LLC  
Attn: Michael J. Gausling  
1512 Colesville Road  
Bethlehem, Pennsylvania 18015

(b) To Tenant:

OraSure Technologies, Inc.  
Attn: Ronald H. Spair, CFO  
150 Webster Street  
Bethlehem, Pennsylvania 18015

All notices and demands shall be deemed given or served upon the date of receipt thereof if by personal delivery, two (2) business days following mailing if by certified mail, and one (1) business day following sending if by any national overnight delivery. Either Landlord or Tenant may change its address to which notices and demands shall be delivered or mailed by giving written notice of such change to the other as herein provided.

Section 37. BROKERAGE. Except as otherwise disclosed in writing to Landlord, Tenant warrants to Landlord that Tenant dealt and negotiated solely and only with Landlord for this Lease and with no other broker, firm, company or person.

Tenant hereby agrees to indemnify, defend and hold Landlord harmless from and against any and all claims, suits, proceedings, damages, obligations, liabilities, counsel fees, costs, losses, expenses, orders and judgments imposed by or asserted against Landlord by reason of the falsity or error of Tenant's warranty.

Section 38. FORCE MAJEURE. Landlord and Tenant shall each be excused for the period of any delay in the performance of any of its obligations under this Lease, except for Tenant's obligations to pay Base Rent and Additional Rent, when prevented from so doing by cause or causes beyond their control, which shall include, without limitation, all labor disputes, civil commotion, or Acts of God.

Section 39. SUCCESSORS. The respective rights and obligations of Landlord and Tenant under this Lease shall bind and shall inure to the benefit of Landlord and Tenant and their legal representatives, heirs, successors and assigns, provided, however, that no rights shall inure to the benefit of any successor of Tenant unless Landlord's written consent to the transfer, if any, to such successor has first been obtained in accordance with Section 11(a). The term "Landlord" as used in this Lease means only the owner or the mortgagee in possession of the Leased Premises for the time being. In the event of any sale (including any sale-leaseback) of the Leased Premises, Landlord shall be and hereby is entirely freed and relieved of all of its covenants, obligations and liability hereunder, provided the transferee assumes all of Landlord's obligations hereunder. This subsection shall be applicable to each owner from time to time, and shall not be limited to the first owner of the Leased Premises.

Section 40. GOVERNING LAW. This Lease shall be construed, governed and enforced in accordance with the internal laws of the Commonwealth of Pennsylvania, without regard to conflict of law principles.

Section 41. SEVERABILITY. If any provisions of this Lease shall be held to be invalid, void or unenforceable, the remaining provisions of this Lease shall in no way be affected or impaired and such remaining provisions shall continue in full force and effect.

Section 42. CAPTIONS. Any headings preceding the text of the several sections of this Lease are inserted solely for convenience of reference and shall not constitute a part of this Lease or affect its meaning, construction or effect.

Section 43. GENDER. As used in this Lease the word "person" shall mean and include, where appropriate, an individual, corporation, partnership or other entity; the plural shall be substituted for the singular, and the singular for the plural, where appropriate; and words of any gender shall mean to include any other gender.

Section 44. EXHIBITS. Attached to this Lease and made part hereof are Exhibits A through I.

Section 45. ENTIRE AGREEMENT. This Lease, including the Exhibits contains the agreements, conditions, understandings, representations and warranties made between

Landlord and Tenant with respect to the subject main hereof, and may not be modified other than by an agreement in writing signed by both Landlord and Tenant or their respective successors in interest.

Section 46. CORPORATE AUTHORITY. Each individual executing this Lease on behalf of Tenant or Landlord represents and warrants that he is duly authorized to execute and deliver this Lease on behalf of said party in accordance with a duly adopted resolution of the Board of Directors of said party or in accordance with the By-Laws or other similar document of said party, and that this Lease is binding upon said party in accordance with its terms.

Section 47. SECURITY DEPOSIT. As additional security for the full and prompt performance by Tenant of all of the terms and covenants of this Lease, Tenant has deposited with Landlord the sum of Forty Thousand Dollars (\$40,000) (the "Deposit") which shall not constitute rent for any month (unless so applied by Landlord, at Landlord's discretion, on account of Tenant's default). Tenant shall upon demand restore any portion of the Deposit which may be applied by Landlord to the cure of any default by Tenant hereunder. To the extent Landlord has not applied said sum on account of a default, the Deposit shall be returned (without interest) to Tenant promptly at termination of this Lease. Notwithstanding anything to the contrary contained herein or in any law or statute now existing or hereafter passed: (i) Tenant shall not be entitled to any interest on the Deposit; (ii) Landlord shall not be obligated to hold the Deposit in trust or in a separate account, and (iii) Landlord shall have the right to commingle the Deposit with its other funds.

Section 48. WINDOW TREATMENTS. All window treatments, door coverings and other exterior decorating and interior decorating visible from the outside of the Leased Premises shall be installed as determined by Tenant and at Tenant's sole expense, and shall be subject to Landlord's prior approval, which approval shall not be unreasonably withheld or delayed.

Section 49. LIABILITY OF LANDLORD. Landlord, and (in case Landlord shall be a joint venture, limited liability company, partnership, tenancy-in-common, association or other form of joint ownership) the members of any joint venture, limited liability company, partnership, tenancy-in-common, association or other form of joint ownership, shall have absolutely no personal liability with respect to any provision of this Lease, or any obligation or liability arising therefrom or in connection therewith. Tenant shall look solely to the equity of the Landlord in the Leased Premises or to any insurance which Landlord has obtained with respect to the Leased Premises or Landlord's liability for the satisfaction of any remedies of Tenant in the event of a breach by Landlord of any of its obligations. Such exculpation of liability shall be absolute and without any exception whatsoever.

IN WITNESS WHEREOF, Landlord and Tenant have caused this Lease to be duly executed the day and year first above written.

LANDLORD:

WITNESS:

TECH III PARTNERS, LLC

By: /s/ R. Sam Niedbala

By: /s/ Michael J. Gausling

-----  
Name: R. Sam Niedbala  
Title:

-----  
Name: Michael J. Gausling  
Title: Managing Member

TENANT:

ATTEST:

ORASURE TECHNOLOGIES, INC.

By: /s/ Jack E. Jerrett

By: /s/ Ronald H. Spair

-----  
Name: Jack E. Jerrett  
Title: Secretary

-----  
Name: Ronald H. Spair  
Title: Executive Vice President  
and Chief Financial Officer

(Corporate Seal)

EXHIBIT A

-----

BUILDING/LEASED PREMISES FLOOR PLANS

-----

Document Follows

EXHIBIT B

-----

PROJECT BUDGET

-----

Boyle - Basic Construction	\$3,015,000
Land Purchase	436,000
Interest Payments	50,000
Banking --Commitment Fees	16,000
Insurance Expense	8,000
Miscellaneous	25,000
	-----
Subtotal	\$3,550,000
Tenant Finish Work Allowance	450,000
	-----
	\$4,000,000
Landlord Equity Contribution	\$ 800,000
Landlord Borrowing Amount	3,200,000
	-----
Total	\$4,000,000



EXHIBIT C

-----

PROJECT BUDGET AMENDMENT

-----

THIS PROJECT BUDGET AMENDMENT (this "Amendment") is made this \_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_, by and between TECH III PARTNERS, LLC, a Pennsylvania limited liability company, having an office at 1512 Colesville Road, Bethlehem, Pennsylvania 18015 ("Landlord"), and ORASURE TECHNOLOGIES, INC., a Delaware corporation, having its principal offices at 150 Webster Street, Bethlehem, Pennsylvania 18015 ("Tenant"), with reference to the following background. Capitalized terms used herein have the meanings assigned to them in the Lease (defined below).

WHEREAS, by Commercial Lease dated \_\_\_\_\_ ("Lease"), Landlord demised and leased unto Tenant, and Tenant leased and took from Landlord, for the term, at the rent and upon the terms and conditions therein set forth, certain Leased Premises known as \_\_\_\_\_, and located at \_\_\_\_\_, Bethlehem, Pennsylvania, which Leased Premises are more particularly described on Exhibit A annexed to the Lease; and

-----

WHEREAS, Section 1(d) of the Lease provides that when the final Project Budget set forth in Exhibit B to the Lease has been agreed to by the parties, Landlord and Tenant shall execute and deliver this Amendment setting forth the Revised Exhibit B containing such final Project Budget;

NOW THEREFORE, Landlord and Tenant, intending to be legally bound hereby, agree as follows:

1. Exhibit B to the Lease is hereby amended and restated as set forth in the Revised Exhibit B attached to this Amendment.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their duly authorized officers or representatives as of the day and year first above written.

WITNESS:  
  
By: \_\_\_\_\_  
Name:

TECH III PARTNERS, LLC  
  
By: \_\_\_\_\_  
Name:  
Title: Managing Member

ATTEST:

ORASURE TECHNOLOGIES, INC.

By: \_\_\_\_\_

Name:

Title: (Assistant) Secretary

By: \_\_\_\_\_

Name:

Title: Executive Vice President  
and Chief Financial Officer

(Corporate Seal)

REVISED EXHIBIT B

-----

(As Revised Pursuant to Section 1(d) of the Lease)

Document Follows

EXHIBIT D

-----

LEASE COMMENCEMENT DATE AMENDMENT

-----

THIS LEASE COMMENCEMENT DATE AMENDMENT TO LEASE (this "Amendment") is made this \_\_\_ day of \_\_\_\_\_, \_\_\_\_\_, by and between TECH III PARTNERS, LLC, a Pennsylvania limited liability company, having an office at 1512 Colesville Road, Bethlehem, Pennsylvania 18015 ("Landlord"), and ORASURE TECHNOLOGIES, INC., a Delaware corporation, having its principal offices at 150 Webster Street, Bethlehem, Pennsylvania 18015 ("Tenant"), with reference to the following background. Capitalized terms used herein have the meanings assigned to them in the Lease (defined below).

WHEREAS, by Commercial Lease dated \_\_\_\_\_ ("Lease"), Landlord demised and leased unto Tenant, and Tenant leased and took from Landlord, for the term, at the rent and upon the terms and conditions therein set forth, certain Leased Premises known as \_\_\_\_\_, and located at \_\_\_\_\_, Bethlehem, Pennsylvania, which Leased Premises are more particularly described on Exhibit A annexed to the Lease; and

-----

WHEREAS, Section 2 of the Lease provides that when such dates have been determined, Landlord and Tenant shall execute and deliver an instrument setting forth the Commencement Date and Expiration Date of the term if the Lease;

NOW THEREFORE, Landlord and Tenant, intending to be legally bound hereby, agree as follows:

1. The Commencement Date of the Lease is \_\_\_\_\_, \_\_\_\_\_; the Expiration Date of the Lease will be \_\_\_\_\_. \_\_\_\_\_, unless extended or earlier terminated as provided in the Lease.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their duly authorized officers or representatives as of the day and year first above written.

WITNESS: TECH III PARTNERS, LLC

By: \_\_\_\_\_  
Name:

By: \_\_\_\_\_  
Name:  
Title: Managing Member

ATTEST:

ORASURE TECHNOLOGIES, INC.

By: \_\_\_\_\_

Name:

Title: (Assistant) Secretary

By: \_\_\_\_\_

Name:

Title: Executive Vice President  
and Chief Financial Officer

(Corporate Seal)

EXHIBIT E

-----

RULES AND REGULATIONS

-----

Document Follows

EXHIBIT E

-----

BETHLEHEM TECHNOLOGY CENTER III

-----

Rules and Regulations

1. Landlord reserves the right to control and operate the Common Area.

2. Tenant shall not obstruct the entrances, exits, corridors, elevators and stairways of the Building and Tenant shall not use or permit their use for any purpose other than ingress to or egress from the Leased Premises. Fire exits are for emergency use only.

3. Landlord may, from time to time, adopt appropriate procedures for the security or safety of the Building and Tenant shall comply with such procedures. Landlord may refuse admission to the Building to any person not properly identified, or to any person whose presence, in Landlord's judgment, would be prejudicial to the safety, character, reputation and interests of the Building or its tenants. Landlord may limit or restrict access to the Building outside Business Hours (as herein defined) and Tenant shall comply with such off-hours procedures as Landlord may reasonably establish. Landlord shall in no way be liable to any Tenant for damages or loss arising from the admission, exclusion or ejection of any person to or from the Building or the Leased Premises.

4. Tenant shall not install awnings, shades or other coverings on or in any window of the Building or on any terrace. Tenant shall use only such window blinds as Landlord has approved and Tenant shall not remove them. Tenant shall keep window sills in the Leased Premises in a neat and orderly appearance and shall not hang items from the ceilings so as to be visible from the exterior of the Building.

5. Tenant shall not use or permit the use of hand trucks in the Common Area unless they are equipped with rubber tires and side guards.

6. The entrance doors to the Leased Premises shall not be left open at any time and shall be locked when Tenant is not in the Leased Premises.

7. Tenant shall not make or permit to be made any noise, including the playing of musical instruments, radio or television, which in the Landlord's judgment may disturb other tenants. Tenant shall not bring into or keep in the Leased Premises anything which may impair or interfere with any of the Building services, heating or cleaning of the Building, including, without limitation, ventilating, air conditioning, electrical or other equipment. Tenant shall not bring any dangerous, inflammable,

combustible or explosive objects or materials into the Building or any Common Area except as approved by the Landlord.

8. Except with the Landlord's prior written approval, Tenant shall not discharge or permit any acids, vapors or other materials to be discharged into the waste lines, vents or flues of the Building. Tenant shall not use the water, wash closets and other plumbing fixtures in or servicing the Leased Premises for any purpose other than for which they were designed and constructed nor shall Tenant deposit any sweepings, rubbish, rags, acids or other foreign substances therein. Tenant shall be liable for any damage resulting from negligence or misuse by Tenant, its agents, employees, servants, permitted subtenants and assignees, contractors or subcontractors, visitors or licensees.

9. Tenant may not install or maintain any sign, advertisement or notice in or at the Land or visible from the outside of the Land without the prior written consent of the Landlord. If Tenant installs such sign, advertisement or notice, Landlord may remove same at Tenant's expense. Tenant may identify its business name by lettering on the entrance door to the Leased Premises pursuant to the terms of the Lease. Tenant may display its name, location and such reasonable number of the principal officers and employees of Tenant as Landlord in its sole discretion may approve in the Building directory provided by Landlord in the first-floor Lobby of the Building.

10. Neither the Leased Premises nor the Common Area shall be used by Tenant, any affiliates thereof or any of their respective employees, representatives, agents or servants, at any time, in any manner prohibited by the applicable zoning laws.

11. Tenant shall be responsible for providing electricity and other utility services (excluding HVAC) for Landlord's agents, employees, representatives, servants or contractors who are performing janitorial and cleaning services or repairs or alterations to the Leased Premises.

12. Tenant shall not in any way deface any part of the Building or the Leased Premises. Tenant shall not install linoleum or other similar floor covering without affixing an interlining of builder's deadening felt to the floor by paste or other water soluble material; the use of cement or similar adhesive is expressly prohibited. Tenant shall not place equipment, desks, files or other heavy objects on any trench header in the floor in the Leased Premises.

13. Tenant shall not place any additional locks or bolts on the doors of the Leased Premises nor shall Tenant change or replace any existing locks. Upon Tenant's request, new locks will be installed or changed by Landlord at Tenant's expense; any new locks will remain operable by Landlord's Master Key. Upon termination of the tenancy, Tenant shall deliver to Landlord all keys to the Leased Premises and Building which Landlord has furnished to Tenant. In the event of loss, Tenant shall pay to Landlord the cost of replacing the keys.

14. Canvassing, peddling, soliciting and distributing handbills or other written materials are prohibited in the Building.



15. Landlord may designate certain places in the Parking Area for visitor, reserved, handicapped or emergency parking.

16. Tenant, its employees, agents or servants, shall not conduct itself in any manner inconsistent with the character of the Building or which will impair the comfort and convenience of other tenants in the Building.

EXHIBIT F

-----

RESTRICTIVE COVENANTS

-----

Document Follows

EXHIBIT F

-----

RESTRICTIVE COVENANTS

-----

The Lease is subject to those restrictive covenants as set forth in that Deed from Bethlehem Steel Corporation and Bethlehem Development Corporation (hereinafter referred to collectively as the "Grantors") to Landlord (for the purposes of this Exhibit F, Landlord shall be referred to as the "Grantee") dated October 10, 2001 and recorded in the office of the Recorder of Deeds in and for Northampton County on October 12, 2001 in Deed Book Volume 2002-1, page 212661 et seq. (hereinafter referred to as the "Deed"). All capitalized terms used in this Exhibit F, if not otherwise defined herein, shall have the meanings as set forth in the Deed.

A. 1. Subject to the provisions of Paragraph 5 below, the Premises shall be used for a facility for technology-related purposes; except, that in

-----

the event such facility cannot be used for technology-related purposes, such facility may also be used- for commercial office purposes. Such facility, as to be used for the foregoing purposes, is hereby defined as the "Project".

2. Prior to the commencement of any construction on the Premises, the final architectural plans and specifications for the Project shall be submitted, in duplicate, to the Grantors for approval. Said architectural plans and specifications shall be consistent with the Architectural Design Guidelines and Criteria of the unrecorded document entitled "Bethlehem Works Declaration of Covenants, Conditions, Easements and Restrictions". The Grantors shall, within fifteen (15) days from the date said plans and specifications are received, either approve them, which approval shall not be unreasonably withheld, conditioned or delayed, or specify in writing its objections to them, failing which the Grantors shall be deemed to have approved them. If the Grantors shall raise objections to such plans or such specifications, the Grantee shall revise them accordingly and resubmit them, in duplicate, to the Grantors, in which event the Grantors shall have the same right to approve or to specify objections as on first submission. The Project shall be constructed in accordance with the approved plans and specifications. After the Grantors shall have given the abovementioned approval, the plans and specifications shall not be substantially amended.

3. If the Premises are sold prior to the commencement of construction of the Project, other than a sale in the context of a financing, all proceeds from such sale in excess of the purchase price stated herein shall be paid to the Grantors.

4. For a period of seven (7) years after commencement of normal business operations, the Premises may be used only for the above-mentioned purposes to the extent such uses are allowed by the provisions of applicable federal, state, and local laws, ordinances, rules and regulations. For purposes of this Paragraph 4, the term "normal business operations" shall mean the opening of the Project. After such seven (7) year period, the Premises may be used for any other purpose as may then be permitted under the above-mentioned unrecorded Declaration.

5. In no event shall the Premises or any part thereof be used for the following purposes:

(i) single family or multi-family dwellings or otherwise as a residence or dwelling quarters for any person or persons;

(ii) unpaved parks or unpaved playgrounds having playground equipment, including without limitation, swing sets and sandboxes, erected or installed on such parks or playgrounds;

(iii) campgrounds;

(iv) day care centers, nurseries, kindergartens, elementary and secondary schools or similar facilities;

(v) hospitals, nursing homes, shelters or similar facilities;

(vi) cemeteries; and

(vii) the planting and raising of plants and crops for human consumption.

6. Groundwater from beneath the surface of the Premises or any part thereof shall not be used for any purpose and no wells for the extraction thereof shall be installed, permitted or utilized on the Premises or any part thereof.

7. Any digging, excavating, grading, piledriving or other earthmoving activities on the Premises or any part thereof including, without limitation, the excavation or removal of asphalt, concrete, soil, or other ground cover and foundations and the digging of foundations for buildings and trenches for utility facilities, shall be conducted in compliance with all applicable federal, state and local laws, regulations and ordinances including, without limitation, those pertaining to the environment and those pertaining to human health and occupational safety. For purposes of the restrictions contained herein, laws, regulations and ordinances pertaining to the environment, human health and occupational safety shall be deemed to include, without limitation, all applicable laws, regulations and ordinances relating to worker health and occupational safety plans.

8. Without limiting the generality of Paragraph 7 above, if any asphalt, concrete, soil or other ground cover is excavated or removed from any part of the Premises, such asphalt, concrete, soil and other ground cover shall be stored, managed, transported and disposed of in compliance with all applicable federal, state and local laws, regulations and ordinances including,

without limitation, those pertaining to the environment and those pertaining to human health and occupational, safety.

9. If any asphalt, concrete, soil or other ground cover is excavated or removed from any part of the Premises, remaining soils or other materials in the area where such excavation or removal occurred shall either (a) be demonstrated to meet, by the sampling and analysis thereof or such other means as may then be generally accepted, all applicable federal, state and local laws, regulations and ordinances pertaining to the environment, human health and occupational safety, or (b) be covered with material that provides protection to the extent necessary to eliminate pathways of exposure to the underlying soil, which cover material shall consist of (1) new asphalt, (2) new concrete, (3) not less than twelve (12) inches of (A) clean soil, (B) clean fill (as defined by applicable laws and regulations) or (C) materials approved by the Commonwealth of Pennsylvania, Department of Environmental Protection or any successor agency thereto or (4) such other material that provides such protection to the extent necessary to eliminate pathways of exposure to and from the underlying soil (the materials referred to in subparagraphs (3) and (4) being herein defined as "Alternate Cover"). Such new asphalt, new concrete or Alternate Cover shall be placed on the Premises in the area where the excavation or removal occurred within such period of time as shall be prescribed by the worker health and occupational safety plan developed with respect to such excavation or removal, if such plan was required by applicable laws, regulations and ordinances, or as shall otherwise be protective of workers' health. All asphalt, concrete, soil or other ground cover, including Alternate Covers, located on the Premises on or 'after the date hereof shall be maintained by Grantee, its successors and assigns, in good and proper repair.

B. 1. The Grantors shall have the power to dedicate to the public (for public utilities) or to the City of Bethlehem that portion of the Premises shown as a sixty- (60-) foot wide public utility easement on said subdivision plan. In making such dedication, the Grantors may act in their own names or, at their option, may secure the joinder of the Grantee or the joinder of the successors in interest to the Grantee.

2. Upon such dedication, any private rights to use the property so dedicated in a manner inconsistent with the use of said property for public utilities or with the use of said property by the City of Bethlehem will terminate pro tanto, whether such rights arise from the existence or filing of a subdivision plan or by the grant contained in this Deed or otherwise, and the Grantee and its successors in interest shall thereafter use the property so dedicated only in a manner that is not inconsistent with the use of such property for public utilities or with the use of said property by the City of Bethlehem.

3. Any powers conferred upon the Grantors are intended to vest in the Grantors as the owners of adjacent and nearby lands, and they shall not pass by implication to the purchasers of the property from the Grantors. Nevertheless, the Grantors may by express assignment assign such powers.

EXHIBIT G

-----

DEED RESTRICTIONS

-----

Document Follows

EXHIBIT G

-----

DEED RESTRICTIONS

-----

The Lease is subject to those deed restrictions as set forth in that Deed from Bethlehem Steel Corporation and Bethlehem Development Corporation to Landlord dated October 10, 2001 and recorded in the office of the Recorder of Deeds in and for Northampton County on October 12, 2001 in Deed Book Volume 2002-1, page 212661 et seq. All capitalized terms used in this Exhibit G, if not otherwise defined herein, shall have the meanings as set forth in the Deed. The restrictions in the deed are as follows:

(1) unrecorded Articles of Agreement between Bethlehem Steel Company and the Borough of South Bethlehem dated May 5, 1913 relating to the construction of a storm sewer and other improvements;

(2) unrecorded Agreement between Bethlehem Steel Company and the City of Bethlehem dated December 8, 1941, relating to the maintenance and repair of storm water sewers and sanitary sewers, as amended by the unrecorded Agreement between the same parties dated July 11, 1945;

(3) Indenture between Bethlehem Steel Company and Philadelphia and New England Railroad Company and Bethlehem Authority dated August 30, 1950, and recorded in said Office in Miscellaneous Book Vol. 110 page 366, as amended by Partial Release between Bethlehem Steel Corporation and Bethlehem Authority dated February 3, 1987, and recorded in said Office in Miscellaneous Book Vol. 321, at page 1089, relating to an easement for a sanitary sewer pipeline;

(4) rights-of-way for existing storm sewer facilities contained in the Deed between Bethlehem Steel Corporation and Ralph A. Puerta and Robert J. Peartree dated July 24, 1986, and recorded in said Office in Deed Book Vol. 705, page 727;

(5) conditions, easements and restrictions that appear on the drawing entitled "Columbia Street Subdivision" dated November 6, 1986, last revised November 19, 1986, and recorded in said Office in said Office in Map Book 87, at page 33;

(6) rights to discharge water as contained in the Deed between Bethlehem Steel Corporation and Ralph A. Puerta and Robert J. Peartree dated February 24, 1987, and recorded in said Office in Deed Book Vol. 722, at page 280;

(7) unrecorded Infrastructure Improvements Agreement made February 24, 2000 among Bethlehem Steel Corporation, Bethlehem Development Corporation and the City of Bethlehem;

(8) unrecorded Development Agreement made February 24, 2000 among Bethlehem Steel Corporation, Bethlehem Development Corporation and the City of Bethlehem;

(9) unrecorded Programmatic Agreement having an effective date of August 25, 2000 among the City of Bethlehem, the Federal Highway Administration and the Advisory Council on Historic Preservation and having as concurring parties the Pennsylvania Department of Transportation, Bethlehem Steel Corporation, Bethlehem Development Corporation, the United States Department of Housing and Urban Development and the United States Economic Development Commission;

(10) Right of Entry between Bethlehem Steel Corporation and the Commonwealth of Pennsylvania, Department of Environmental Protection dated October 19, 2000, and recorded in said Office in Vol. 2000-1, page 139856;

(11) unrecorded Tax Incremental Financing Cooperation Agreement Regarding Bethlehem Works District and Bethlehem Works Tax Increment Financing Plan made and entered into as of November 16, 2000 among the City of Bethlehem, the County of Northampton, the Bethlehem Area School District, the Redevelopment Authority of the City of Bethlehem and Bethlehem Steel Corporation;

(12) Right-of-Way Agreement between Bethlehem Steel Corporation and PPL Electric Utilities Corporation dated April 12, 2001, and recorded in said Office in Misc. Book Vol. 2001-1, at page 078339, relating to an easement for electric transmission lines;

(13) Right-of-Way Agreement between Bethlehem Development Corporation and PPL Electric Utilities Corporation dated April 12, 2001, and recorded in said Office in Misc. Book Vol. 2001-1, at page 078321, relating to an easement for electric transmission lines;

(14) Agreement between Bethlehem Steel Corporation and Verizon Pennsylvania, Inc. dated April 25, 2001, and recorded in said Office in Misc. Vol. 2001-1, at page 094003, relating to underground conduits and telephone lines;

(15) Right-of-Way Agreement between Bethlehem Steel Corporation and Service Electric Cable TV, Inc., dated May 2, 2001, and intended to be recorded, relating to an easement for conduits and communication lines;

(16) Right-of-Way Agreement between Bethlehem Steel Corporation and RCN, Telecon Services, Inc., dated August 24, 2001, and intended to be recorded, relating to an easement for conduits and communication lines;

(17) the rights of the public in and to those portions of the Premises, if any, that lie within the right of way of East First Street and Webster Street; and



(18) all other matters of record or shown on the subdivision plan relative to the Premises.

EXHIBIT H

-----

RENEWAL TERM RENT

-----

LEASE MONTH	RENTABLE SQ. FEET	ANNUALIZED BASE RENT	MONTHLY BASE RENT	BASE RENT RATE/SF
121-180	48,000	\$600,000	\$50,000	\$12.50

EXHIBIT I

MEMORANDUM OF LEASE, PURCHASE OPTION  
AND RIGHT OF FIRST REFUSAL

1. Name and Address of Landlord: TECH III PARTNERS, LLC, a Pennsylvania

-----

limited liability company, with a mailing address 1512 Colesville Road,  
Bethlehem, Pennsylvania 18015 (hereinafter called "Landlord").

2. Name and Address of Tenant: ORASURE TECHNOLOGIES, INC., a Delaware

-----

corporation, with a mailing address of 150 Webster Street, Bethlehem,  
Pennsylvania 18015 (hereinafter called "Tenant").

3. Date of Lease: \_\_\_\_\_, 200\_.

-----

4. Premises: A building with an aggregate square footage of

-----

approximately 48,000 square feet which includes certain Common Areas (as  
defined in the Lease) in such building ("Building"), which Building is located  
at \_\_\_\_\_ Bethlehem, Northampton County, Pennsylvania  
("Land"), together with the right to use the Common Areas (defined in the  
Lease) (the Building, Land and Common Areas are referred to, collectively, as  
the "Leased Premises"), which Leased Premises are more particularly described  
on Exhibit A annexed hereto.

5. Term; Renewal Option, Right of First Refusal: The term of this Lease

-----

shall begin on the Commencement Date, and shall terminate on the last day of  
the tenth (10th) Lease Year of the term hereof. Tenant shall have the right, at  
its election, to extend the original term of this Lease for one (1) additional  
period of five (5) years. The Commencement Date of the Lease is \_\_\_\_\_  
\_\_\_\_\_, 200\_. In the event that the Term is renewed, tenant shall have a right  
of first refusal during the renewal term in the event that the Landlord offers  
the Leased Premises for sale or receives a bona fide offer from a third party  
purchaser.

6. Purchase Option: Tenant: At any time on or prior to the end of the  
tenth (10th) Lease Year, Tenant shall have the right, privilege and option,  
upon the terms, conditions and provisions set forth in the Lease, to purchase  
the Lease Premises.

This Memorandum of Lease, Purchase Option and Right of First Refusal is  
for information purposes only, and shall not be deemed to modify, alter or  
change in any way the respective rights and obligations of, or restrictions  
on, the Tenant and Landlord.

[text continued on next page]

IN WITNESS WHEREOF, the parties hereto have respectively executed this Memorandum of Lease this \_\_\_\_\_ day of \_\_\_\_\_, 200\_.

WITNESS: TECH III PARTNERS, LLC

By: \_\_\_\_\_  
Name: R. Sam Niedbala

By: \_\_\_\_\_  
Name: Michael J. Gausling  
Title: Managing Member

ATTEST: ORASURE TECHNOLOGIES, INC.

By: \_\_\_\_\_  
Name: Jack E. Jerrett  
Title: Secretary

By: \_\_\_\_\_  
Name: Ronald H. Spair  
Title: Executive Vice President  
and Chief Financial Officer

(Corporate Seal)

COMMONWEALTH OF PENNSYLVANIA :  
: ss. :  
COUNTY OF :

On this, the \_\_\_\_\_ day of \_\_\_\_\_, 200\_, before me a notary public the undersigned officer, personally appeared \_\_\_\_\_, Managing Member of TECH III PARTNERS, LLC, known to be (or satisfactorily proven) the person whose name subscribed to the within instrument, and acknowledged that he executed the same for the purpose therein contained.

IN WITNESS WHEREOF, I have hereunto set my hand and notarial seal.

\_\_\_\_\_  
Notary Public

MY COMMISSION EXPIRES:

COMMONWEALTH OF PENNSYLVANIA :  
: ss. :  
COUNTY OF :

On this, the \_\_\_\_\_ day of \_\_\_\_\_, 200\_, before me, a Notary Public in and for the Commonwealth of Pennsylvania, personally appeared \_\_\_\_\_, who acknowledged \_\_\_\_\_ self to be the \_\_\_\_\_ of ORASURE TECHNOLOGIES, INC., a Delaware corporation, and that he as such officer being authorized to do so, executed the same for the purpose therein contained by signing the name of the corporation by \_\_\_\_\_ self as \_\_\_\_\_.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal.

\_\_\_\_\_  
Notary Public

My Commission Expires:

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation of our report included in this Form 10-K, into the Company's previously filed Registration Statements File Nos. 333-73498, 333-50340 and 333-48662

/s/ ARTHUR ANDERSEN LLP

Philadelphia, Pennsylvania  
March 28, 2002

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8 (Numbers 333-50340 and 333-48662) and S-3 (Number 333-73498) of OraSure Technologies, Inc. of our report dated January 15, 2001, relating to the financial statements appearing in this Form 10-K.

PricewaterhouseCoopers LLP

Portland, Oregon  
March 28, 2002

-----

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2001, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of March 15, 2002.

/s/ Michael G. Bolton  
-----  
Signature

Michael G. Bolton  
-----  
Print Name



POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2001, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of March 15, 2002.

/s/ William W. Crouse

-----  
Signature

William W. Crouse

-----  
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2001, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of March 15, 2002.

/s/ Carter H. Eckert

-----  
Signature

Carter H. Eckert

-----  
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2001, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of March 15, 2002.

/s/ Michael J. Gausling  
-----  
Signature

Michael J. Gausling  
-----  
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2001, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of March 15, 2002.

/s/ Frank G. Hausmann

-----  
Signature

Frank G. Hausmann

-----  
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2001, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of March 15, 2002.

/s/ Gregory B. Lawless  
-----  
Signature

Gregory B. Lawless  
-----  
Print Name

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that the undersigned constitutes and appoints Michael J. Gausling, Ronald H. Spair, and Jack E. Jerrett, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign the Annual Report on Form 10-K of OraSure Technologies, Inc., for the year ended December 31, 2001, and any and all amendments to such report and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or each of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, this Power of Attorney has been signed by the undersigned effective as of March 15, 2002.

/s/ Roger L. Pringle

-----  
Signature

Roger L. Pringle

-----  
Print Name

OraSure Technologies, Inc.  
150 Webster Street  
Bethlehem, Pennsylvania 18015  
(610) 882-1820

March 28, 2002

Securities and Exchange Commission  
450 Fifth Street, N.W.  
Washington, DC 20549

Re: Representations from Arthur Andersen LLP  
-----

Gentlemen:

OraSure Technologies, Inc. (the "Company") engaged Arthur Andersen LLP to audit (the "Audit") the Company's financial statements for the year ended December 31, 2001. Andersen's Audit report was delivered to the Company after March 14, 2002, and is included in the Company's Annual Report on Form 10-K for the year ended December 31, 2001 (the "2001 10-K"). This letter is being provided as an exhibit to the 2001 10-K pursuant to Temporary Note 3T to Article 3 of Regulation S-X.

Andersen has represented to the Company that the Audit was subject to Andersen's quality control system for the U.S. accounting and auditing practice to provide reasonable assurance that the engagement was conducted in compliance with professional standards, and that there was appropriate continuity of Andersen personnel working on the Audit, availability of national office consultation and availability of personnel at foreign affiliates of Andersen to conduct the relevant portions of the Audit.

Please feel free to contact the undersigned (610- 882-1820, Ext 3279), if you wish to discuss this matter further.

Sincerely,

/s/ Ronald H. Spair

Ronald H. Spair  
Executive Vice President and  
Chief Financial Officer  
OraSure Technologies, Inc.

RHS:kfo