

ORASURE TECHNOLOGIES INC

Form S-3/A

February 04, 2002

As filed with the Securities and Exchange Commission on February 4, 2002  
Registration No. 333-73498

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SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549  
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AMENDMENT NO. 2 TO FORM S-3

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933  
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ORASURE TECHNOLOGIES, INC.  
(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or Other  
Jurisdiction of  
Incorporation or  
Organization)

36-4370966  
(IRS Employer  
Identification Number)

150 Webster Street  
Bethlehem, Pennsylvania 18015  
(610) 882-1820  
(Address, Including Zip Code, and Telephone  
Number, Including Area Code, of Registrant's  
Principal Executive Offices)

Jack E. Jerrett, Esq.  
Vice President and General Counsel  
OraSure Technologies, Inc.  
150 Webster Street  
Bethlehem, Pennsylvania 18015  
(610) 882-1820  
(Name, Address, Including Zip Code, and  
Telephone Number, Including Area Code, of Agent  
For Service)

COPIES TO:  
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(610) 640-7800

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. A REGISTRATION STATEMENT RELATING TO THESE SECURITIES HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. THESE SECURITIES MAY NOT BE SOLD NOR MAY OFFERS TO BUY BE ACCEPTED PRIOR TO THE TIME THE REGISTRATION STATEMENT BECOMES EFFECTIVE. THIS PROSPECTUS SHALL NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY NOR SHALL THERE BE ANY SALE OF THESE SECURITIES IN ANY STATE IN WHICH SUCH OFFER, SOLICITATION OR SALE WOULD BE UNLAWFUL PRIOR TO THE REGISTRATION OR QUALIFICATION UNDER THE SECURITIES LAWS OF ANY SUCH STATE.

Subject to Completion, dated February 4, 2002

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PROSPECTUS

[GRAPHIC OMITTED][GRAPHIC OMITTED]

4,049,882

SHARES OF COMMON STOCK

This prospectus relates to the resale of common stock that we issued and sold to the selling stockholders listed on page 10. We will not receive any proceeds from the sale of the shares by the selling stockholders.

The selling stockholders, or their pledgees, donees, transferees or other successors-in-interest, may offer the common stock through public or private transactions, at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices.

Our common stock is listed on The Nasdaq National Market under the symbol "OSUR." On January 31, 2002 the reported last sale price of our common stock on The Nasdaq National Market was \$5.681 per share.

Our principal offices are located at 150 Webster Street, Bethlehem, Pennsylvania 18015, and our telephone number is (610) 882-1820.

INVESTING IN OUR COMMON STOCK INVOLVES RISKS. YOU SHOULD CAREFULLY CONSIDER THE "RISK FACTORS" BEGINNING ON PAGE 1 OF THIS PROSPECTUS BEFORE YOU DECIDE TO INVEST.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2002

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You should rely only on the information contained in this prospectus. We

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have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

Until [ ], 2002, all dealers that buy, sell or trade the common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

### WHO WE ARE

Our company was formed in May 2000 under Delaware law solely for the purposes of combining two companies, STC Technologies, Inc. and Epitope, Inc., and changing the state of incorporation of Epitope from Oregon to Delaware. STC Technologies and Epitope were merged into our company on September 29, 2000. Our principal offices are located at 150 Webster Street, Bethlehem, Pennsylvania 18015, and our telephone number is (610) 882 -1820.

We develop, manufacture and market oral fluid specimen collection devices using our 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, and hospitals, and for workplace testing.

Our business focuses on the following principal platform technologies: (1) the OraSure(R) oral fluid collection device, (2) the OraQuick(R) rapid diagnostics test device, and (3) the new up-converting phosphor technology, or UPT(TM), including its first application, UPLink(TM).

The OraSure(R) collection device is used to collect a sample of oral fluid, or saliva, which is then sent to a laboratory for screening and confirmatory tests for HIV-1 (the virus that causes AIDS) and/or for cocaine and cotinine (an indicator of the use of nicotine). The OraSure(R) device is sold predominantly in the insurance market for the screening of life insurance applicants and in physician offices and in the public health market. A collection device that is substantially similar to the OraSure(R) device is marketed under the name Intercept(R) and is used to collect oral fluid to be tested in a laboratory for various drugs, such as marijuana, cocaine, opiates, amphetamines, PCP, benzodiazepines, barbiturates, and methadone. Intercept(R) is used primarily by companies to test their employees and prospective employees, in crime and medical examiner laboratories for forensic toxicology testing, in the criminal justice system for testing prison inmates and parolees, and in drug treatment and community/family service programs.

The OraQuick(R) device is a recently developed product designed to test oral fluid, whole blood or serum/plasma for the presence of HIV. No laboratory test is required, as the OraQuick(R) test results can be visually read in approximately 20 minutes after the sample is collected. We plan to market the

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OraQuick(R) device in the hospital, physician office and public health markets, focusing initially on international markets.

Up-converting phosphor technology, or UPT(TM), uses phosphor particles to detect the presence of small quantities of a variety of substances, such as drugs, proteins and DNA. The first application of UPT(TM) is called UPLink(TM), a system which collects, analyzes and measures substances in a variety of samples, including oral fluid, blood, serum, urine and stool samples, and provides results in about 10 minutes without laboratory testing. The UPLink(TM) system provides a high degree of sensitivity and can test for multiple substances at the same time. We are nearing completion of an UPLink(TM) oral fluid test for various drugs and are developing UPLink(TM) applications to test for various infectious diseases.

In addition, we sell certain other products, including the Histofreezer(R) cryosurgical system for the removal of warts and other skin lesions, certain tests and related products for insurance risk assessment and forensic toxicology applications, an oral fluid Western Blot confirmatory test for HIV-1, and the Q.E.D.(R) saliva alcohol test.

### RISK FACTORS

You should carefully consider the risks described below before making an investment decision. They are the material risks currently known to us. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment.

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This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this prospectus.

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

#### OUR RESEARCH AND DEVELOPMENT EFFORTS MAY NOT SUCCEED OR OUR COMPETITORS MAY DEVELOP MORE EFFECTIVE OR SUCCESSFUL DIAGNOSTIC PRODUCTS.

In order to remain competitive, we 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.

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This process is conducted in various stages, and during each stage there is a substantial risk that we will not achieve our goals and will have to abandon a product in which we have invested substantial amounts.

During the year ended December 31, 2000 and the nine months ended September 30, 2001, we incurred approximately \$10.4 million and \$6.8 million, respectively, in research and development expenses. We expect to continue to incur significant costs in our research and development activities. Moreover, there can be no assurance that we will succeed in our research and development efforts. If we fail to develop commercially successful products, or if competitors develop more effective products or a greater number of successful new products, customers may decide to use products developed by our competitors, which would result in a loss of revenues.

IF ACCEPTANCE AND ADOPTION OF OUR ORAL FLUID TESTING IN THE MARKET DOES NOT CONTINUE, OUR FUTURE RESULTS MAY SUFFER.

We have made significant progress in gaining acceptance and adoption of oral fluid testing for HIV in the insurance and public health markets. We also expect that oral fluid testing for drugs of abuse will continue to be accepted and adopted in workplace and criminal justice testing markets. Other markets, particularly the physician market, may resist the adoption of oral fluid testing as a replacement for other testing methods in use today. There can be no assurance that we will be able to expand the use of our oral fluid testing products in these or other markets.

WE MAY REQUIRE FUTURE ADDITIONAL FUNDING TO STAY IN BUSINESS.

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

OUR FAILURE TO MAINTAIN EXISTING DISTRIBUTION CHANNELS OR DEVELOP NEW DISTRIBUTION CHANNELS, MAY RESULT IN LOWER REVENUES.

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We have marketed many of our products by collaborating with diagnostic companies and distributors. For example, our OraSure(R) oral fluid collection device is distributed to the insurance industry through major insurance testing laboratories. One of these laboratories, LabOne, Inc., is a significant customer, accounting for approximately 23% and 21.8% of our revenues for the year ended December 31, 2000 and the nine months ended September 30, 2001, respectively. Our sales depend to a substantial degree on our ability to sell products to these customers and develop new product distribution channels and on the marketing abilities of the companies with which we collaborate. In addition, some of our distributors have recently consolidated, and such consolidation has, and many continue to have, an adverse impact on the level orders for our products. There can be no assurance that such companies will continue to be able to purchase or distribute our products or maintain order volume, or that new

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distribution channels will be available on satisfactory terms.

THE TIME NEEDED TO OBTAIN REGULATORY APPROVALS AND RESPOND TO CHANGES IN REGULATORY REQUIREMENTS COULD ADVERSELY AFFECT OUR BUSINESS.

Many of our proposed and existing products are subject to regulation by the United States Food and Drug Administration ("FDA") and other international governmental agencies. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products. The process of obtaining required approvals from government agencies varies according to the nature of, and uses for, our 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 us a license to market the product. Each authority may impose its own requirements and delay or refuse to grant approval, even though our product has been approved in another country.

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

Changes in government regulations could also require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. Other changes in government regulations, such as the adoption of the FDA's Quality System Regulation, may not affect our products directly but may, nonetheless, adversely affect our financial condition and results of operations by requiring that we 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 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 our products. We will not be permitted to sell our products in European countries without a CE mark after December 2003, which could lead to the termination of strategic alliances for sales of those products in Europe. While we intend to apply for CE marks for certain of our existing and future products, and are 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, we have 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. We have also received CE mark approval for the OraSure(R), Intercept(R) and Histofreezer(R) products. We have submitted to the FDA an application for pre-market approval of our OraQuick(R) rapid HIV test using whole blood and expect to file an application for oral fluid applications early next year. We have also submitted an application to the FDA for clearance of the ULink (TM) drugs of abuse rapid detection system and are presently gathering additional data requested by the FDA in response to our application.

WE HAVE A HISTORY OF LOSSES.

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We have not achieved full-year profitability. We incurred a net loss of approximately \$12.7 million and \$4.2 million for the years ended December 31, 2000 and September 30, 1999, respectively, and a net loss of

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approximately \$1.4 million for the nine months ended September 30, 2001. As of September 30, 2001, we had an accumulated deficit of approximately \$123.8 million. On January 18, 2002, we announced preliminary results for the fourth quarter and full-year 2001, which indicate that we expect to incur a net loss for both the quarter and full year.

Our limited combined operating history makes it difficult to forecast our future operating results. In order to achieve sustainable profitability, our revenue will have to continue to grow at a significant rate. Our ability to reach our estimated revenue growth will be dependent upon a number of factors including, without limitation, achieving growth in international markets through our OraQuick(R) rapid HIV test, our ability to create market acceptance for the Intercept(R) drugs of abuse products and our ability to commercially develop, and obtain regulatory approval and create market acceptance for, UPT(TM) and other products in a time frame consistent with our objectives. We have not yet achieved these objectives. In the event that we cannot create a significant commercial market for our OraQuick(R) test, the Intercept(R) and UPT(TM) products or our other products, our revenue, and consequently profitability, will be lower than estimated. Even if we achieve profitability, we cannot assure you that we will be able to sustain such profitability in the future.

FAILURE TO COMPLY WITH FDA REQUIREMENTS MAY REQUIRE US TO SUSPEND PRODUCTION OF OUR PRODUCTS WHICH COULD RESULT IN A LOSS OF REVENUES.

We can manufacture and sell many of our products, both in the U.S. and in some cases abroad, only if we comply with regulations of governmental agencies such as the FDA. We have implemented quality assurance and other systems that are intended to comply with such applicable regulations. The FDA has issued warning letters and a letter of intent to revoke our license with respect to the serum Western Blot product, stating that we are not in compliance with the FDA's regulations. We have responded to each of these letters. Although we believe that we are addressing all of the points raised by the FDA, the FDA could force us to stop manufacturing products if the FDA concludes that we still remain out of compliance with applicable regulations. Until the FDA agrees that we have resolved all of the points raised in their letters, we may not be able to obtain regulatory clearance certificates needed in certain foreign countries. The FDA could also require us to recall products if we fail to comply with applicable regulations which could force us to stop manufacturing such products.

A MARKET FOR OUR PRODUCTS MAY NOT DEVELOP.

Our future success will depend, in part, on the market acceptance, and the timing of such acceptance, of our recently introduced products such as the Intercept(R) oral fluid drug test service, the OraQuick(R) rapid oral fluid HIV test, products currently under development such as UPlink(TM) 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, we must make substantial marketing efforts and spend significant funds to inform potential customers and the public of the benefits of these products. We currently have limited evidence on which to evaluate the market reaction to products that may be developed, and there can be no assurance that any products will meet with market acceptance and fill the market need that is perceived to exist.



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OUR SUCCESS DEPENDS ON OUR ABILITY TO PROTECT OUR PROPRIETARY TECHNOLOGY.

The diagnostics industry places considerable importance on obtaining patent, trademark, and trade secret protection, as well as other intellectual property rights, for new technologies, products and processes. Our success depends, in part, on our ability to develop and maintain a strong intellectual property portfolio of products and technologies both in the United States and in other countries.

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

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Many of our employees, including scientific and management personnel, were previously employed by competing companies. Although we encourage and expect all of our employees to abide by any confidentiality agreement with a prior employer, competing companies may allege trade secret violations and similar claims against us.

To facilitate development and commercialization of a proprietary technology base, we may need to obtain licenses to patents or other proprietary rights from other parties. If we are unable to obtain these types of licenses, our product development and commercialization efforts may be delayed.

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

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

THE SALES POTENTIAL FOR ORAQUICK WILL BE AFFECTED BY OUR ABILITY TO OBTAIN CERTAIN LICENSES.

There are several factors that will affect the specific countries in which we will be able to sell our OraQuick(R) rapid HIV test and therefore the overall sales potential of the test. One factor is whether we can arrange a sublicense or distribution agreement related to patents for detection of the HIV-2 virus. HIV-2 is a type of the HIV virus estimated to represent less than 2% of known

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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 U.S., we may be restricted from manufacturing our OraQuick(R) rapid HIV test in the U.S. and selling into other countries, even if there were no HIV-2 patents in those other countries.

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

Another factor that may affect the specific countries in which we will be able to sell our OraQuick(R) rapid HIV test, and therefore the overall sales potential, concerns whether we can arrange a sublicense or distribution agreement related to any patents which claim lateral flow assay methods and devices covering the OraQuick(R) rapid HIV test or its use. The OraQuick(R) rapid HIV test is a lateral flow assay device that tests for specific antibodies or other substances. The term "lateral flow" generally refers to a test strip through which a sample flows and which produces a visible test result on a portion of the strip downstream from where the sample is applied. There are numerous patents in the U.S. and other countries which claim lateral flow assay methods and devices. Some of these patents broadly cover the type of technology used in the OraQuick(R) assay and are in force in the U.S. and other countries. We may not be able to make the OraQuick(R) rapid HIV test in the U.S. and sell it in countries where there is no patent on the device. We have licenses under several lateral flow patents and are considering the need for licenses under others.

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In the event that it is not possible to negotiate a license or other agreement under a necessary patent, we 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 U.S. and other markets.

IF WE LOSE OUR KEY PERSONNEL OR ARE UNABLE TO ATTRACT AND RETAIN QUALIFIED PERSONNEL AS NECESSARY, OUR BUSINESS COULD BE HARMED.

Our success will depend to a large extent upon the contributions of our executive officers, management, sales and marketing, and scientific staff. We may not be able to attract or retain qualified employees in the future due to the intense competition for qualified personnel among medical products businesses. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively sell and market our products, to meet the demands of our strategic partners in a timely fashion or to support internal research and development programs. In particular, product development

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programs depend on the ability to attract and retain highly skilled scientists, including molecular biologists, biochemists and engineers. Recruiting qualified personnel can be an intensely competitive and time-consuming process. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms. All of our employees, other than a few senior officers who have employment agreements, are at-will employees, which means that either the employee or we may terminate their employment at any time. If we experience difficulty in recruiting and retaining qualified personnel, and in particular scientific personnel, we may need to provide higher compensation to such personnel than currently anticipated or we may incur additional expenses for the recruitment of qualified personnel.

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

OUR INCREASING INTERNATIONAL PRESENCE MAY BE AFFECTED BY REGULATORY, CULTURAL OR OTHER RESTRAINTS.

We intend to devote significant resources to increase international sales of our OraSure(R), Intercept(R), OraQuick(R) and UPT(TM) products. The Company's international operations accounted for approximately \$4 million or 14% of total revenues for the year ended December 31, 2000 and approximately \$3.9 million or 15.9% of total revenues for the nine months ended September 30, 2001.

Compliance with foreign regulatory requirements can be difficult and can impede international marketing efforts. In the past, we have not had significant direct experience with the governmental regulatory agencies in foreign countries that control sale of products into those countries. In addition to economic and political issues, a number of factors can slow or prevent international sales, or substantially increase the cost of international sales, including those set forth below:

- o Regulatory requirements (including compliance with applicable customs regulations) may slow, limit, or prevent the offering of products in foreign jurisdictions;
- o Cultural and political differences may make it difficult to effectively market, sell and gain acceptance of products in foreign jurisdictions;
- o Inexperience in international markets may slow or limit our ability to sell products in foreign countries;
- o Exchange rates, currency fluctuations, tariffs and other barriers, extended payment terms and dependence on and difficulties in managing international distributors or representatives may affect our revenues even when product sales occur; and

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- o The credit-worthiness of foreign entities may be less certain and accounts receivable collection may be more difficult.

We have entered into a contract for the manufacture and supply of the

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OraQuick(R) HIV device in Thailand. However, we do 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 our products in countries other than the United States. Interruption of the supply of our products could reduce revenues or cause us to incur significant additional expense in finding an alternative source of supply.

WE MAY BE SUED FOR PRODUCT LIABILITIES FOR INJURIES RESULTING FROM THE USE OF OUR DIAGNOSTIC PRODUCTS.

We may be held liable if any of our products, or any product which is made with the use or incorporation of any of our technologies, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. Although we have obtained product liability insurance, this insurance may not fully cover potential liabilities. As new products come to market, we may need to increase our product liability coverage. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could affect our decision to commercialize products that we develop independently or with our strategic partners. If we are sued for any injury caused by our products, our liability could exceed our policy limits.

WE MAY NOT BE ABLE TO COMMERCIALIZE OUR UPT(TM) PRODUCTS WHICH COULD NEGATIVELY AFFECT OUR FUTURE REVENUES.

Our up-converting phosphor technology is new and is in the early stage of development. Commercial development of UPT(TM) may not be successful. Successful products require significant development and investment, including testing, to demonstrate their cost-effectiveness or other benefits prior to their commercialization. In addition, regulatory approval must be obtained before most products based upon UPT(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 our future revenues.

WE ARE DEPENDENT UPON STRATEGIC PARTNERS TO ASSIST IN DEVELOPING AND COMMERCIALIZING SOME OF OUR DIAGNOSTIC PRODUCTS.

Although we intend to pursue some product opportunities independently, opportunities that require a level of investment for development and commercialization may necessitate involving one or more strategic partners. In particular, our strategy for development and commercialization of UPT(TM) and certain other products may entail entering into additional arrangements with corporate partners, universities, research laboratory licensees, and others. We may be required to transfer material rights to such strategic partners, licensees, and others. While we expect that our current and future partners, licensees, and others have and will have an economic motivation to succeed in performing their contractual responsibilities, 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.

WE ARE DEPENDENT UPON PATENTS, LICENSES AND OTHER PROPRIETARY RIGHTS FROM THIRD PARTIES, INCLUDING RIGHTS TO UP-CONVERTING PHOSPHOR COMPOSITIONS, METHODS AND APPARATUSES.

We have licensed the worldwide rights to up-converting phosphor compositions, methods, and apparatuses for use in diagnostic applications, which are the subject of nine issued U.S. patents, and of four pending U.S. patent applications. Corresponding patents and patent applications have been granted or

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issued in numerous foreign countries, including, for example, European countries, Japan, and Canada. We cooperate with the licensor to prosecute such patent applications and protect such patent rights. If the licensors do not meet their obligations under the license agreements or do not reasonably consent to sublicenses by us, or if the license agreement is terminated,

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we could lose the opportunity to develop the up-converting phosphor technology.

THE RECENT ECONOMIC DOWNTURN AND TERRORIST ATTACKS MAY ADVERSELY AFFECT OUR BUSINESS.

Since the September 11, 2001 terrorist attacks, the United States economy has experienced a decline. Changes in economic conditions could adversely affect our business. For example, in a difficult economic environment, customers may be unwilling or unable to invest in new diagnostic products 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 us to increased business or credit risk in dealing with customers adversely affected by economic conditions.

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

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Because we want to provide you with more meaningful and useful information, this prospectus contains, and incorporates by reference, certain forward-looking statements that reflect our current expectations regarding our future results of operations, performance and achievements. We have tried, wherever possible, to identify these forward-looking statements by using words such as "anticipates," "believes," "estimates," "expects," "plans," "intends," "may," "will," "should," "could" and similar expressions. These statements reflect our current beliefs and are based on information currently available to us. Accordingly, these statements are subject to certain risks, uncertainties and contingencies, including the factors set forth under the caption "Risk Factors," which could cause our actual results, performance or achievements for 2001 and beyond to differ materially from those expressed in, or implied by, any of these statements. You should not place undue reliance on any forward-looking statements. Except as otherwise required by federal securities laws, we undertake no obligation to release publicly the results of any revisions to any such forward-looking statements that may be made to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

### USE OF PROCEEDS

We will not receive any proceeds from the sale by the selling stockholders of our common stock. The selling stockholders will receive all of the net

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proceeds from the sale of the shares.

### SELLING STOCKHOLDERS

Each of the selling stockholders was a stockholder of STC Technologies, Inc. We issued an aggregate of 4,049,882 shares of common stock to the selling stockholders in the merger of STC Technologies, Inc. and Epitope, Inc. into our company on September 29, 2000. Mr. William W. Crouse, a member of our board of directors, is a general partner of HealthCare Partners V, L.P., the general partner of HealthCare Ventures V, L.P. Mr. Crouse has been a member of the board since September 29, 2000 and previously was a member of the board of directors of STC Technologies, Inc. since April 1999. Mr. Michael G. Bolton, a member of our board of directors, is the managing director of Pennsylvania Early Stage Partners GP, LLC, the manager of Pennsylvania Early Stage Partners, L.P. Mr. Bolton has been a member of the board since September 29, 2000 and previously was a member of the board of directors of STC Technologies, Inc. since April 1999. Messrs. Crouse and Bolton were designated as directors pursuant to the Agreement and Plan of Merger dated May 6, 2000 between STC Technologies and Epitope.

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The shares listed under the column "Number of Shares Being Offered" in the table below represent the number of shares that may be sold by each selling stockholder pursuant to this prospectus. Pursuant to Rule 416 under the Securities Act, the registration statement of which this prospectus is a part also covers any additional shares of our common stock which become issuable in connection with such shares because of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration which results in an increase in the number of outstanding shares of our common stock.

We do not know when or in what amounts the selling stockholders may offer shares for sale. The selling stockholders may not sell all or any of the shares offered by this prospectus. The selling stockholders may distribute the shares, from time to time, to one or more of its respective limited and/or general partners, who may sell shares pursuant to this prospectus. We may amend or supplement this prospectus from time to time to update the disclosure set forth herein. Because the selling stockholders may from time to time offer all or some of the shares pursuant to this offering, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares that will be held by the selling stockholders after completion of the offering, we cannot estimate the number of the shares that will be held by the selling stockholders after completion of the offering. However, for purposes of the table below, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholders.

The following table sets forth, to our knowledge, certain information regarding the beneficial ownership of the shares of common stock by the selling stockholders as of January 31, 2002. We prepared this table based on the information supplied to us by the selling stockholders named in the table. Beneficial ownership is calculated based upon SEC requirements and is not necessarily indicative of beneficial ownership for any other purpose. The table is based on 37,415,004 shares of our common stock outstanding as of January 31, 2002:

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Name of Selling Stockholders(1)	Shares Beneficially Owned Prior to Offering		Number of Shares Being Offered	Shares Beneficially Owned After Offering	
	Number	Percentage		Number	Percent
Healthcare Ventures V, L.P. (2) 44 Nassau Street Princeton, New Jersey 08542	3,115,292	8.3%	3,115,292	0	-
Pennsylvania Early Stage Partners, L.P. (3) Building 500, Suite 510 435 Devon Park Drive Wayne, Pennsylvania 19087	934,590	2.5%	934,590	0	-

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(1) Includes partners, donees, transferees, pledgees and other successors-in-interest selling shares that are received from a named selling stockholder.

(2) HealthCare Ventures V, L.P. shares voting and dispositive control with respect to the 3,115,292 shares with HealthCare Partners V, L.P. ("HCP") and with the six General Partners of HCP, James H. Cavanaugh, William W. Crouse, Augustine Lawlor, John W. Littlechild, Christopher K. Mirabelli and Harold R. Werner.

(3) Pursuant to a management agreement, voting and dispositive control with respect to the 934,590 shares has been delegated to Pennsylvania Early Stage Partners GP, LLC, which exercises such control through a Board of Managers consisting of Michael G. Bolton, Robert M. McCord, Warren V. Musser and Paul J. Schmitt.

### PLAN OF DISTRIBUTION

The shares covered by this prospectus may be offered and sold from time to time by the selling stockholders. The term "selling stockholders" includes partners, pledgees, donees, transferees or other successors-in-interest selling shares received after the date of this prospectus from the selling stockholders as a pledge, gift,

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partnership distribution or other non-sale related transfer. To the extent required, we may amend and supplement this prospectus from time to time to describe a specific plan of distribution.

The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. The selling stockholders may make these sales at prices and under terms then prevailing or at prices related to the then current market price. The selling stockholders may also make sales in negotiated transactions, including pursuant to one or more of the following methods:

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- o purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;
- o ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- o one or more block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o an over-the-counter distribution in accordance with the rules of The Nasdaq National Market; and
- o in privately negotiated transactions.

In connection with distributions of the shares or otherwise, the selling stockholders may:

- o enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares in the course of hedging the positions they assume;
- o sell the shares short and redeliver the shares to close out such short positions;
- o enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to them of shares offered by this prospectus, which they may in turn resell; and
- o pledge shares to a broker-dealer or other financial institution, which, upon a default, they may in turn resell.

In addition, the selling stockholders may sell all or a portion of the shares that qualify for sale pursuant to Rule 144 and 145 of the Securities Act, as amended, under Rule 144 or 145 rather than pursuant to this prospectus.

Sales through brokers may be made by any method of trading authorized by any stock exchange or market on which the shares may be listed or quoted, including block trading in negotiated transactions. Without limiting the foregoing, such brokers may act as dealers by purchasing any or all of the shares covered by this prospectus, either as agents for others or as principals for their own accounts, and reselling such shares pursuant to this prospectus. The selling stockholders may effect such transactions directly, or indirectly through underwriters, broker-dealers or agents acting on their behalf. In effecting sales, broker-dealers or agents engaged by the selling stockholders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the selling stockholders, in amounts to be negotiated immediately prior to the sale.

In offering the shares covered by this prospectus, the selling stockholders, and any broker-dealers and any other participating broker-dealers who execute sales for the selling stockholders, may be deemed to be "underwriters" within the meaning of the Securities Act in connection with these sales. Any profits realized by the selling stockholders and the compensation of such broker-dealers may be deemed to be underwriting discounts and commissions.

In order to comply with the securities laws of certain states, the shares must be sold in those states only through registered or licensed brokers or dealers. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.



We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

At the time a particular offer of shares is made, if required, we will distribute a prospectus supplement that will set forth:

- o the number of shares being offered;
- o the terms of the offering, including the name of any underwriter, dealer or agent;
- o the purchase price paid by any underwriter;
- o any discount, commission and other underwriter compensation;
- o any discount, commission or concession allowed or reallocated or paid to any dealer; and
- o the proposed selling price to the public.

We have agreed to indemnify the selling stockholders against certain liabilities, including certain liabilities under the Securities Act.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (i) such time as all of the shares covered by this prospectus have been disposed of pursuant to the registration statement, or (ii) the second anniversary of the effective date of this prospectus, plus any periods during which the selling stockholders were not permitted to sell the shares covered by this prospectus.

All costs, expenses and fees in connection with the registration of the shares offered hereby will be borne by us. Brokerage commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by the selling stockholders.

#### LEGAL MATTERS

The validity of the shares of our common stock offered by this prospectus will be passed upon for us by Pepper Hamilton LLP, Philadelphia, Pennsylvania.

#### EXPERTS

The audited annual financial statements incorporated into this prospectus by reference to our annual report on Form 10-K for the year ended December 31, 2000 have been audited by Arthur Andersen LLP, independent public accountants, as indicated in their report with respect thereto, and are included herein in reliance upon the authority of said firm as experts in giving said report.

The financial statements of Epitope, Inc. as of December 31, 1999 and for

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the three months ended December 31, 1999 and each of the two years in the period ended September 30, 1999, incorporated into this prospectus by reference to OraSure Technologies, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2000 have been so incorporated in reliance on the report from PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

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### INDEMNIFICATION

Delaware law authorizes a corporation to limit or eliminate the personal liability of its directors for monetary damages for breach of a director's fiduciary duty of care. Delaware law further enables corporations to limit available relief to equitable remedies such as injunction or rescission. Absent the limitations authorized by Delaware law, directors are accountable for monetary damages for conduct constituting gross negligence in the exercise of their duty of care. Our Certificate of Incorporation limits the liability of our directors to the fullest extent permitted by Delaware law. Accordingly, our directors will not be personally liable to us or our stockholders for monetary damages for breach of a fiduciary duty as a director, except for liability for breach of the duty of loyalty, for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, for unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the General Corporation Law of the State of Delaware, or for any transaction in which a director has derived an improper personal benefit.

Our Bylaws require us to indemnify to the fullest extent permitted by Delaware law any person who is a party or is threatened to be made a party to any action, suit or proceeding by reason of the fact that such person is or was our director, officer, employee or agent, or is serving as a director, officer, employee or agent of another enterprise at our request. Indemnification is not, however, permitted under the Bylaws unless the person acted in good faith and in a manner that such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal action or proceeding, that such person had no reasonable cause to believe such person's conduct was unlawful. The Bylaws further provide that we shall not indemnify any person for any liabilities or expenses incurred by such person in connection with an action, suit or proceeding by or in the right of OraSure Technologies in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless and only to the extent that the court in which the action, suit or proceeding is brought determines that the person is entitled to indemnity for such expenses. The indemnification provided by the Bylaws is not exclusive of any other rights to which those seeking indemnification may be otherwise entitled.

We have entered into indemnification agreements with certain of our directors and officers. The indemnification agreements provide that we will indemnify these directors and officers against all liabilities and expenses actually and reasonably incurred in connection with any action, suit or proceeding (including an action by or in the right of OraSure Technologies) to which any of them is, was or at any time becomes a party, or is threatened to be made a party, by reason of their status as a director or officer, or by reason of their serving or having served at the request or on behalf of OraSure Technologies as a director, officer, trustee or in any other comparable position of any other enterprise to the fullest extent allowed by law. No indemnity will be provided under the indemnification agreements for any amounts for which indemnity is provided by any other indemnification obligation or insurance maintained by us or otherwise. Indemnity will not be available to any director

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or officer on account of conduct which is finally adjudged by a court to have been knowingly fraudulent, deliberately dishonest or willful misconduct. No indemnification will be provided if a final court adjudication determines that such indemnification is not lawful, or in respect of any suit in which judgment is rendered against any director or officer for an accounting of profits made from a purchase or sale of securities of OraSure Technologies in violation of Section 16(b) of the Exchange Act or of any similar law, or on account of any remuneration paid to any director or officer which is adjudicated to have been paid in violation of law.

We have also obtained director's and officer's liability insurance.

### ADDITIONAL INFORMATION

This prospectus is part of a registration statement we have filed with the Securities and Exchange Commission ("SEC"). This prospectus does not contain all of the information contained in the registration statement or the exhibits to the registration statement. For further information about us, please see the complete registration statement. Summaries of agreements or other documents in this prospectus are not necessarily complete. Please refer to the exhibits to the registration statement for complete copies of these documents.

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We are subject to the information requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and file reports, proxy statements and other information with the SEC. You may read and copy such reports, proxy statements and other information, including the registration statement and all of its exhibits, at the following SEC public reference rooms:

450 Fifth Street, N.W.  
Judiciary Plaza  
Room 1024  
Washington, D.C. 20549

Citicorp Center  
500 West Madison Street  
Suite 1400  
Chicago, IL 60661

You may obtain information on the operation of the SEC public reference room in Washington, D.C. by calling the SEC at 1-800-SEC-0330. Our SEC filings, including the registration statement of which this prospectus forms a part and the documents incorporated by reference that are listed below, are also available from the SEC's Web site at <http://www.sec.gov>, which contains reports, proxy and information statements and other information regarding issuers that file electronically.

The SEC allows us to "incorporate by reference" into this prospectus certain information that we file with it. This means that we can disclose important information to you by referring you to another document that we filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus, except for any information superseded by information in this prospectus. You should read the information incorporated by reference because it is an important part of this prospectus.

We incorporate by reference the following documents that we previously filed with the SEC pursuant to the Exchange Act and any future filings we will make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act:

1. Our Annual Report on Form 10-K for our fiscal year ended December 31, 2000.

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2. Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.
3. Our definitive Proxy Materials for the 2001 Annual Meeting of Stockholders filed on April 30, 2001.
4. Our Current Report on Form 8-K dated March 30, 2001.
5. Our Current Report on Form 8-K dated April 2, 2001.
6. The description of our common stock contained in Exhibit 99 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.
7. The description of rights to purchase preferred shares contained in the Registration Statement on Form 8-A filed with the SEC on June 11, 2001.
8. Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
9. Our Current Report on Form 8-K dated October 31, 2001.
10. Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.
11. Our Current Report on Form 8-K dated January 18, 2002 (except for the information disclosed under Item 9 of such Report which is not incorporated by reference).
12. Our Current Report on Form 8-K dated February 1, 2002.

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The documents incorporated by reference in this prospectus that are not delivered with this prospectus may be obtained from us without charge. You may obtain these documents incorporated by reference in this prospectus by telephoning us at (610) 882-1820 or writing us at the following address:

Corporate Secretary  
OraSure Technologies, Inc.  
150 Webster Street  
Bethlehem, Pennsylvania 18015

Our Web site is located at <http://www.orasure.com>. Information contained in our Web site is not a part of this prospectus.

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## Part II

### Information Not Required In Prospectus

#### Item 14. Other Expenses of Issuance and Distribution

The following table sets forth the various expenses in connection with the sale and distribution of the securities being registered. All of the amounts

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shown are estimates except the SEC registration fee.

SEC registration fee.....	\$ 10,636
Printing and EDGAR filing fees .....	5,000
Legal fees and expenses.....	5,000
Accounting fees and expenses .....	3,000
Miscellaneous fees and expenses .....	5,000
	-----
TOTAL .....	\$ 28,636

### Item 15. Indemnification of Directors and Officers

Delaware law authorizes a corporation to limit or eliminate the personal liability of its directors for monetary damages for breach of a director's fiduciary duty of care. Delaware law further enables corporations to limit available relief to equitable remedies such as injunction or rescission. Absent the limitations authorized by Delaware law, directors are accountable for monetary damages for conduct constituting gross negligence in the exercise of their duty of care. Our Certificate of Incorporation limits the liability of our directors to the fullest extent permitted by Delaware law. Accordingly, our directors will not be personally liable to us or our stockholders for monetary damages for breach of a fiduciary duty as a director, except for liability for breach of the duty of loyalty, for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, for unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the General Corporation Law of the State of Delaware, or for any transaction in which a director has derived an improper personal benefit.

Our Bylaws require us to indemnify to the fullest extent permitted by Delaware law any person who is a party or is threatened to be made a party to any action, suit or proceeding by reason of the fact that such person is or was our director, officer, employee or agent, or is serving as a director, officer, employee or agent of another enterprise at our request. Indemnification is not, however, permitted under the Bylaws unless the person acted in good faith and in a manner that such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal action or proceeding, that such person had no reasonable cause to believe such person's conduct was unlawful. The Bylaws further provide that we shall not indemnify any person for any liabilities or expenses incurred by such person in connection with an action, suit or proceeding by or in the right of OraSure Technologies in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless and only to the extent that the court in which the action, suit or proceeding is brought determines that the person is entitled to indemnity for such expenses. The indemnification provided by the Bylaws is not exclusive of any other rights to which those seeking indemnification may be otherwise entitled.

We have entered into indemnification agreements with certain of our directors and officers. The indemnification agreements provide that we will indemnify these directors and officers against all liabilities and expenses actually and reasonably incurred in connection with any action, suit or proceeding (including an action by or in the right of OraSure Technologies) to which any of them is, was or at any time becomes a party, or is threatened to be made a party, by reason of their status as a director or officer, or by reason of their serving or having served at the request or on behalf of OraSure Technologies as a director, officer, trustee or in any other comparable position of any other enterprise to the fullest extent allowed by law. No indemnity will be provided under the indemnification agreements for any amounts for which indemnity is provided by any other indemnification obligation or insurance maintained by us or otherwise. Indemnity will not be available to any director or officer on account of conduct which is finally adjudged by a court to have

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been knowingly fraudulent, deliberately dishonest or willful misconduct. No indemnification will be provided if a final court adjudication determines that such indemnification is not lawful, or in respect of any suit in which judgment is rendered against any director or officer for an accounting of profits made from a purchase or sale of securities of OraSure

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Technologies in violation of Section 16(b) of the Exchange Act or of any similar law, or on account of any remuneration paid to any director or officer which is adjudicated to have been paid in violation of law.

We have also obtained director's and officer's liability insurance.

### Item 16. List of Exhibits

The exhibits filed as part of this registration statement are as follows:

Exhibit	Description
4.1	Specimen certificate representing shares of OraSure Technologies \$.000001 par value Common Stock is incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-4 (No. 333-39210).
4.2	Rights Agreement dated as of May 6, 2000 between OraSure Technologies and ChaseMellon Shareholder Service, L.L.C., as Rights Agent, is incorporated by reference to Exhibit 4.2 to the Registrant'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 Registrant's Registration Statement on Form S-4 (No. 333-39210).
4.4	Amendment to Stockholders Agreement filed as Exhibit 4.3 is incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-4 (No. 333-39210).
4.5	Second Amendment to Stockholders Agreement dated as of June 29, 2001 is incorporated by reference to Exhibit 4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
5.1**	Opinion of Pepper Hamilton LLP regarding legality of securities being registered.
23.1*	Consent of Arthur Andersen LLP.
23.2*	Consent of PricewaterhouseCoopers LLP, Independent Accountants.
23.3**	Consent of Pepper Hamilton LLP (included in its Opinion filed as Exhibit 5.1 hereto).
24.1**	Powers of Attorney (included on signature page).

\* Filed herewith.

\*\* Previously filed.

### Item 17. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

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(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

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provided, however, that paragraphs (i) and (ii) above do not apply if the Registration Statement is on Form S-3 or Form S-8 and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or

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controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Bethlehem, Pennsylvania on February 4, 2002.

OraSure Technologies, Inc.

By: /s/ Michael J. Gausling

-----  
Michael J. Gausling  
Chief Executive Officer  
and President

Pursuant to the requirements of the Securities Act of 1933, as amended (the "Securities Act"), this Registration Statement has been signed below by the following persons in the capacities and on the dates indicated.

Signature -----	Title -----	Date ----
/s/ Michael J. Gausling -----	Chief Executive Officer, President and Director (Principal Executive Officer) Chief Executive Officer	February 4, 2002
/s/ Ronald H. Spair ----- Ronald H. Spair	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	February 4, 2002
* ----- Mark L. Kuna	Controller (Principal Accounting Officer)	
* ----- Michael G. Bolton	Director	
* -----	Director	



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William W. Crouse

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Director

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Frank G. Hausmann

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Director

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Roger L. Pringle

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Director

-----  
Gregory B. Lawless

\* By: /s/ Ronald H. Spair

-----  
Ronald H. Spair  
Attorney-in-Fact  
Dated: February 4, 2002

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Exhibit Index

Exhibit	Description
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23.1	Consent of Arthur Andersen LLP.
23.2	Consent of PricewaterhouseCoopers LLP, Independent Accountants.