ORASURE TECHNOLOGIES INC
Form 424B5
September 10, 2003
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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 and has been declared effective. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED SEPTEMBER 10, 2003

Filed pursuant to Rule 424(b)(5) Registration: 333-106786

PROSPECTUS SUPPLEMENT

(To Prospectus dated August 8, 2003)

5,000,000 Shares

Common Stock

OraSure Technologies, Inc. is selling 5,000,000 shares of common stock. We have granted the underwriters a 30-day option to purchase up to an additional 750,000 shares from us to cover over-allotments, if any.

Our common stock is traded on the Nasdaq National Market under the symbol OSUR . The last reported sale price on September 9, 2003 was $9.96 per share.

INVESTING IN OUR COMMON STOCK INVOLVES RISKS. SEE RISK FACTORS BEGINNING ON PAGE 4 OF THE ACCOMPANYING PROSPECTUS.

	Per Share	Total
Public offering price	$	$

Underwriting discount	$	$
Proceeds, before expenses, to us	$	$

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

Thomas Weisel Partners LLC

SG Cowen

Wells Fargo Securities, LLC

The date of this prospectus supplement is , 2003

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ABOUT THIS PROSPECTUS SUPPLEMENT

You should read this prospectus supplement along with the accompanying prospectus carefully before you invest. Both documents contain important information you should consider when making your investment decision. This prospectus supplement contains information about the common stock offered hereby, and the prospectus contains information about our securities generally. This prospectus supplement may add, update or change information in the prospectus. You should rely only on the information provided in this prospectus supplement or in the accompanying prospectus, or information incorporated by reference in the accompanying prospectus. We have not authorized anyone to provide you with different information.

We are offering to sell shares of common stock and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. The information in this prospectus supplement is accurate only as of the date of this prospectus supplement, regardless of the time of delivery of the prospectus supplement or the sale of any common stock.

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PROSPECTUS SUPPLEMENT SUMMARY

The following information supplements, and should be read together with, the information contained or incorporated by reference in other parts of this prospectus supplement and in the accompanying prospectus. This summary highlights selected information from this prospectus supplement and the accompanying prospectus to help you understand our business. Because the following is only a summary, it does not contain all of the information that may be important to you. You should carefully read this prospectus supplement and the accompanying prospectus before deciding whether to invest in our common stock. You should pay special attention to the Risk Factors section beginning on page 4 of the accompanying prospectus to determine whether an investment in our common stock is appropriate for you.

Our Company

We are a market leader in the field of oral fluid diagnostics. Our business principally involves the development, manufacture, marketing and sale of oral fluid specimen collection devices using our proprietary oral fluid technologies, but includes other proprietary diagnostic products including *in vitro* diagnostic tests using other specimen types and other medical devices. Our diagnostic products include tests which are processed in a laboratory and tests which are performed on a rapid basis at the point of care. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians offices, and commercial and industrial entities.

We believe our products and technology platforms, our financial condition and our senior management team provide us with key competitive advantages, including, most notably, the following:

- We are a market leader in oral fluid diagnostic products and technologies, particularly in the HIV and substance abuse testing markets. We believe oral fluid diagnostic testing offers significant advantages over other testing methods (i.e., blood and urine), including that it is less invasive than other methods, easier to use and safer for patients and healthcare providers, difficult to adulterate, and accurate, portable and cost effective.

- We have a diversified portfolio of product and technology platforms that we currently sell into a variety of markets. This will enable us to pursue multiple new products and product improvements and substantial market opportunities.

- Our OraQuick® technology represents a proprietary point-of-care testing platform that has the potential to effect major changes in testing for infectious diseases. Currently, our OraQuick® HIV-1 test is the only rapid, point-of-care test that has received FDA approval and a CLIA (the Clinical Laboratory Improvements Amendments of 1988) waiver. We are currently seeking FDA approval for use of OraQuick® in detecting HIV-1 in oral fluid and plasma samples in addition to its approved use with finger-stick and venipuncture whole blood. We are also seeking FDA approval for use of OraQuick® in detecting HIV-2.

- Our current financial position is strong. As of June 30, 2003, we had more than $15 million of cash, cash equivalents and short-term investments, more than $19 million in working capital and approximately $6.4 million in available bank credit facilities. We believe this strong financial position, along with the net proceeds of this offering, will provide a solid foundation for future growth.

- Our board of directors and senior management team are comprised of experienced professionals from the medical diagnostic and pharmaceutical industries, with the experience and expertise to substantially grow our business.

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Our Products

Our principal products include the following:

Product	Description	FDA Approval Status	Commercial Status
OraQuick®	The only rapid, point-of-care test for HIV-1 that has FDA approval and a CLIA waiver; the test can be visually read at the point of care in approximately 20 minutes.	Finger-stick whole blood PMA approved November 2002, CLIA waived January 2003.	Marketed
		Venipuncture whole blood PMA supplement approved September 2003; final approval of labeling pending.	Pending
		HIV-2 PMA supplement filed June 2003.	
		Plasma expected PMA supplement filing Q3 of 2003.	
		Oral fluid expected PMA supplement filing Q3 of 2003.	Pending
			Pending
			Pending
OraSure®	The only FDA approved oral fluid collection device for the detection of antibodies to HIV-1 in an oral fluid sample in a laboratory setting.	PMA approved December 1994.	Marketed
		Also have FDA clearance for use of this device in detecting cocaine and an	Marketed

		indicator of nicotine in oral fluid.	
Intercept®	Oral fluid collection device, along with nine related oral fluid immunoassays, which is the only laboratory-based oral fluid drug testing system that has been cleared by the FDA.	Collection device 510(k) cleared 2000.	Marketed
	Used to detect the following drugs in an oral fluid sample: marijuana, cocaine, opiates, amphetamines, methamphetamines, PCP, benzodiazepines, barbiturates and methadone.	Nine drug assays 510(k) cleared 2000-2001.	Marketed
Histofreezer® Rx	A cryosurgical (freezing) system for the removal of warts and other benign skin lesions; marketed to the physicians office market.	Nine indications 510(k) cleared 1991-1999.	Marketed
Histofreezer® OTC	Sold under the Freeze Off and Compound W® tradenames in the over-the-counter market in the U.S. for removal of common and plantar warts.	Two indications 510(k) cleared February 2003.	Marketed

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In addition to these products, we also sell certain immunoassay tests and reagents for insurance risk assessment, substance abuse and forensic toxicology applications; an oral fluid Western blot HIV-1 confirmatory test used to confirm positive indications from the use of our OraSure® product; and the Q.E.D.® saliva alcohol test.

We believe that oral fluid testing has several significant advantages over blood or urine-based testing systems for both health care professionals and the individuals being tested. These advantages include eliminating the risk of needle-stick accidents, providing a noninvasive collection technique, requiring minimal training to administer, providing rapid and efficient collection in almost any setting, and reducing the cost of administration by a trained health care professional.

In addition to our current product portfolio, over the past few years, our research and development efforts have focused on our Up-Converting Phosphor Technology (UPT) and the first UPT application expected to be commercialized, our UP*link*® rapid, point-of-care system for detecting the NIDA-5 panel of drugs (i.e., marijuana, opiates, cocaine, amphetamines/methamphetamines and PCP) in a single oral fluid sample. UPT is a proprietary label detection platform technology that uses phosphor particles to detect minute quantities of various substances. UP*link*® is designed to be a rapid, point of-care system utilizing a collector, lateral flow test cassette, and analyzer (including software), that can quickly provide instrument-read results on a variety of samples, including oral fluid, blood, serum, urine and stool samples.

Our Strategy

We have adopted a three-part growth strategy, pursuant to which we intend to leverage our extensive diagnostic experience in order to maximize the available opportunities from our existing products and technologies, and supplement our existing product pipeline through the strategic acquisition of other technologies and products. We intend to follow a disciplined approach to maximize the value of our business for the benefit of our stockholders. Specifically, our business strategy includes the following key elements:

We intend to maximize the sales potential of our existing product lines in the markets where they are currently sold. This would principally involve fully capitalizing on the potential market reach of our OraQuick®, OraSure®, Intercept® and Histofreezer® products by investing in our sales and marketing efforts where appropriate, making product improvements and enhancements and optimizing our distribution channels. We also expect to selectively expand the distribution of our established products into certain international markets.

We intend to expand the use of our existing products and technology platforms into new applications and new markets. For example, we believe that both the OraQuick® and OraSure® product technologies are very flexible and could be used potentially for the detection of diseases or conditions other than HIV. We also expect to complete development of the UP*link*® rapid drug detection system and explore other potential applications for both the UP*link*® and UPT technology platforms in the future.

We will evaluate potential acquisitions that may provide new products and technology platforms to supplement our existing product pipeline.

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Corporate Collaborations

Based on the strength of our product portfolio and technology platforms, we have established several collaborations with leading commercial laboratories, *in vitro* diagnostic companies and other parties. These include:

Rapid HIV-1 Testing: We have entered into an agreement with Abbott Laboratories for the distribution, on a co-exclusive basis, of our OraQuick® rapid HIV-1 antibody test in the United States. However, Abbott is substantially behind in meeting its minimum purchase obligations under the agreement, and we are working with Abbott to correct this deficiency. We are also discussing amending our agreement with Abbott and may consider terminating the agreement if Abbott does not meet its obligations and an amendment is not completed, as further described under the heading Business Products in this prospectus supplement. The risks relating to our use of collaborations is also further described under the heading Risk Factors Risks Relating to Collaborators in the accompanying prospectus.

Insurance Testing: We have entered into agreements with Lab*One*, Inc., Clinical Reference Laboratories and Heritage Labs for the distribution of our OraSure® oral fluid collection device to insurance companies for risk assessment testing in connection with the underwriting of life insurance.

Substance Abuse Testing: We have entered into agreements with Quest Diagnostics and Lab*One*, Inc., two large commercial laboratories, for the distribution of our Intercept® oral fluid drug test system into the workplace market. We have also collaborated with several smaller commercial laboratories to distribute Intercept® into the criminal justice market in the United States and with Altrix HealthCare plc to market and sell Intercept® in the United Kingdom and Ireland.

Wart Removal: We have entered into an agreement with Medtech Holdings, Inc., the owner of the Compound W® wart removal product line, for the distribution of Freeze Off, a cryosurgical wart removal product similar to Histofreezer®, in the over-the-counter market in the United States.

Uplink® Rapid Drug Detection System: We have entered into research and development and supply agreements with Dräger Safety AG Co. & KGaA, located in Germany, for the development and sale of our UP*link*® oral fluid point-of-care drug detection system, principally in the roadside testing market in Europe and other foreign countries.

Up-Converting Phosphor Technology: We have obtained world-wide rights under patents and know-how owned by SRI International and the Sarnoff Corporation (a subsidiary of SRI International) to develop and market products that use up-converting phosphor technology, or UPT.

Lab-Based HIV-1 Testing: We have entered into agreements with bioMerieux, Inc. (BMX) under which we manufacture an oral fluid Western blot HIV-1 confirmatory test for use with our OraSure® collection device, and BMX distributes this test on an exclusive, worldwide basis.

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The Offering

Common stock offered by OraSure	5,000,000 shares
Common stock to be outstanding after the offering	43,470,426 shares
Use of proceeds	To fund general working capital, commercialization of new products, research and development, potential acquisitions, capital expenditures, patent license fees, debt service and retirement and general corporate purposes.
Risk factors	See Risk Factors beginning on page 4 and Special Note Regarding Forward-Looking Statements on page 17 of the accompanying prospectus, for a discussion of factors you should consider before buying shares of our common stock.
Nasdaq National Market Symbol	OSUR

The number of shares of common stock to be outstanding after the offering is based on the number of shares outstanding as of June 30, 2003, and does not include up to 750,000 shares of common stock issuable upon exercise of the underwriters over-allotment option. As of that date, we had 38,470,426 shares of common stock outstanding. In addition, as of June 30, 2003, we had 4,472,419 shares of common stock underlying options outstanding at a weighted average exercise price of $6.21 per share, 120,000 shares underlying a warrant with an exercise price of $6.125 per share, and 1,249,791 shares available for future grant under our stock option plans.

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SUMMARY FINANCIAL DATA

We derived the following information from our audited financial statements for each of the years in the three-year period ended December 31, 2002 and from our unaudited financial statements as of June 30, 2003 and for the six months ended June 30, 2002 and 2003. In the opinion of our management, our unaudited financial statements include all adjustments, consisting only of normal and recurring adjustments, considered necessary for a fair presentation of the financial information. The following information should be read in conjunction with our financial statements and related notes incorporated by reference in the accompanying prospectus.

Operating results for the six months ended June 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003. For more details on how you can obtain our SEC reports and other information, you should read the section entitled, Where You Can Find More Information, beginning on page S-42 of this prospectus supplement. The as adjusted balance sheet data gives effect to the sale of our common stock in this offering, at an assumed offering price of $9.96 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses.

	Year ended December 31,			Six months ended June 30,	
	2002	2001	2000	2003	2002
				(unaudited)	
	(in thousands, except per share data)				
Statement of Operations Data					
Revenues	$ 32,010	$ 32,573	$ 28,788	$18,239	$15,656
Costs and expenses	$ 35,550	$ 36,906	$ 42,917	$19,917	$18,672
Net loss	$ (3,342)	$ (3,728)	$ (12,747)	$ (1,623)	$ (2,874)
Net loss per share, basic and diluted	$ (0.09)	$ (0.10)	$ (0.36)	$ (0.04)	$ (0.08)
Shares used in computing basic and diluted net loss per share	37,583	36,868	35,002	38,331	37,464

	As of June 30, 2003	
	Actual	As Adjusted
	(unaudited) (in thousands)	
Balance Sheet Data		
Cash, cash equivalents and short-term investments	$ 15,408	$ 61,969
Working capital	$ 19,195	$ 65,756
Total assets	$ 36,531	$ 83,092
Long-term debt, less current portion	$ 3,008	$ 3,008
Accumulated deficit	$ (131,058)	$ (131,058)
Total stockholders equity	$ 25,951	$ 72,512

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RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risk factors related to our business, our financial condition, regulatory risks, our industry, business and strategy, our collaborators and this offering in the accompanying prospectus beginning on page 4. You should also carefully consider the other information included in the accompanying prospectus and information in our periodic reports filed with the SEC. If any of the described risks actually occur, our business, financial condition or results of operations could be materially and adversely affected, and you may lose some or all of your investment.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as may, will, intend, expect, anticipat believe, estimate, predict, potential, or continue or the negative of such terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under Risk Factors beginning on page 4 of the accompanying prospectus and elsewhere in this prospectus supplement and the accompanying prospectus, that may cause our or our industry s actual results, levels of activity, performance or achievements to differ from those expressed or implied by such forward-looking statements. Before deciding to purchase our common stock, you should carefully consider the risks described in the Risk Factors section of the accompanying prospectus, in addition to other information set forth in this prospectus supplement, the accompanying prospectus and in the documents incorporated by reference in this prospectus supplement and the accompanying prospectus.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as may be required by law, we do not intend to update any of the forward-looking statements for any reason after the date of this prospectus supplement to conform such statements to actual results or if new information becomes available.

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USE OF PROCEEDS

We estimate that the proceeds we will receive from this common stock offering will be approximately $46.6 million after deducting estimated underwriting discounts, commissions and offering expenses payable by us in connection with this offering. If the underwriters exercise the over-allotment option in full, we will receive net proceeds from this offering of approximately $53.6 million.

The net proceeds will be added to our general funds and used for general working capital purposes, which may include, but are not limited to:

- commercialization of new products;
- ongoing research and development activities;
- potential acquisitions;
- capital expenditures;
- patent license fees;
- debt service and retirement; and
- general corporate purposes.

The amounts and timing of our actual expenditures for each purpose may vary significantly depending upon numerous factors, including the status of our research and product development efforts, regulatory approvals, competition, marketing and sales activities, the market acceptance of any products introduced by us, and economic or other conditions. Pending such uses, we intend to invest the net proceeds of this offering in short-term, investment grade, interest-bearing securities.

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CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2003:

- on an actual basis; and
- on an adjusted basis to give effect to our receipt of an estimated $46.6 million of net proceeds from the sale of our common stock pursuant to this offering, after deducting estimated underwriting discounts, commissions and offering expenses.

This table should be read in conjunction with our financial statements and the notes thereto, which are incorporated by reference in the accompanying prospectus.

	June 30, 2003	
	Actual	As Adjusted
	(unaudited) (in thousands)	
Long-term debt	$ 3,008	$ 3,008
Stockholders equity:		
Preferred stock, par value $0.000001, 25,000,000 shares authorized, no shares issued		
Common stock par value, $0.000001, 120,000,000 shares authorized, 38,470,426 shares issued and outstanding as of June 30, 2003; and 43,470,426 shares issued and outstanding as adjusted		
Additional paid-in capital	157,191	203,752
Accumulated other comprehensive loss	(182)	(182)
Accumulated deficit	(131,058)	(131,058)
Total stockholders equity	25,951	72,512
Total capitalization	$ 28,959	$ 75,520

The information in the table above does not include:

- 4,472,419 shares of common stock subject to options outstanding at June 30, 2003, at a weighted average exercise price of $6.21 per share;
- 1,249,791 shares of common stock that have been reserved for issuance upon future grants under our stock option plans as of June 20, 2003;

120,000 shares of common stock issuable upon exercise of a warrant at an exercise price of $6.125 per share; and

up to 750,000 shares of common stock issuable upon exercise of the underwriters over-allotment option.

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PRICE RANGE OF COMMON STOCK

Our common stock is quoted on the Nasdaq National Market under the symbol OSUR. The following table sets forth, for the periods indicated, the high and low sale prices per share of our common stock as reported on the Nasdaq National Market since January 1, 2001.

	High	Low
2001		
First Quarter	$ 10.000	$ 5.875
Second Quarter	$ 12.640	$ 6.688
Third Quarter	$ 15.000	$ 7.260
Fourth Quarter	$ 12.880	$ 8.890
2002		
First Quarter	$ 12.280	$ 4.750
Second Quarter	$ 8.350	$ 5.500
Third Quarter	$ 6.820	$ 3.330
Fourth Quarter	$ 8.150	$ 3.700
2003		
First Quarter	$ 8.620	$ 5.050
Second Quarter	$ 8.290	$ 5.470
Third Quarter (through September 9, 2003)	$ 10.490	$ 7.363

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all future earnings for the operation and expansion of our business. We do not anticipate declaring or paying cash dividends on our common stock in the foreseeable future. Any future payment of cash dividends on our common stock will be at the discretion of our board of directors and will depend upon our results of operations, earnings, capital requirements, contractual restrictions and other factors deemed relevant by our board of directors.

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BUSINESS

The following information supplements, and should be read together with, the information contained or incorporated by reference in other parts of this prospectus supplement and in the accompanying prospectus. This description of our business provides selected information incorporated by reference in the accompanying prospectus. Because the following is only a summary, it does not contain all of the information that may be important to you.

Overview

Our Company was formed in May 2000 under Delaware law solely for the purposes of combining two companies, STC Technologies, Inc. (STC Technologies) and Epitope, Inc. (Epitope), and changing the state of incorporation of Epitope from Oregon to Delaware. STC Technologies and Epitope were merged into our Company on September 29, 2000. Our principal offices are located at 220 East First Street, Bethlehem, Pennsylvania 18015, and our telephone number is (610) 882-1820.

We develop, manufacture and market oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other *in vitro* diagnostic tests, and other medical devices. These products are sold in the United States as well as internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians offices, and commercial and industrial entities.

Products

Our principal products currently include the following:

- The OraQuick® rapid antibody test for detecting the Human Immunodeficiency Virus Type 1 (HIV-1);
- The OraSure® and Intercept® oral fluid collection devices;
- The Histofreezer® and Freeze Off wart removal products;
- Certain immunoassay tests and reagents for insurance risk assessment, substance abuse and forensic toxicology applications;
- An oral fluid Western blot HIV-1 confirmatory test; and
- The Q.E.D.® saliva alcohol test.

OraQuick® Rapid Test. OraQuick® is our rapid test platform designed to test an oral fluid, whole blood or plasma sample for the presence of various antibodies or analytes. The device uses a porous flat pad to collect an oral fluid specimen. After collection, the pad end of the device 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. In both cases, the specimen and solution then flow through the testing device where test results are observable in approximately 20 minutes. The OraQuick® device is a screening test and requires a confirmation test where an initial positive result is obtained.

Our first product utilizing this technology is the OraQuick® rapid HIV-1 antibody test, a rapid test for the presence of antibodies against HIV-1. On November 7, 2002, we received premarket approval of this test from the U.S. Food and Drug Administration, or FDA, for detecting HIV-1 antibodies in finger-stick whole blood samples. This FDA approval is based on data indicating that the OraQuick® test has sensitivity of 99.6% and specificity of 100%, based on clinical studies we performed using finger-stick whole blood specimens. Sensitivity is a measure of the accuracy for detecting positive specimens, and specificity is a measure of the accuracy for identifying negative specimens.

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As a result of this FDA approval, the OraQuick® test is available for use by the nearly 40,000 locations in the United States certified under the Clinical Laboratory Improvements Amendments of 1988 (CLIA), to perform moderately complex diagnostic tests. Additionally, in January 2003, we received a waiver under CLIA for the OraQuick® rapid HIV-1 antibody test. This waiver will also permit the use of the OraQuick® test by approximately 140,000 additional sites in the United States not certified under CLIA to perform moderately complex tests, such as outreach clinics, community-based organizations and physicians offices.

On September 5, 2003, we received FDA approval for use of the OraQuick® test in detecting HIV-1 antibodies in venipuncture whole blood samples. We believe this claim will help us further penetrate the hospital market where venipuncture whole blood samples are routinely taken from patients. Our ability to sell the test for use with venipuncture whole blood is subject to completion of final product labeling incorporating the venipuncture whole blood claim, which is currently under review by the FDA.

We intend to seek FDA approval for certain other claims for OraQuick® in addition to its approved usage to detect HIV-1 antibodies in finger-stick and venipuncture whole blood. We are performing the clinical trials for usage of the device with oral fluid and plasma and expect to make the related FDA submissions for these claims in the third quarter of 2003. However, there is no assurance that we will receive FDA approval of these claims.

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

In June 2002, we appointed Abbott Laboratories as a co-exclusive distributor of our OraQuick® device in the United States under a five-year agreement (with annual renewals). Under this agreement, Abbott is required to make minimum monthly purchases through February 2004 totaling approximately $4 million. In order to maintain its co-exclusive distribution rights, Abbott must also purchase at least $4 million of devices through December 31, 2003 and at least $6 million of devices annually in future years. Required monthly purchases and other purchases are credited against the co-exclusive minimums. Abbott s purchases through September 1, 2003 have been substantially below its minimum obligations and we are working with Abbott to increase its future purchases of OraQuick® devices. We recently obtained FDA approval of a venipuncture whole blood claim and intend to seek approval of a plasma claim for our OraQuick® device in order to help Abbott increase its sales to the hospital market.

It is possible that we may amend our agreement with Abbott in light of these developments. In addition, if Abbott is not able to satisfy the minimum purchase levels required under the agreement and the parties do not reach agreement on appropriate amendments, we may consider terminating the agreement. There is no assurance that the agreement will be amended or that the agreement will continue. If the agreement is terminated, there is no assurance that we would be able to maintain or increase sales volumes of our OraQuick® devices ourselves or with other distributors, if needed.

OraSure®/Intercept® Collection Devices. Our OraSure® oral fluid collection device is used in conjunction with screening and confirmatory tests for HIV-1 antibodies and other analytes. This device consists of a small, treated cotton-fiber pad on a nylon handle that is placed in a person s mouth for two to five minutes. The device collects oral mucosal transudate (OMT), a serum-derived fluid that contains higher concentrations of certain antibodies and analytes than saliva. As a result, OMT testing is a highly accurate method for detecting HIV-1 infection and other analytes.

We have received premarket approval from the FDA to sell the OraSure® collection device for use with a laboratory-based enzyme immunoassay (EIA) screening test for HIV-1 antibody detection. This

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EIA screening test has been approved by the FDA for use with our OraSure® device and is manufactured and sold by another party.

We have also received FDA 510(k) clearance for use of the OraSure® collection device with EIAs to test for cocaine and cotinine (a metabolite of nicotine) in oral fluid specimens.

A collection device that is substantially similar to the OraSure® device is sold under the name Intercept®, and is used to collect OMT for oral fluid drug testing. We have received FDA 510(k) clearance to use the Intercept® collection device with our laboratory-based EIAs to test for drugs of abuse commonly identified by the National Institute for Drug Abuse (NIDA) as the NIDA-5 (i.e., cannabinoids (marijuana), cocaine, opiates, amphetamines/methamphetamines, and phencyclidine (PCP)), and for barbiturates, methadone and benzodiazepines. Each of these EIAs is also FDA 510(k) cleared for use with the Intercept® device.

Histofreezer®. In 1991, we obtained initial FDA 510(k) clearance for, and became the exclusive United States distributor of, the Histofreezer® wart removal system, a low-cost alternative to liquid nitrogen and other methods for removal of warts and other benign skin lesions by physicians. In June 1998, we acquired the Histofreezer® product from Koninklijke, Utermöhlen, N.V., The Netherlands. As part of the acquisition, we established a sales office in Reeuwijk, The Netherlands and are selling the Histofreezer® product through a dealer network in more than 20 countries worldwide. Most of our Histofreezer® sales occur in the United States to distributors who, in turn, sell to family practitioners, pediatricians and podiatrists.

The Histofreezer® product mixes two environmentally friendly cryogenic gases in a small aerosol canister. When released, these gases are delivered to a specially designed foam bud, cooling the bud to 50°C. The frozen bud is then applied to the wart or lesion for 15 to 40 seconds (depending on the type of lesion) creating localized destruction of the target area by freezing.

In February 2003, we received FDA clearance to market and sell the Histofreezer® product in the retail or over-the-counter market for the removal of common and planter warts. This product is being distributed under the name Freeze Off by Medtech Holdings, Inc., the owner of the Compound W® line of wart removal products.

Immunoassay Tests and Reagents. We develop and sell immunoassay tests in two formats, known as MICRO-PLATE and AUTO-LYTE®, to meet the specific needs of our customers.

In 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 we may also provide to our laboratory customers. MICRO-PLATE tests can be performed on commonly used instruments and can detect drugs in urine, serum, and sweat specimens. MICRO-PLATE tests are also used as part of the Intercept® product line to detect drugs of abuse in oral fluid specimens.

AUTO-LYTE® tests are sold in the form of bottles of liquid reagents. These reagents are run on commercially available laboratory-based automated analytical instruments, which are manufactured by a variety of third parties. AUTO-LYTE® is typically used in high volume, automated, commercial reference insurance laboratories to detect certain drugs or chemicals in urine. Test results are produced quickly, allowing for high throughput. Our AUTO-LYTE® sales are expected to be substantially reduced in 2003 and beyond as a result of competition from

internally developed urine reagents by our insurance laboratory customers.

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Whenever possible, we enter into multi-year sales agreements with our customers. These agreements generally are entered into with a laboratory that has agreed to purchase a minimum number of tests over a two-to-five-year period. We also offer these customers the option of a reagent rental agreement under which we sell the tests at an increased price over a fixed period of time, which includes an additional equipment charge in exchange for providing the customer with the required analytical laboratory equipment. We obtain this equipment from third party vendors.

Western Blot HIV-1 Confirmatory Test. We sell an oral fluid Western blot HIV-1 confirmatory test that received premarket approval from the FDA in 1996. This test uses the original specimen collected with the OraSure® oral fluid collection device to confirm positive results of initial oral fluid HIV-1 EIA screening tests. The oral fluid Western blot HIV-1 confirmatory test is marketed under an exclusive arrangement with bioMerieux, Inc.

Q.E.D.® Saliva Alcohol Test. Our Q.E.D.® saliva alcohol test is an on-site, cost-effective test device that is an alternative to breath or blood alcohol testing. The test is a quantitative, saliva-based method for the detection of ethanol, and has been cleared for sale by the FDA and the U.S. Department of Transportation (DOT). In 1998, the product also received a CLIA waiver.

Products Under Development

UPT and UPlink® Development. During the past several years, much of our research and development efforts have been focused on our Up-Converting Phosphor Technology, or UPT, and our UP*link*® technology platform.

UPT is a proprietary label detection platform that uses phosphor particles to detect minute quantities of various substances. UPT utilizes the same particle shell that is coated onto a television screen, but the internal chemistry of the particle has been changed. These changes result in a particle that is excited by infrared light as compared to an ultraviolet light source for television screens. With assistance from our research partners, we have developed phosphorescent particles that up-convert infrared light to visible light, which we believe 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. Our patented improvements on this base technology employ chemical changes inside the phosphor particles so that low energy infrared light can be used to produce a high energy visible colored signal and is the basis for UPT. This use of infrared light to create a colored signal is called up-conversion as opposed to down-conversion, which occurs in phosphors designed to be used with ultraviolet light.

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

We believe that UPT has the potential to overcome some of the limitations of other diagnostic detection methods and offers features not commercially available today. For example, UPT testing

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produces zero background interference, which dramatically increases the potential sensitivity of any test system using this technology. In addition, we believe that, through additional development, UPT may offer the following other key competitive features:

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

We have reached certain important milestones in the development of UPT, including improving the manufacturing process to produce UPT particles, working to optimize UPT particle coating techniques, producing four distinct colors of UPT particles to permit multiplexing, demonstrating initial feasibility for the use of UPT particles in infectious disease, cancer, and limited DNA detection applications, and developing a UPT collector, test cassette, and analyzer for use in testing oral fluid for drugs of abuse. We believe UPT may have several potential applications for *in vitro* diagnostics, including human clinical testing for cancer, allergies, and thyroid and cardiac conditions, and for therapeutic drug monitoring, biological warfare testing, food and environmental testing, pharmaceutical research, genomics and pharmacogenomics, veterinary testing, and surgical imaging. We also believe that UPT labels may be used for the detection of infectious diseases with DNA probes. However, we have not yet completed development of UPT or fully explored potential UPT applications. We also have not determined which applications to pursue or the manner in which these opportunities will be pursued, if at all. Additional research and development will be required to determine the full potential of UPT. In addition, we believe that we may need to enter into partnering arrangements with other entities and devote substantial funds and other resources to exploit fully the potential of UPT.

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

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

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

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In March 2000, we signed a research and development agreement with Dräger Safety AG & Co. KGaA (Dräger Safety), a European manufacturer and supplier of medical and safety technology products for health care and industrial applications. This agreement provided for the development of the UP*link*® system for rapid detection of drugs of abuse in oral fluid. After research and development activities are completed, Dräger Safety has the option to become our exclusive distributor of this product in Europe and certain other countries to law enforcement officials for rapidly assessing whether an operator or passenger in a motor vehicle is under the influence of one or more drugs of abuse (the roadside market) and ultimately to certain military, criminal justice, and workplace testing markets. We received a non-refundable fee from Dräger Safety under the agreement and will receive additional fees upon achievement of certain technical milestones.

In September 2000, we signed a research and development agreement with Meridian Bioscience, Inc. (Meridian), a medical diagnostics company. Under this agreement, we intended to develop a range of UP*link*® point-of-care tests for the rapid detection of parasites, and gastrointestinal and upper respiratory diseases. Development of one test, for detection of the respiratory syncytial virus (RSV), has been substantially completed. However, due to development delays and certain other events, we have agreed in principle with Meridian to terminate this agreement. We may seek funding from other potential parties if we attempt to commercialize the RSV test or develop any of the other infectious disease applications for UP*link*® that we had previously intended to develop with Meridian.

We are participating in a $4.2 million, four-year grant for research and development of saliva/oral fluid-based diagnostic technologies, awarded by the National Institutes of Health (the NIH) to the University of Pennsylvania. The grant will cover basic research in the following three main areas:

- New technologies for collecting bacterial/viral protein and nucleic acid samples from the human mouth;
- The combination of the University of Pennsylvania s microfluidic processing technology with our UPT echnology for sample preparation; and
- The detection of viral or bacterial markers.

The research plan under the grant contemplates achieving these goals through the use of our UP*link*® rapid detection system.

Our portion of funding under the grant is expected to be made available over a four-year period, with approximately $400,000 available in the first year and, if the grant is renewed by the NIH as we expect, each year thereafter. Payments under the grant in the second, third and fourth years will be subject to availability of funds from the NIH and satisfactory progress of the research and development project.

OraSure®/Intercept® Applications. Oral mucosal transudate, or OMT, contains many constituents found in blood and serum, although in lower concentrations. We believe the OraSure® and Intercept® devices are a platform technology with a wide variety of potential applications, where laboratory testing is available. For example, the OraSure® device may be used for the collection of a variety of antibodies or markers for infectious diseases or conditions in addition to HIV-1, such as antibodies for viral hepatitis. We also believe these devices may be useful for the collection of DNA in oral fluid.

OraQuick® Platform. We believe that OraQuick® has significant potential as a rapid, point-of-care test platform for physicians offices, hospitals, and other markets. Like the OraSure® device, we believe that OraQuick® provides a platform technology that can be modified for detection of a variety of infectious diseases in addition to HIV, such as viral hepatitis and certain sexually transmitted diseases.

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Sales and Marketing

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

Insurance Risk Assessment. We currently market the OraSure® oral fluid collection device for use in screening life insurance applicants in the United States and internationally to test for three of the most important underwriting risk factors: HIV-1, cocaine, and cotinine (a metabolite of nicotine). Devices are sold to insurance testing laboratories, including Lab*One*, Heritage Labs and Clinical Reference Laboratories. These laboratories in turn provide the collection devices to insurance companies, usually in combination with testing services.

We also maintain a direct sales force that promotes use of the OraSure® device directly to insurance companies. Insurance companies then make their own decision regarding which laboratory to use to supply their collection devices and testing services. Our OraSure® Western blot confirmatory test is distributed through BMX to laboratories and is used to confirm oral fluid specimens that initially test positive for HIV-1.

Because insurance companies are in various stages of their adoption of the OraSure® device, there exists a wide range of policy limits where the product is being applied. Some insurance companies have chosen to extend their testing to lower policy limits where they did not test at all before, while others have used OraSure® to replace some of their blood and urine-based testing. In general, most of our insurance company customers use the OraSure® device in connection with life insurance policies having face amounts of up to $250,000, with some customers using the device for policies of up to $500,000 in amount. One large insurance customer uses the OraSure® device with policies having face amounts up to $3 million.

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

Infectious Disease Testing. Our sales personnel market the OraSure® oral fluid collection device, separately and as a kit in combination with laboratory testing services (as described below), and the OraQuick® rapid HIV-1 antibody test directly to customers in the public health market for HIV-1 testing. This market consists of a broad range of clinics and laboratories and includes states, counties, and other governmental agencies, The Centers for Disease Control and Prevention, colleges and universities, correctional facilities and the military. There are also a number of organizations in the public health market such as AIDS service organizations and various community-based organizations set up primarily for the purpose of encouraging and enabling HIV testing.

To better serve our public health customers, we have entered into agreements with Lab*One* and Heritage Labs to provide prepackaged OraSure® test kits, with prepaid laboratory testing and specimen shipping costs included. We also sell the OraSure® and OraQuick® devices in the international public health markets.

In June 2002, we entered into an agreement under which the Diagnostics Division of Abbott Laboratories was appointed as the co-exclusive distributor of the OraQuick® rapid HIV-1 antibody test in the United States. Currently, Abbott focuses primarily on the hospital and physician office market, while

we primarily target our direct sales to the public health and criminal justice markets, the military, the Centers for Disease Control and Prevention and other agencies. For a further discussion of our agreement with Abbott, see the section of this prospectus supplement entitled, Products.

Substance Abuse Testing. Our 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.

We have entered into agreements for the distribution of Intercept® collection kits and associated reagents for drugs-of-abuse testing in the workplace testing market in the United States and Canada through several laboratory distributors, including Lab*One*, Quest Diagnostics, Clinical Reference Laboratory and NWT, Inc., and internationally for workplace and forensic toxicology testing through Bio-Rad Laboratories, Altrix HealthCare, plc, and other distributors. We assist our laboratory customers in customizing their testing services by selling them equipment required to test oral fluid specimens collected with the Intercept® device.

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

Cryosurgical Systems. We sell the Histofreezer® product line to distributors that market to more than 150,000 primary care physicians and podiatrists in the United States. Major U.S. distributors include Cardinal Healthcare, McKesson HBOC, Physicians Sales & Service, AmerisourceBergen Corporation, and Henry Schein. Internationally, we market Histofreezer® in a number of countries through a network of distributors. In addition, we have engaged several contract sales firms in order to further penetrate the physicians office market in the United States. We have also commenced sales of Freeze Off, a product similar to Histofreezer®, in the over-the-counter market in the U.S. pursuant to a distribution agreement with Medtech Holdings, Inc., the owner of the Compound W® line of wart removal products.

International Markets. We sell a number of our products into international markets primarily through distributors with knowledge of their local markets. Principal markets include physicians offices, insurance risk assessment, public health, laboratory testing, criminal justice and forensic toxicology.

We assist our international distributors in registering the products and obtaining required regulatory approvals in each country, and we provide training and support materials. Our international marketing program includes direct assistance to distributors in arranging for laboratory services, cooperation from screening test manufacturers, and performance of Western blot confirmatory tests when necessary.

Significant Products and Customers. Several different products have contributed significantly to our financial performance, accounting for 15% or more of total revenues during the past three years. The OraSure® and Intercept® oral fluid collection devices, Histofreezer® product, and immunoassay tests and reagents accounted for total revenues of approximately $14.3 million, $7.2 million and $7.6 million in 2002, $13.0 million, $6.7 million and $7.4 million in 2001, and $11.2 million, $6.8 million and $6.7 million in 2000, respectively. As new products are developed and commercialized, we expect to reduce our dependence on these products.

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We currently have one customer, Lab*One*, that accounted for 20% and 26% of our total revenues during the six months ended June 30, 2003 and the year ended December 31, 2002, respectively.

As of June 30, 2003, Lab*One* stopped purchasing our urine assays. Our revenues are expected to be negatively impacted by the loss of this business by as much as $1.5 million in 2003 and $2.0 million in 2004, when compared to 2002 revenues in the insurance risk assessment market. There can be no assurance that sales to Lab*One* will not decrease in an amount greater than our current expectations, or that this customer will not choose to replace additional assays or other products with internally-developed products or products manufactured by our competitors. The loss of Lab*One* or a significant decrease in the volume of products purchased by it would have a material adverse effect on our results of operations.

In August 2003, Lab*One* announced that it had agreed to acquire the MetLife Insurance Testing Laboratory (MetLife). MetLife has been a long time purchaser of our urine assays for life insurance risk assessment testing. In light of Lab*One* s recent decision to stop purchasing our urine assays, this acquisition could result in further revenue loss for those products above the levels set forth above. Lab*One* has indicated that it expects the MetLife acquisition to close in the fourth quarter of 2003.

Supply and Manufacturing

We have entered into an agreement with a contractor in the United States for the assembly and supply of our OraSure® and Intercept® oral fluid collection devices. This agreement has a current term through December 31, 2003 and automatically renews for additional annual periods, unless either party provides timely notice of termination prior to the end of an annual period. A change in the manufacturer of the OraSure® device would require FDA review and approval, which could require significant time to complete and could disrupt our ability to manufacture this product. Subject to receipt of the applicable FDA approval, we intend to terminate the agreement with this contractor and transfer manufacturing of both the OraSure® and Intercept® collection devices to our Bethlehem, Pennsylvania facility. The completion of the transfer is expected during the first half of 2004 and is expected to lower our manufacturing costs and help assure we can maintain our quality control for these products.

We manufacture the OraQuick® test in our Bethlehem, Pennsylvania facilities. Our facilities were inspected by the FDA and approved for the manufacture of this test in November 2002, when the FDA first granted pre-market approval of the OraQuick® device. In addition, we have entered into a supply agreement for the assembly of the OraQuick® device in Thailand, in order to supply certain international markets. This 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. We believe that other firms would be able to manufacture the OraQuick® test on terms no less favorable than those set forth in the agreement if the Thailand contractor would be unable or unwilling to continue manufacturing this product.

We can purchase the HIV antigen and the nitrocellulose strips required for the OraQuick® test only from a limited number of sources. The antigen is currently purchased from a single contract supplier under a long-term agreement with an initial term ending in January 2010 and one-year automatic renewal terms thereafter. The nitrocellulose is also provided by a single contract supplier, and we are presently negotiating a long-term supply agreement with this party. If for any reason these suppliers are no longer able to supply our antigen or nitrocellulose needs, we believe that alternative supplies could be obtained at a competitive cost. However, a change in the antigen or nitrocellulose or the suppliers of these materials would require FDA approval and some additional development work. This would require significant time to complete and could disrupt our ability to manufacture and sell the OraQuick® device.

The oral fluid Western blot HIV-1 confirmatory test is manufactured in our Beaverton, Oregon facility. Subject to receipt of FDA approval, we expect to transfer the manufacturing of this product to

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our Bethlehem, Pennsylvania facility. In August 2003, we completed certain equivalency and validation studies and filed a submission with the FDA seeking approval of the transfer. The HIV antigen needed to manufacture the Western blot test is available from only a limited number of sources. For many years, we have purchased the antigen for this product from BMX on an exclusive basis. BMX is also the exclusive distributor of the Western blot test kits.

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

Histofreezer® is assembled in The Netherlands by Koninklijke, Utermöhlen, N.V. (Utermöhlen), the company from which we acquired the product in 1998. We purchase the product pursuant to an exclusive production agreement. This agreement provides that Utermöhlen will be the exclusive supplier of the Histofreezer® product until at least December 31, 2006. Utermöhlen also manufactures Freeze Off, the over-the-counter version of Histofreezer®.

We believe that additional manufacturers of the Histofreezer® and Freeze Off products are available on terms no less favorable than the terms of the production agreement with Utermöhlen, in the event that Utermöhlen would be unable or unwilling to continue manufacturing these products.

Our AUTO-LYTE® and MICRO-PLATE assays are manufactured in our Bethlehem, Pennsylvania facility. These tests require the production of highly specific and sensitive antibodies corresponding to the antigen of interest. Substantially all our antibody requirements are provided by contract suppliers. We believe that we have adequate reserves of antibody supplies and that we have access to sufficient raw materials for these products.

The Q.E.D.® saliva alcohol test is manufactured and packaged for shipment in our Bethlehem, Pennsylvania facility.

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

Employees

As of June 30, 2003, we had 179 full-time employees, including 41 in sales, marketing, and client services; 45 in research and development; 77 in operations, manufacturing, quality control, purchasing and shipping; and 16 in administration and finance. This compares to 187 employees as of December 31, 2002 and 225 employees as of December 31, 2001. As of June 30, 2003, 15 of our employees held Ph.D. degrees. Our employees are not currently represented by a collective bargaining agreement.

Competition

The diagnostic industry is a multi-billion dollar international industry and is intensely competitive. Many of our competitors are substantially larger and have greater financial, research, manufacturing, and marketing resources.

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Important competitive factors for our products include product quality, price, ease of use, customer service, and reputation. Industry competition is based on the following:

- Scientific and technological capability;
- Proprietary know-how;
- The ability to develop and market products and processes;
- The ability to obtain FDA or other required regulatory approvals;
- The ability to manufacture products that meet applicable FDA requirements (i.e., good manufacturing practices);
- Access to adequate capital;
- The ability to attract and retain qualified personnel; and
- The availability of patent protection.

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

The future market for diagnostic tests is expected to be characterized by consolidation, greater cost consciousness, and tighter reimbursement policies. The purchasers of diagnostic products are expected to place increased emphasis on lowering costs, reducing inventory levels, automation, service, and volume discounts. The increased complexity of the market is expected to force many competitors to enter into joint ventures or license certain products or technologies.

We expect competition to intensify as technological advances are made and become more widely known, and as new products reach the market. Furthermore, new testing methodologies could be developed in the future that render our products impractical, uneconomical or obsolete. There can be no assurance that our competitors will not succeed in developing or marketing technologies and products that are more effective than those we develop or that would render our technologies and products obsolete or otherwise commercially unattractive. In addition, there can be no assurance that our competitors will not succeed in obtaining regulatory approval for these products, or introduce or commercialize them before we can do so. These developments could have a material adverse effect on our business, financial condition and results of operations.

Several companies market or have announced plans to market oral specimen collection devices and tests outside the United States. We expect the number of devices competing with our Intercept® and OraSure® devices to increase as the benefits of oral specimen-based testing become more widely accepted.

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

Significant competitors for our OraQuick® rapid HIV-1 antibody test, such as the Ortho Diagnostics division of Johnson & Johnson and Bio-Rad Laboratories, sell laboratory-based HIV-1 EIAs, and Calypte, Inc. sells an HIV-1 screening test for urine, in the United States. Abbott Laboratories sells a competing rapid HIV test internationally, but earlier in 2003 terminated the manufacture of a rapid HIV test sold primarily into the U.S. hospital market. In addition, MedMira recently received FDA approval to sell a competing rapid HIV test in the United States. We believe several other companies, including Trinity Biotech, may seek FDA approval to sell competing rapid HIV tests in the United States.

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In the insurance risk assessment market, our AUTO-LYTE® homogeneous assays for cocaine and cotinine compete with reagents from Microgenics, Inc. (a subsidiary of Apogent Technologies). Our AUTO-LYTE® homogeneous assays for beta-blockers and thiazide as well as MICRO-PLATE heterogeneous assays specifically designed for the detection of cocaine, cotinine, and Immunoglobulin G, or IgG, in oral fluid are the only assays available in the marketplace. In urine chemistries, our significant competitors include The Diagnostics Systems Group of Olympus America Inc. and Diagnostic Reagents International. However, the most significant competition facing our AUTO-LYTE® assays is from assays developed internally by our laboratory customers (i.e., home brews), which can be produced at a cost lower than the price typically paid for our products. For example, effective June 30, 2003, Lab*One*, Inc. ceased purchasing our AUTO-LYTE® urine assays in order, we believe, to use internally-developed assays. As a result, we expect revenues from these products to be substantially lower in 2003 and may eventually be eliminated.

The Intercept® drug testing system competes with laboratory-based drug testing products and services using testing matrices such as urine, hair, sweat and oral fluid. Major competitors include Ansys Technologies, Inc., Dade Behring, Psychemedics, and Immunalysis.

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

In the forensic toxicology market, we compete with both homogeneous and heterogeneous tests manufactured by many companies. Significant competitors in the market for these assays include Microgenics, Inc., Roche Diagnostics, and Immunalysis.

The Histofreezer® product s delivery system and warmer operating temperatures compared to liquid nitrogen provide us with the opportunity to target sales to primary care physicians, such as family practitioners, pediatricians, and podiatrists. We do not generally target sales to dermatologists because they have the volume of patients required to support the capital costs associated with a liquid nitrogen delivery system, which is also used to remove warts and other benign skin lesions. There is limited competition for convenient cryosurgical products for wart removal in the primary care physician market. Major competitors for the Histofreezer® product include CryoSurgery, Inc. in the United States and Wartner in Europe.

The Freeze Off product, sold by Medtech under its Compound W® tradename, competes with other over-the-counter wart removal products in the United States. In addition, Wartner currently sells a competing cryosurgical wart removal product in the over-the-counter market.

Q.E.D.® has two direct competitors, Ansys Technologies and Chematics. These companies offer semi-quantitative saliva-based alcohol tests and have received DOT approval. Indirect competitors who offer breath testing equipment include Intoximeters, Dräger Safety, and CMI. Although there are lower priced tests on the market that use oral fluid or breath as a test medium, these tests are qualitative tests that are believed to be substantially lower in quality and scope of benefits than our Q.E.D.® test.

Our UP*link*® product is expected to compete with other on-site, rapid drug assays and instrument-read tests. Major competitors in this area include American Biomedica, Roche Diagnostics, Biosite Diagnostics, Avitar, Inc., Ansys Technologies, Inc., and eScreen. Another potential competitor, LifePoint, Inc., has announced plans to sell a reader-based saliva test panel that will include alcohol testing.

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Patents and Proprietary Information

We seek patent and other intellectual property rights to protect and preserve our proprietary technology and our right to capitalize on the results of our research and development activities. We also rely on trade secrets, know-how, continuing technological innovations, and licensing opportunities to provide competitive advantages for our products in our markets and to accelerate new product introductions. We regularly search for third-party patents in fields related to our business to shape our own patent and product commercialization strategies as effectively as possible and to identify licensing opportunities. United States patents generally have a maximum term of 20 years from the date an application is filed.

We have 16 United States patents and numerous foreign patents for the OraSure® and Intercept® collection devices and related technology relating to oral fluid collection, containers for oral fluids, methods to test oral fluid, formulations for the manufacture of synthetic oral fluid, and methods to control the volume of oral fluid collected and dispersed. We have also applied for additional patents, in both the United States and certain foreign countries, on such products and technology.

We have a patent application for the OraQuick® rapid HIV antibody test pending in the United States. We may also apply for additional patents for this product. We have obtained licenses to certain lateral flow patents and to certain HIV-1 patents held by other parties in order to market the OraQuick® test. We obtained these licenses through the payment of certain upfront fees and ongoing royalties. We believe these royalties are comparable to rates generally paid by other companies under similar arrangements.

We may also need to obtain licenses or other rights under, or enter into distribution or other business arrangements in connection with, certain patents for the Human Immunodeficiency Virus Type 2 (HIV-2) and certain other lateral flow patents, in order to manufacture and sell the OraQuick® HIV test. See the Section entitled Risk Factors in the accompanying prospectus beginning on page 4 for a further discussion of these issues.

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

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

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

We have or have licensed rights under 16 U.S. patents and numerous foreign patents for methods, compositions, apparatuses and designs relating to our UPT and Up*link*® technologies. Several additional UPT and Up*link*® patent applications remain pending in the United States and abroad. We expect to continue to expand our UPT patent portfolio in 2003.

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We have one U.S. patent relating to the method for detecting blood in urine specimens using our AUTO-LYTE® products.

We have five U.S. patents and numerous foreign patents issued for apparatuses and methods for the topical removal of skin lesions relating to our Histofreezer® product. We have also licensed another patent relating to apparatuses and methods for the topical removal of skin lesions relating to our Histofreezer® product.

We have four U.S. patents and numerous foreign patents and patent applications for the technology used in the Q.E.D.® test. These patents are related to the analog-to-digital technology color control systems and methods, systems and devices for the test, and detection of biochemical molecules.

We require our employees, consultants, outside collaborators, and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed by or made known to the individual during the course of the individual s relationship with us, is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual during his or her tenure with us will be our exclusive property.

We own rights to trademarks and service marks that we believe are necessary to conduct our business as currently operated. In the United States, we own the UPT, UP*link*®, OraSure®, Intercept®, OraQuick®, Histofreezer®, Q.E.D.®, and AUTO-LYTE® trademarks. We also own many of these marks and others in several foreign countries.

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

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

Government Regulation

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

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

Additional information regarding the domestic, international and environmental regulations to which we are subject is included in our annual report on Form 10-K for the year ended December 31, 2002 under the heading Government Regulation and is incorporated herein and into our prospectus attached hereto by reference.

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MANAGEMENT S DISCUSSION AND ANALYSIS OF

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes. This discussion and analysis 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, but not limited to, those discussed in Risk Factors in the accompanying prospectus and elsewhere disclosed in this prospectus supplement and the accompanying prospectus.

Results of Operations

Six months ended June 30, 2003 compared to June 30, 2002

Total revenues increased 17% to approximately $18.2 million for the six months ended June 30, 2003 from approximately $15.7 million in the comparable six month period in 2002, primarily as a result of increased sales of our OraQuick® rapid HIV-1 antibody test and increased sales of our Intercept® oral fluid collection device and related drug assays, partially offset by a previously anticipated decline in urine assay revenues in the insurance risk assessment market, compared to the first six months of 2002. Revenues derived from products sold in countries outside the U.S. were approximately $2.3 million and $2.0 million for the six months ended June 30, 2003 and 2002, respectively, or 13% of total revenues for each period.

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.

	Six months ended June 30,				
	Dollars		%	Percentage of Total Revenues	
	2003	2002	Change	2003	2002
Market Revenues					
Insurance risk assessment	$ 5,458	$ 5,913	(8)%	30%	38%
Infectious disease testing	5,471	3,074	78	30	19
Substance abuse testing	3,433	2,963	16	19	19
Cryosurgical systems	3,419	3,393	1	19	22
Product revenues	17,781	15,343	16	98	98
Licensing and product development	459	313	47	2	2
Total revenues	$ 18,240	$ 15,656	17%	100%	100%

Sales to the insurance risk assessment market declined by 8% to approximately $5.5 million for the six months ended June 30, 2003 from approximately $5.9 million in the comparable period in 2002, primarily as a result of lower urine assay and reagent sales. We expect that sales of our insurance assays and reagents will continue to come under competitive pressure because of sluggish sales and competitive conditions in the life insurance market. As a result of these conditions, our laboratory customers have reduced and are expected to continue to reduce their purchases of these products and instead use lower cost, internally-developed assays or reagents or testing products purchased from our competitors. For example, as of June 30, 2003, Lab*One*, Inc. stopped purchasing our urine assays. Our revenues are expected to be negatively impacted by the loss of this business by as much as $1.5 million in 2003 and $2.0 million in 2004, when compared to 2002 revenues in the insurance risk assessment market.

Sales to the infectious disease testing market increased 78% to approximately $5.5 million for the six months ended June 30, 2003, primarily as a result of sales of our OraQuick® rapid HIV-1 antibody test.

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OraQuick® and OraSure® sales for the six months ended June 30, 2003 totaled approximately $2.5 million and $3.0 million, respectively, as compared to approximately $59,000 and $3.0 million, respectively, for the comparable period in 2002.

We shipped approximately 245,000 OraQuick® devices, or approximately 52% of total OraQuick® device sales for the six months ended June 30, 2003, to Abbott Laboratories, Inc. (Abbott), our co-exclusive distribution partner in the U.S. marketplace. We are working with Abbott to increase its future purchases of OraQuick® tests and to ensure Abbott meets its purchase obligations under our distribution agreement, as further described in this prospectus supplement under the heading Business Products.

Sales to the infectious disease testing market are expected to increase as a result of the recently announced $2 million purchase order received from The Centers for Disease Control and Prevention (CDC) for our OraQuick® rapid HIV-1 antibody test. Pursuant to the CDC s purchase order, we expect to sell 250,000 devices to the CDC by December 31, 2003. In addition to supplying the tests, we will provide training to prospective OraQuick® customers at various sites throughout the U.S. It is expected that the training will generally precede the purchase of the OraQuick® devices. Consequently, most of the CDC sales are expected to occur in the fourth quarter of 2003.

Although sales of our OraQuick® test are expected to increase, such sales may negatively impact sales of our OraSure® oral fluid collection device in the infectious disease testing market. Customers who now or in the future may purchase our OraSure® device for HIV-1 testing may elect instead to purchase our OraQuick® test. However, it is not possible at this time to estimate the timing or extent of such change in purchasing patterns or the financial impact of replacing OraSure® sales with sales of our OraQuick® test, if it occurs at all.

We are currently seeking FDA approval for certain other claims for OraQuick®. On September 5, 2003, we received FDA approval for use of the OraQuick® test in detecting HIV-1 antibodies in venipuncture whole blood samples. The test is now approved for use with both finger-stick and venipuncture whole blood samples. However, our ability to sell the test for use with venipuncture whole blood is subject to completion of the final product labeling incorporating that claim, which is currently under review by the FDA. We are also performing the clinical trials for usage of the device with oral fluid and plasma and expect to make the related FDA submissions for these claims in the third quarter of 2003. We believe the venipuncture whole blood claim (once final labeling is approved) and the plasma claim are needed in order to fully penetrate the hospital market in the U.S. with our OraQuick® product. Until such time as we can distribute the product for one or both of those indications, we will likely not see optimal sales penetration for OraQuick® in the hospital market.

We have also completed the necessary clinical trials and filed for FDA approval for use of the OraQuick® device to detect antibodies to HIV-2. We have taken this action in anticipation of obtaining access to an HIV-2 patent license, either through our distribution arrangement with Abbott or directly with Bio-Rad Laboratories, the holder of the HIV-2 patents. Although we believe the addition of an FDA-approved HIV-2 claim would enhance the versatility of our OraQuick® test and allow us to more fully implement a strategy to sell OraQuick® internationally, there is no assurance that we will receive FDA approval of our HIV-2 claim or be able to obtain access to an HIV-2 patent license.

Sales to the substance abuse testing market increased 16% to approximately $3.4 million for the six months ended June 30, 2003 as a result of higher sales of our Intercept® oral fluid collection device and related drug assays in the workplace, criminal justice and the international marketplaces, which more than offset the absence of over $250,000 in laboratory equipment sales to Quest Diagnostics included in our revenues for the six months ended June 30, 2002. Sales of our Intercept® device and related drug assays for the six months ended June 30, 2003, increased 43% or by approximately $525,000 over the comparable period in 2002.

Sales of our products in the cryosurgical systems market (which includes both the physicians office and over-the-counter (OTC) markets) increased 1% to approximately $3.4 million for the six months ended June 30, 2003. This increase was primarily the result of $1.2 million of

initial sales of our OTC

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cryosurgical system to Medtech Holdings, Inc. (Medtech), the owner of the Compound W® line of wart removal products, offset by lower sales of Histofreezer® in the professional markets in both the U.S. and international markets. We entered into an agreement with Medtech following receipt of FDA 510(k) clearance for the sale of Histofreezer® in the OTC market in the U.S.

The product, which is expected to be launched by Medtech in the third quarter of 2003, will be called Freeze Off and will be sold under Medtech s Compound W® trademark. We expect to ship the balance of the approximately $2.0 million of minimum contractual purchases of this product in the third quarter of 2003. The five-year distribution agreement provides for comparable annual minimum purchases by Medtech over the life of the contract in order for Medtech to maintain its exclusive distribution rights to the OTC market in the U.S.

Sales of our Histofreezer® product to physicians offices in the U.S. and international markets declined 46% and 4% to approximately $1.4 million and $0.8 million, respectively, for the six months ended June 30, 2003, when compared to 2002 as a result of lower end-user purchases and an effort by some of our distributors to reduce their inventory levels. We anticipate that U.S. sales of Histofreezer® in the professional market will increase in the third quarter of 2003 as a result of new sales initiatives involving the use of contract sales organizations and the replenishment of low inventory levels at our distributors. Sales in the international market are expected to remain at approximately the levels experienced in 2002 until we are able to secure additional distributors in countries where the product is currently not sold.

It is possible that sales of the Freeze Off product in the OTC market may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the professional market. However, it is not possible at this time to estimate the timing or financial impact of such a change, if it occurs at all.

Licensing and product development revenue increased 47% to approximately $459,000 for the six months ended June 30, 2003 from approximately $313,000 in the comparable period in 2002. Licensing and product development revenues for the six months ended June 30, 2003 were primarily related to our collaborative UP*link*® and oral fluid research project with the University of Pennsylvania, under a grant awarded by the National Institutes of Health.

The Company s gross margin decreased to approximately 59% for the six months ended June 30, 2003 from 61% for the comparable period in 2002. This decrease was primarily attributable to the decrease in high-margin Histofreezer® sales in the U.S. professional market.

Research and development expenses decreased 13% to approximately $4.0 million for the six months ended June 30, 2003 from approximately $4.6 million for the comparable period in 2002, primarily as a result of lower clinical trial expenses and staffing costs, partially offset by higher materials expense and consulting fees related to the transfer of manufacturing operations from Oregon to our Bethlehem, Pennsylvania facilities.

Sales and marketing expenses increased 14% to approximately $5.0 million for the six months ended June 30, 2003 from approximately $4.4 million in the comparable period in 2002. This increase was primarily the result of higher advertising, travel, market research and public relations fees, partially offset by lower outside consulting fees for the development of strategic marketing plans. We expect sales and marketing expenses to increase during the remainder of 2003 as we attempt to increase market awareness for our OraQuick® and Intercept® products. In addition, pursuant to our agreement with Medtech, we will co-invest in Medtech s marketing activities for the Compound W® Freeze Off product. As a result, we will reimburse Medtech, on a declining basis over the first four years of the agreement, for a portion of Medtech s out-of-pocket costs of advertising and promoting this product in the OTC market.

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General and administrative expenses decreased 1% to approximately $3.5 million for the six months ended June 30, 2003 from approximately $3.6 million for the comparable period in 2002. This decrease was primarily attributable to the absence of a $0.5 million severance charge related to the departure of the Company s former Chief Executive Officer, partially offset by higher facility-related expenses.

Interest expense decreased to approximately $96,000 for the six months ended June 30, 2003 from approximately $163,000 for the comparable period in 2002, as a result of lower effective interest rates. Interest income decreased to approximately $169,000 for the six months ended June 30, 2003 from approximately $304,000 for the comparable period in 2002, as a result of lower interest rates on investments.

During the six months ended June 30, 2003, a provision for foreign income taxes of approximately $15,000 was recorded.

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

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

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

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

Sales to the insurance risk assessment market increased by 3% to approximately $12.0 million in 2002 from approximately $11.7 million in 2001, as a result of increased sales of our OraSure® laboratory-based HIV-1 test, partially offset by lower sales of assays and reagents. We expect that sales of our insurance assays and reagents will come under increased competitive pressure in the future. The laboratories that

purchase these products are facing pressure from their insurance customers to reduce the cost of testing services. As a result, these laboratories are expected to reduce their purchases of our products and instead use lower cost internally developed assays or reagents or testing products purchased from our competitors. Although we will make every effort to retain this business, our revenues could be negatively impacted by as much as $1.5 million in 2003 and $2.0 million in 2004, when compared to 2002 revenues in the insurance risk assessment market.

Sales to the infectious disease testing market increased 5% to approximately $6.1 million in 2002 from approximately $5.8 million in 2001, as a result of a $0.6 million increase in sales of our OraSure® laboratory-based HIV-1 test into the public health market, offset by a $300,000 decrease in international

sales of the OraQuick® rapid HIV antibody test. In June 2002, we entered into an agreement with Abbott Laboratories for the co-exclusive distribution of the OraQuick® test in the United States. We received FDA approval of the OraQuick® test for detecting HIV-1 in finger-stick whole blood samples in November 2002 and received a CLIA waiver for this product in January 2003.

We shipped an initial order for approximately $200,000 of OraQuick® devices to Abbott in the fourth quarter of 2002, representing our first domestic sale of this product following FDA approval. We expect that sales of OraQuick® will increase substantially in 2003, the first full year that this product is commercially available in the United States. Sales of our OraSure® laboratory-based HIV-1 test are expected to be negatively affected by the successful penetration of the OraQuick® device in the public health market, as some customers will likely substitute OraQuick® for OraSure®. However, the degree of this substitution and resulting financial impact cannot be determined at this time. International sales of OraQuick® are also expected to contribute to our revenues in the infectious disease testing market in 2003.

Sales to the substance abuse testing market decreased 7% to approximately $6.4 million in 2002 from approximately $7.0 million in 2001, primarily as a result of the absence of $1.0 million in sales of laboratory equipment manufactured by third party vendors and $0.5 million in sales of UP*link*® analyzers, which occurred in 2001. Offsetting this aggregate decrease were an approximate $400,000 increase in international sales of our Intercept® collection device and related assays and an approximate $500,000 increase in sales of domestic substance abuse products. We intend to aggressively support our Intercept® product line in 2003 through the deployment of additional sales representatives and increased marketing expenditures.

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

As a percentage of total revenues, international revenues decreased to approximately 12% in 2002 from approximately 16% in 2001, with Histofreezer® accounting for approximately 43% of 2002 international revenues. This decrease is primarily attributable to lower international sales of OraQuick® and the absence of UP*link*® analyzer sales to Dräger Safety, which occurred in 2001.

Lab*One*, our largest customer, and Osborne Group, which was acquired by Lab*One* in 2001, together accounted for approximately 26% and 29% of total revenues in 2002 and 2001, respectively. We expect this percentage to decrease further in 2003, reflecting lower anticipated sales of insurance assays and reagents to Lab*One* and increased sales of the OraQuick® rapid HIV-1 antibody test, as described above.

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

companies advanced to a stage where we became responsible for funding, and the termination of work under the NIH grant for the development of the syphilis test.

We do not expect significant research and development funding from Dräger Safety in 2003 and we agreed in principle to terminate our agreement with Meridian in early 2003. However, we expect licensing and product development revenues to increase modestly in 2003 as a result of approximately $400,000 in annual research and development funding expected under our collaborative UP*link*® and oral fluid research project with The University of Pennsylvania, which will be received under a grant awarded by the NIH.

Our gross margin decreased to approximately 60% in 2002 from 62% in 2001. This decrease was primarily the result of lower licensing and product development revenues, offset by a more favorable product mix and our ongoing cost savings efforts. Additionally, as we prepared for FDA approval and the commercial launch of OraQuick® in the United States during 2002, we incurred substantial expenses related to staffing, materials and overhead. These expenses were included in our cost of goods throughout 2002, however, we did not begin to generate revenues from OraQuick® until the initial sales of this product in the United States in December 2002. We anticipate that the benefits of these expenditures will be realized during 2003 and that the incremental revenues associated with the production and sale of OraQuick® will positively impact our gross margin in the future. We also recognized approximately $1.4 million of inventory scrap in 2002 and are implementing programs designed to reduce scrap levels in 2003. We expect that these programs will also help improve our gross margin in 2003 and beyond.

Research and development expenses declined 12% to approximately $8.3 million in 2002 from approximately $9.4 million in 2001. Decreased expenditures for staffing, consulting and travel were partially offset by increased clinical trials costs related to our efforts to obtain FDA approval of the OraQuick® rapid HIV-1 antibody test. We expect that our expenditures in support of regulatory filings for our products will increase in 2003, primarily related to clinical trials for the CLIA waiver and the oral fluid and certain other claims for OraQuick® and the transfer of manufacturing from our Beaverton, Oregon facilities to Bethlehem, Pennsylvania.

Sales and marketing expenses increased 1% to approximately $8.1 million in 2002 from approximately $8.0 million in 2001. This increase was primarily the result of additional consulting fees for the development of our strategic marketing plans and increased staffing costs, offset by lower travel expenses, sales commissions and freight costs. We expect sales and marketing expenses to increase substantially in 2003 as we support the launch of OraQuick® and invest in the promotion of our Intercept® products. We plan to increase our staffing levels in support of these, and other key products, and to incur higher related expenses for travel, sales commissions, advertising and public relations.

General and administrative expenses declined 6% to approximately $6.3 million in 2002 from approximately $6.8 million in 2001. This decrease was primarily the result of lower legal, recruiting, and staffing costs offset by an approximate $0.5 million severance charge related to the departure of our former Chief Executive Officer in the first quarter of 2002. Additionally, we had an approximate $174,000 loss on disposal of equipment in 2001, which we did not have in 2002. We expect general and administrative costs to increase during 2003, reflecting additional facility-related costs from the occupancy of our new corporate headquarters in Bethlehem, Pennsylvania, higher premium costs for directors and officers liability insurance, and higher professional advisor fees as a result of compliance with the Sarbanes-Oxley Act of 2002.

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

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

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

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

Liquidity and Capital Resources

	June 30, 2003	December 31, 2002
	(in thousands)	
Cash and cash equivalents	$ 1,730	$ 4,364
Short-term investments	13,678	10,544
Working capital	19,195	18,931

Our cash, cash equivalents and short-term investment position increased approximately $500,000 during the first six months of 2003 to approximately $15.4 million at June 30, 2003, primarily as a result of the receipt of approximately $1.5 million in proceeds from the exercise of stock options and cash provided by operations of approximately $273,000, partially offset by capital equipment expenditures of approximately $0.7 million, a $250,000 payment under our distribution agreement with bioMerieux, Inc., and net term debt repayments of approximately $330,000. At June 30, 2003, our working capital was approximately $19.2 million.

Net cash provided by operating activities was approximately $273,000 for the six months ended June 30, 2003, primarily as a result of the net loss of approximately $1.6 million for the six months ended June 30, 2003, an increase in accounts receivable of approximately $1.1 million and an increase in inventories of approximately $410,000, offset by non-cash items totaling approximately $362,000 related to inventory reserves and stock-based compensation, depreciation and amortization of approximately $1.3 million, decreases in prepaid expenses of approximately $234,000 and an aggregate increase of approximately $1.6 million in accounts payable and accruals.

Net cash used in investing activities during the six months ended June 30, 2003 was approximately $4.1 million, primarily as a result of an approximate $3.1 million net increase in short-term investments, the purchase of approximately $0.7 million of capital equipment and the payment of $250,000 pursuant to our distribution agreement with bioMerieux, Inc.

Net cash provided by financing activities was approximately $1.2 million during the six months ended June 30, 2003 as a result of approximately $1.5 million in proceeds from the exercise of stock options, partially offset by approximately $330,000 of net term debt repayments.

In September 2002, we entered into a $10.9 million credit facility (Credit Facility) with Comerica Bank. The Credit Facility is comprised of an $887,000 mortgage loan, a $3.0 million term loan, a $3.0 million non-revolving equipment line of credit, and a $4.0 million revolving working capital line of credit. We are currently in discussions with Comerica to renew and extend our credit facilities.

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica s prime rate, and is repayable in fixed monthly principal and interest installments of $7,426 through September 2007, at which time the interest rate and fixed monthly repayment amount will be reset for the remaining 60 monthly installments. The outstanding balance of the loan at June 30, 2003 was $848,182.

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The $3.0 million term loan matures in March 2006, bears interest at a fixed rate of 4.99% and is repayable in forty-two consecutive equal monthly principal payments of $71,429, plus interest. The outstanding balance of the loan at June 30, 2003 was $2,357,143.

Under the non-revolving equipment line of credit, we can borrow up to $3.0 million to finance eligible equipment purchases through September 9, 2003. Interest on outstanding borrowings accrues at a rate, selected at our option, equal to Comerica s prime rate, 180-day or 360-day LIBOR plus 2.625%, or the 4-year Treasury Note Rate plus 2.30%, determined at the time of each borrowing. Borrowings are repayable in 48 consecutive, equal monthly principal installments, plus interest. As of June 30, 2003, we had an outstanding balance of $574,000 under this facility consisting of four individual loans of (i) $155,814 with a fixed annual interest rate of 5.07%, (ii) $213,388 with a floating annual interest rate equal to Comerica s prime rate of 4.00% at June 30, 2003, (iii) $101,890 with a floating annual interest rate equal to Comerica s prime rate of 4.00% at June 30, 2003, and (iv) $102,908 with a floating annual interest rate equal to Comerica s prime rate of 4.00% at June 30, 2003. We had approximately $2.4 million available for future borrowings under this facility as of June 30, 2003.

Under the revolving working capital line of credit, we can borrow up to $4.0 million to finance working capital and other needs. Interest on outstanding borrowings accrues at a rate, selected at our option, equal to Comerica s prime rate less 0.25%, or 30-day LIBOR plus 2.55%, determined at the time of the initial borrowing. Borrowings are repayable by September 9, 2003, with interest payable monthly. We had no outstanding borrowings under this facility at June 30, 2003.

All borrowings under the Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our manufacturing facility in Bethlehem, Pennsylvania. Borrowings under the equipment and working capital lines of credit are limited to commercially standard percentages of equipment purchases and accounts receivable, respectively. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth and requires that we achieve positive net income for the year ending December 31, 2003 and for each year thereafter. The Credit Facility also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica. We are currently in discussions with Comerica to extend and modify certain financial covenants contained in the Credit Facility.

We have entered into a ten-year facility lease with Tech III Partners, LLC (Tech Partners), an entity owned and controlled by two of our executive officers. Under the terms of this operating lease, we began leasing a 48,000 square-foot facility in October 2002 at a base rent of $780,000 per year, increasing to $858,240 per year, during the initial 10-year term. The base rental may be increased after the fifth year of the initial term in order to reflect changes in the interest rate on debt incurred by Tech Partners to finance construction of the leased facilities. We have not guaranteed any debt incurred by Tech Partners. The lease also provides us with options to renew the lease for an additional five years at a rental rate of $975,360 per year, and to purchase the facility at any time during the initial ten-year term based on a formula set forth in the lease.

The combination of our current cash position and available borrowings under our New Credit Facility is expected to be sufficient to fund our foreseeable operating and capital needs. However, our cash requirements may vary materially from those now planned due to many factors, including, but not limited to, the cost and timing of the expansion of our manufacturing capacity, the progress of our research and development programs, the scope and results of clinical testing, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the time and cost of obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, the timing

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of commercial launch of new products, market acceptance of new products, competing technological and market developments, the scope and timing of strategic acquisitions, and other factors.

Critical Accounting Policies and Estimates

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

Our significant accounting policies are described in Note 2 to the financial statements included in our 2002 Annual Report on Form 10-K filed with the Securities and Exchange Commission. We consider the following accounting estimates, which have been discussed with our Audit Committee, to be most critical in understanding the more complex judgments that are involved in preparing our financial statements and the uncertainties that could impact our results of operations, financial condition, and cash flows.

Revenue Recognition. We follow U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements (SAB 101). SAB 101 draws on existing accounting rules and provides specific guidance on revenue recognition of up-front non-refundable licensing and development fees. We license certain products or technology to outside third parties, in return for which we receive up-front licensing fees. Some of these fees can be significant. In accordance with SAB 101, we are required to defer these fees and ratably recognize this revenue over the related license period.

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

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

Allowance for Uncollectible Accounts Receivable. Accounts receivable are reduced by an estimated allowance for amounts that may become uncollectible in the future. On an ongoing basis, we perform

credit evaluations of our customers and adjust credit limits based upon the customer s payment history and creditworthiness, as determined by a review of their current credit information. We also continuously monitor collections and payments from our customers.

Based upon historical experience and any specific customer collection issues that are identified, we use our judgment to establish and evaluate the adequacy of our allowance for estimated credit losses, which was $302,000 at June 30, 2003. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period ($213,000, $5,000 and $4,000 for the years ended December 31, 2002, 2001 and 2000, respectively). Furthermore, there is no assurance that credit losses will continue at the same rates as in the past. Also, at June 30, 2003, approximately $611,000 or 10% of our accounts receivable were due from one major customer. Any significant changes in the liquidity or financial position of this customer, or others, could have a material adverse impact on the collectibility of our accounts receivable and future operating results.

Inventories. Our inventories are valued at the lower of cost or market, determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating. We continually evaluate the carrying value of our inventories and when, in the opinion of management, factors indicate that impairment has occurred, either a reserve is established against the inventories carrying value or the inventories are completely written off. We base these decisions on the level of inventories on hand in relation to our estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. During the years ended December 31, 2002, 2001 and 2000, we wrote-off inventory which had a cost of approximately $1.4 million, $0.6 million and $1.1 million, respectively, as a result of increased scrap levels and product expiration issues. Forecasting product demand can be a complex process, especially for a new product such as our OraQuick® rapid HIV-1 antibody test, which was launched in the United States in November 2002. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of our inventories and reported operating results.

Long-lived and Intangible Assets. Our long-lived assets are comprised of property and equipment and an investment in a nonaffiliated entity, and our intangible assets primarily consist of patents and product rights. Together, these assets have a net book value of approximately $9.7 million or 26% of our total assets at June 30, 2003. Our investment in a privately-held nonaffiliated company is recorded under the cost method of accounting, because we do not have a controlling interest in this company nor do we have the ability to exert significant influence over the operating and financial policies of this investee company. Property and equipment, patents and product rights are amortized on a straight-line basis over their useful lives, which we determine based upon our estimate of the period of time over which each asset will generate revenues. An impairment of long-lived or intangible assets could occur whenever events or changes in circumstances indicate that the net book value of these assets may not be recoverable. Events which could trigger an asset impairment include significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of our use of an asset or in our strategy for our overall business, significant negative industry or economic trends, shortening of product life-cycles or changes in technology, and negative financial performance of our nonaffiliated investee company. If we believe impairment of an asset has occurred, we measure the amount of such impairment by comparing the net book value of the affected assets to the fair value of these assets, which is generally determined based upon the present value of the expected cash flows associated with the use of these assets. If the net book value exceeds the fair value of the impaired assets, we would incur an impairment expense equal to this difference. We currently believe the future cash flows to be received from our long-lived and intangible assets will exceed their book value and, as such, we have not recognized any impairment losses through June 30, 2003. Any unanticipated significant impairment in the future, however, could have a material adverse impact on our balance sheet and future operating results.

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Deferred Tax Assets. We have a history of losses, which has generated a sizeable federal tax net operating loss (NOL) carryforward of approximately $79.6 million as of December 31, 2002. The deferred tax asset associated with these NOL s and other temporary differences is approximately $31.8 million at December 31, 2002. Under generally accepted accounting principles, we are required to record a valuation allowance against our deferred tax asset associated with these NOL s and temporary differences if it is more likely than not that some portion or all of the deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of taxable income in the future. Due to the size of the NOL carryforward in relation to our history of unprofitable operations, we have not recognized any of our net deferred tax asset. It is possible that we could be profitable in the future at levels which would cause us to conclude that it is more likely than not that we will realize all or a portion of the deferred tax asset. Upon reaching such a conclusion, we 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 our combined federal and state effective rates, which we believe would approximate 40%. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

Contingencies. In the ordinary course of business, we have entered into various contractual relationships with strategic corporate partners, customers, distributors, research laboratories and universities, licensors, licensees, suppliers, vendors and other parties. As such, we could be subject to litigation, claims or assessments arising from any or all of these relationships. We account for contingencies such as these in accordance with Statement of Financial Accounting Standards No. 5, Accounting for Contingencies (SFAS No. 5). SFAS No. 5 requires us to record an estimated loss contingency when information available prior to issuance of our financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and the amount of the loss can be reasonably estimated. Accounting for contingencies arising from contractual or legal proceedings requires that we use our best judgment when estimating an accrual related to such contingencies. As additional information becomes known, our accrual for a loss contingency could fluctuate, thereby creating variability in our results of operations from period to period. Likewise, an actual loss arising from a loss contingency which significantly exceeds the amount accrued for in our financial statements could have a material adverse impact on our operating results for the period in which such actual loss becomes known.

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MANAGEMENT

The following table sets forth information regarding our executive officers and directors, including their ages as of June 30, 2003:

Name	Age	Position
Douglas G. Watson(1)(2)	58	Director, Chairman of the Board and Chairman of the Strategic Planning Committee
Carter H. Eckert(2)(3)	61	Director
Michael J. Gausling(2)	45	Director, President and Chief Executive Officer
Frank G. Hausmann(3)	45	Director and Chairman of the Audit Committee
Ronny B. Lancaster(3)	51	Director
Gregory B. Lawless(1)	63	Director
Roger L. Pringle(1)(3)	61	Director and Chairman of the Compensation Committee
Ronald H. Spair	47	Executive Vice President and Chief Financial Officer
R. Sam Niedbala, Ph.D.	43	Executive Vice President and Chief Science Officer
P. Michael Formica	52	Executive Vice President, Operations
Joseph E. Zack	51	Executive Vice President, Marketing and Sales
Jack E. Jerrett	44	Senior Vice President, General Counsel and Secretary
Mark L. Kuna	40	Vice President, Controller and Assistant Secretary

(1) Member of the Compensation Committee.
(2) Member of the Strategic Planning Committee.
(3) Member of the Audit Committee.

Douglas G. Watson became a member of the Board in May 2002 and became Chairman of the Board in March 2003. From 1997 to 1999, Mr. Watson served as President and Chief Executive Officer of Novartis Corporation, the U.S. subsidiary of Novartis A.G. Prior to that, Mr. Watson was President and Chief Executive Officer of Ciba-Geigy Corporation, President of the Ciba Pharmaceuticals Division and Senior Vice President of Planning and Business Development of Ciba s U.S. Pharmaceuticals Division. From 1986 through 1996, Mr. Watson was on the Board of the Pharmaceutical Research & Manufacturers Association. Mr. Watson holds an M.A. degree in pure mathematics from Churchill College, Cambridge University, and is a member of the Chartered Institute of Management Accountants. Mr. Watson also serves on the boards of Engelhard Corporation, Dendreon Corporation and Genta Incorporated, as well as a number of privately-held biotech companies.

Carter H. Eckert became a member of the Board in December 2001. Since February 2003, Mr. Eckert has served as Chairman of the Board and Chief Executive Officer of IMPATH Inc., a medical diagnostics company. From 1995 to 2001, Mr. Eckert served as President of Knoll

Pharmaceutical Company and as President of the Americas for Knoll s parent company, BASF Pharma. During that period, Mr. Eckert also

was a member of BASF Pharma s Global Pharmaceutical Board, where he was responsible for global therapeutic franchises and corporate transactions. Prior to joining Knoll and BASF Pharma in 1995, Mr. Eckert was President and Chief Executive Officer of Boots Pharmaceuticals, Inc., a pharmaceutical company, where he was responsible for North American operations. Mr. Eckert joined Boots Pharmaceuticals in 1985 as Executive Vice President and Chief Operating Officer after more than a decade at Baxter Travenol Laboratories, where he served as President of the Pharmaceutical Products Division. Mr. Eckert currently serves as a director of Boron LePone, Inc. and Andrx Corporation, a trustee of Caldwell College and an operating partner of the Athena Group. Mr. Eckert received his B.S. in Chemical Engineering from the Illinois Institute of Technology and his M.B.A. from Northwestern University.

Michael J. Gausling has been the Company s President and Chief Executive Officer since January 31, 2002. Prior to that, Mr. Gausling was the Company s President and Chief Operating Officer since the September 2000 merger of STC Technologies and Epitope to form the Company. Mr. Gausling is a co-founder of STC Technologies and served as Chairman of STC s board of directors since 1996, President and Chief Executive Officer of STC Technologies since 1990, and a director of STC Technologies since 1987. Prior to forming STC Technologies, Mr. Gausling had been employed in the area of corporate finance at Procter and Gamble. Mr. Gausling received his B.S. in Mechanical Engineering from Rensselaer Polytechnic Institute and his M.B.A. in Finance from Miami University (Ohio). Mr. Gausling is also a director of Keystone Savings Bank.

Frank G. Hausmann had been a member of the board of directors of Epitope since December 1999. Mr. Hausmann has been employed by CenterSpan Communications Corporation since July 1998, serving as President and Chief Executive Officer since October 1998 and as Vice President, Finance and Administration and Chief Financial Officer prior to that time. Mr. Hausmann is also a director of CenterSpan. CenterSpan is a provider of Internet voice and text messaging software designed primarily for use with interactive games. From August 1997 to May 1998, Mr. Hausmann served as Vice President, Finance and Chief Financial Officer of Atlas Telecom, Inc., a developer of enhanced facsimile and voice-mail solutions. From September 1995 to July 1997, he served as Vice President, Corporate Development and General Counsel of Diamond Multimedia Systems, Inc., a designer and marketer of computer video cards, modems and other peripherals. From June 1993 to September 1995, Mr. Hausmann was Executive Vice President and Chief Financial Officer of Supra Corporation, a designer and marketer of computer modems that was acquired by Diamond Multimedia Systems, Inc. in September 1995. From 1983 to 1993, Mr. Hausmann was a consultant and attorney with such firms as Price Waterhouse and Stoel Rives. Mr. Hausmann received B.S. degrees in Economics and Political Science from Willamette University and a J.D. degree from the University of Oregon. He is a member of the Oregon State Bar.

Ronny B. Lancaster became a member of the Board in May 2003. Mr. Lancaster is Senior Vice President and Chief Operating Officer of the Morehouse School of Medicine in Atlanta, Georgia. Prior to that, Mr. Lancaster was Executive Assistant to the Secretary and Principal Deputy Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services (HHS), where his responsibilities included a wide range of policy, program and management matters. Prior to serving at HHS, Mr. Lancaster was General Counsel of Hamilton Enterprises, Inc., Senior Washington Representative for Blue Cross/Blue Shield Association, Chief of the Division of Fee-For-Service Plans at the U.S. Office of Personnel Management and Executive Assistant to the Chairman at the National Institute for Advanced Studies. Mr. Lancaster received his B.A. in Economics from The Catholic University of America, his M.B.A. from the Wharton School of the University of Pennsylvania, and his J.D. degree from The Georgetown University Law Center. He is also admitted to the Bars of Pennsylvania and the District of Columbia and serves as a Board member for the Morehouse College Research Institute and as President for the Minority Health Professions Foundation.

Gregory B. Lawless became a member of the Board in April 2001. Since 1998, Mr. Lawless has been the Managing Partner of Collins Mabry & Co., a strategic advisory firm for the life sciences industry

which he co-founded. From 1992 to 1998, Mr. Lawless served as President and Chief Executive Officer of Cygnus, Inc., a medical diagnostics company, and from 1989 to 1992, was President and Chief Operating Officer of Chiron Corporation, also a medical diagnostics company. Mr. Lawless received his B.S. in Pharmacy from Fordham University, his M.S. in Analytical Chemistry from St. John s University, and his Ph.D. in Physical Organic Chemistry from Temple University.

Roger L. Pringle had been Chairman of the Board and a member of the board of directors of Epitope, and was a director of Agritope, Inc., a plant genetics subsidiary of Epitope, since February 1989. Mr. Pringle is President and founder of The Pringle Company, a strategy and executive consulting firm in Portland, Oregon. Mr. Pringle is a director of North Pacific Group, Bank of the Northwest, and H2F Media, Inc. He is also active in funding and advising start-up and emerging companies.

Ronald H. Spair joined the Company as Executive Vice President and Chief Financial Officer in November 2001. Prior to that time, Mr. Spair was Vice President, Chief Financial Officer and Secretary of Delsys Pharmaceutical Corporation, a pharmaceutical manufacturing system development company, from January 2001 to September 2001. Prior to joining Delsys, he was Senior Vice President, Chief Financial Officer and Secretary of SuperGen, Inc., a pharmaceutical company, from August 1999. Prior to joining SuperGen, Mr. Spair was Senior Vice President, Chief Financial Officer and Secretary of Sparta Pharmaceuticals, Inc., a development stage pharmaceutical company, from March 1996 until August 1999. Mr. Spair received his B.S. in Accounting and M.B.A. from Rider College. He is also a licensed Certified Public Accountant and is a member of the New Jersey Society of Certified Public Accountants and the American Institute of Certified Public Accountants.

R. Sam Niedbala, Ph.D. has been the Company s Executive Vice President and Chief Science Officer since September 2000. Dr. Niedbala is a co-founder of STC Technologies and had served as Executive Vice President, Chief Science Officer and a director of STC Technologies since 1987. Prior to co-founding STC Technologies, Dr. Niedbala had been employed by Hoffman-LaRoche, Inc. as a Senior Scientist. Dr. Niedbala received his B.S. in Chemistry from East Stroudsburg University, and his M.S. in Clinical Chemistry and Ph.D. in Chemistry from Lehigh University. Dr. Niedbala is also a board certified forensic examiner.

P. Michael Formica has served as Executive Vice President, Operations for the Company since November 2002 and as Senior Vice President, Operations for the Company and STC since May 2000. Prior to that time, Mr. Formica was Division Manager, Mobil Measurement Technologies for Dräger Sicherheitstechnik GmbH (now called Dräger Safety AG & Co. KGaA), in Luebeck, Germany, for eight years with worldwide responsibility, and Director Sales and Marketing, National Draeger, Inc. (USA) for two years. Dräger is a world leader in chemical detection systems for the industrial safety market, and breath alcohol detection instrumentation. Mr. Formica received his B.S. in Electrical Engineering from West Virginia University and his M.B.A. from the Graduate School of Industrial Administration, Carnegie Mellon University.

Joseph E. Zack has served as the Company s Executive Vice President, Marketing and Sales since September 2002. Prior to that time, Mr. Zack served as Vice President, Marketing and Sales for OraPharma, Inc., a specialty pharmaceutical company focused on oral healthcare, since 1998. Prior to joining OraPharma, Mr. Zack held executive level marketing and sales positions with Advanced Tissue Sciences, Inc. and the CIBA-GEIGY Pharmaceutical Division. Mr. Zack received his B.A. in Biology from Colgate University and his M.B.A. from St. John s University.

Jack E. Jerrett has served as the Company s Senior Vice President and General Counsel since February 2003 and as Vice President and General Counsel since November 2000. He has also served as the Company s Secretary since February 2001. Prior to joining the Company, Mr. Jerrett served in the positions of Associate General Counsel and Senior Counsel at PPL Electric Utilities Corporation, and

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acted as general counsel to PPL Gas Utilities Corporation, since July 1998. Prior to that, Mr. Jerrett was Senior Corporate Attorney of Union Pacific Corporation and an Associate with Morgan, Lewis & Bockius. Mr. Jerrett received his B.S. in Accounting from Villanova University and his J.D. from the Villanova University School of Law. He is a member of the Pennsylvania Bar and the American Bar Association.

Mark L. Kuna has served as the Company s Vice President and Controller since February 2003 and as Controller since February 2001. He also provided accounting and financial analysis support since joining the Company in October 2000. Prior to that time, Mr. Kuna served as Director of Financial Planning and Analysis for the greater Philadelphia region of XO Communications, Inc. since April 1989. Prior to joining XO Communications, Mr. Kuna served as Vice President and Principal Accounting Officer of Wedco Technology, Inc. since 1989. Prior to joining Wedco Technology, he was an accountant with Deloitte and Touche. Mr. Kuna received his B.S. in Accounting from the University of Scranton, is a licensed Certified Public Accountant, and is a member of the Pennsylvania and American Institutes of Certified Public Accountants.

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UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to the terms and conditions of the underwriting agreement, the underwriters named below have severally agreed to purchase from us the number of shares of our common stock set forth opposite their names on the table below at the public offering price, less the underwriting discounts and commissions set forth on the cover page of this prospectus supplement, as follows:

Name	Number of Shares
Thomas Weisel Partners LLC	
SG Cowen Securities Corporation	
Wells Fargo Securities, LLC	
Total	

The underwriting agreement provides that the obligations of the underwriters to purchase the shares of common stock offered hereby are conditional and may be terminated at their discretion based on their assessment of the state of the financial markets. The obligations of the underwriters may also be terminated upon the occurrence of other events specified in the underwriting agreement. The underwriters are severally committed to purchase all of the shares of common stock being offered by us if any shares are purchased.

The underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus supplement. The underwriters may offer the common stock to securities dealers at the price to the public less a concession not in excess of $ per share. Securities dealers may reallow a concession not in excess of $ per share to other dealers. After the shares of common stock are released for sale to the public, the underwriters may vary the offering price and other selling terms from time to time.

Thomas Weisel Partners LLC expects to deliver the shares of common stock to purchasers on or about , 2003.

We have granted to the underwriters an option, exercisable not later than 30 days after the date of the final prospectus supplement, to purchase up to an aggregate of 750,000 additional shares of common stock at the public offering price set forth on the cover page of this prospectus supplement less the underwriting discounts and commissions. The underwriters may exercise this option only to cover over-allotments, if any, made in connection with the sale of common stock offered hereby. If the over-allotment option is exercised in full, the underwriters will purchase additional shares of common stock from us in approximately the same proportion as shown in the table above.

The following table summarizes the compensation to be paid to the underwriters by us and the proceeds, before expenses, payable to us.

	Per Share	Without Over-Allotment	With Over-Allotment

Public offering price	$	$	$
Underwriting discount	$	$	$
Proceeds, before expenses, to us	$	$	$

We estimate that the total expenses of this offering, excluding underwriting discounts and commissions, will be approximately $500,000.

We have agreed to indemnify the underwriters against certain civil liabilities relating to this offering, including liabilities under the Securities Act of 1933, as amended, and liabilities arising from breaches of

representations and warranties contained in the underwriting agreement, and to contribute to payments the underwriters may be required to make in respect of any such liabilities.

Our directors and executive officers have agreed with the underwriters that for a period which shall be the longer of (i) 30 days following the date of the final prospectus supplement relating to this offering and (ii) the date which is the third business day after we publicly announce our financial results for the nine months ended September 30, 2003, they will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for shares of common stock. Following the expiration of this period, and for a period to continue until 90 days following the date of the final prospectus supplement relating to this offering, our directors and executive officers may offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any shares of our common stock, or any securities convertible into or exchangeable for shares of common stock, that number of shares not to exceed 15% of the common stock, or any securities convertible into or exchangeable for shares of common stock, owned by such executive officer or director on the date of this prospectus supplement. In addition, so long as the transferee agrees to be bound by the terms of the lock-up agreement, a director or executive may transfer his or her securities by gift, for estate planning purposes or upon foreclosure by a lender on a bona fide pledge. A director or officer may also acquire shares upon exercise of an outstanding stock option.

We have entered into an agreement with the underwriters that for a period of 90 days following the date of the final prospectus supplement relating to this offering, we will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for shares of our common stock or any securities convertible into or exchangeable for shares of common stock, provided we may, without the consent of the underwriters, grant options and issue shares pursuant to our stock option plans and issue shares pursuant to a warrant held by a third party.

The underwriters may, in their sole discretion, at any time without prior notice, release all or any portion of the shares from the restrictions in the foregoing agreements.

Pursuant to the terms of a stockholders agreement with us, HealthCare Ventures V, L.P., our largest stockholder, is not permitted to make any short sale, assignment, transfer, pledge, hypothecation, gift or other disposition (including the grant of an option for sale) of its shares of our common stock without our prior consent through November 6, 2003, which is 90 days after the effectiveness of our registration statement relating to this offering.

The underwriters may engage in over-allotment, stabilizing transactions, syndicate covering transactions, penalty bids and passive market making in accordance with Regulation M under the Securities Exchange Act of 1934, as amended. Over-allotment involves syndicate sales in excess of the offering size, which creates a syndicate short position. Covered short sales are sales made in an amount not greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters may close out a covered short sale by exercising their over-allotment option or purchasing shares in the open market. Naked short sales are sales made in an amount in excess of the number of shares available under the over-allotment option. The underwriters must close out any naked short sale by purchasing shares in the open market. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Syndicate covering transactions involve purchases of the shares of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the shares of common stock originally sold by such syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Penalty bids may have the effect of deterring syndicate members from selling to people who have a history of quickly selling their shares. In passive market making, market makers in the shares of common stock who are underwriters or prospective underwriters may, subject to certain limitations, make bids for or purchases of the shares of common stock until the time, if any, at

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which a stabilizing bid is made. These stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the shares of common stock to be higher than it would otherwise be in the absence of these transactions. These transactions may be commenced and discontinued at any time.

VALIDITY OF COMMON STOCK

The validity of the shares of common stock we are offering will be passed upon for us by Pepper Hamilton LLP, Philadelphia, Pennsylvania. Jeffrey P. Libson, Esq., a partner at Pepper Hamilton LLP, owns options to purchase 21,184 shares of our common stock. Certain legal matters in connection with this offering will be passed upon for the underwriters by Ballard Spahr Andrews & Ingersoll, LLP, Philadelphia, Pennsylvania.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the information requirements of 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 statements and all of their exhibits, at the SEC public reference room located at:

450 Fifth Street, N.W.

Judiciary Plaza

Room 1024

Washington, D.C. 20549

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 supplement 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 supplement, except for any information superseded by information in this prospectus supplement. You should read the information incorporated by reference because it is an important part of this prospectus supplement.

We incorporate by reference the following documents that we have filed or may file with the SEC (but we do not incorporate by reference any documents or portions of documents that we furnish to or are otherwise not deemed filed with the SEC):

1. Our Annual Report on Form 10-K for the year ended December 31, 2002;

2. Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2003;

3. Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2003;

4. Our Current Reports on Form 8-K filed on January 31, 2003, February 6, 2003, June 27, 2003 and September 9, 2003;

5. Our Definitive Proxy Statement filed April 11, 2003;

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6. The description of our capital 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 shares of preferred stock contained in the Registration Statement on Form 8-A filed on June 11, 2001;

8. All documents filed by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act on or after the date of this prospectus supplement and prior to the termination of the offering of securities under this prospectus supplement and the accompanying prospectus.

If you request, either orally or in writing, we will provide you with a copy of any or all documents which are incorporated by reference. We will provide such documents to you free of charge, but will not include any exhibits, unless those exhibits are incorporated by reference into the document. You should address written requests for documents as follows:

Corporate Secretary

OraSure Technologies, Inc.

220 East First Street

Bethlehem, Pennsylvania 18015

(610) 882-1820

Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our 10-Q, 8-K and 10-K reports to the SEC.

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PROSPECTUS

$75,000,000

Common Stock

Preferred Stock

Debt Securities

We may sell from time to time in one or more offerings, together or separately:

Common Stock

Preferred Stock

Debt Securities

in one or more series or issuances and their total offering price, in the aggregate, will not exceed $75,000,000. We will provide the specific terms of any securities we actually offer for sale in supplements to this prospectus. This prospectus may not be used to sell securities unless accompanied by a prospectus supplement. The net proceeds we expect to receive from such sales will be set forth in a prospectus supplement.

Our common stock is listed on the Nasdaq National Market under the symbol OSUR . On August 4, 2003, the reported last sale price of our common stock on the Nasdaq National Market was $8.25 per share. None of the other securities are currently publicly traded. We may sell these securities to or through underwriters and also to other purchasers or through agents. We will set forth the names of any underwriters or agents in the accompanying prospectus supplement.

Our principal offices are located at 220 East First Street, Bethlehem, Pennsylvania 18015, and our telephone number is (610) 882-1820.

INVESTING IN OUR SECURITIES INVOLVES RISKS. YOU SHOULD CAREFULLY CONSIDER THE RISK FACTORS BEGINNING ON PAGE 4 OF THIS PROSPECTUS BEFORE YOU DECIDE TO INVEST.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of 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 August 8, 2003

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ABOUT THIS PROSPECTUS

This prospectus is part of a shelf registration statement that we filed with the Securities and Exchange Commission (the SEC). By using a shelf registration statement, we may sell, from time to time over the next two years, in one or more offerings, any combination of the securities described in this prospectus in a dollar amount that does not exceed $75,000,000. For further information about our business, and the securities, you should refer to the registration statement and its exhibits. The exhibits to our registration statement contain the full text of certain contracts and other important documents we have summarized in this prospectus. Since these summaries may not contain all the information that you may find important in deciding whether to purchase the securities we may offer, you should review the full text of these documents. The registration statement can be obtained from the SEC as indicated under the Section entitled, Where You Can Find More Information.

You should rely only on the information contained or incorporated by reference in this prospectus and the prospectus supplement. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We will not make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, as well as information we previously filed with the SEC and incorporated by reference in this prospectus, is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

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WHO WE ARE

General

As the market leader in oral fluid diagnostics, we develop, manufacture and market oral fluid specimen collection devices using our proprietary oral fluid technologies. In addition, we manufacture and sell proprietary diagnostic products including *in vitro* diagnostic tests, and other medical devices. Our diagnostic products include tests which are processed in a laboratory and tests which are performed on a rapid basis and read at the point of care. These products are sold in both the United States and certain foreign countries to various distributors, government agencies, clinical laboratories, physicians offices, hospitals, and commercial and industrial entities.

In vitro diagnostic testing is the process of analyzing oral fluid, blood, urine and other bodily fluids or tissue for the presence of specific substances or markers for infectious diseases, drugs of abuse or other conditions or diseases. *In vitro* diagnostic tests are performed outside the body, in contrast to *in vivo* tests, which are performed directly on or within the body.

Products

Our business includes the following principal products: (1) the OraQuick® rapid HIV-1 antibody test; (2) the OraSure® and Intercept® oral fluid collection devices; and (3) the Histofreezer® portable cryosurgical system. In addition, we sell certain immunoassay tests and reagents for insurance risk assessment, substance abuse and forensic toxicology applications; an oral fluid Western blot HIV-1 confirmatory test; and the Q.E.D.® saliva alcohol test.

OraQuick®. OraQuick® is the only rapid, point-of-care test for HIV-1 (the virus that causes AIDS) that has received U.S. Food and Drug Administration (FDA) approval and a waiver under the Clinical Laboratory Improvements Amendments of 1988 (CLIA). The OraQuick® test does not require a laboratory as it can be visually read at the point of care in approximately 20 minutes after the sample is collected. The initial FDA approval permits the use of the test in detecting antibodies to HIV-1 in finger stick whole blood samples. However, this test is designed for use with oral fluid (or saliva), venous whole blood and plasma samples as well. We have submitted an application for FDA approval of a venous whole blood claim and are currently performing clinical trials and intend to submit FDA applications later in 2003 for oral fluid and plasma claims.

Our OraQuick® test can be used by approximately 180,000 sites in the United States, including hospitals, outreach clinics, community-based organizations and physicians offices. OraQuick® is sold directly by OraSure Technologies primarily into the public health market, to the military and the Centers for Disease Control and Prevention, and to certain international markets. This product is also distributed indirectly in the United States through Abbott Laboratories on a co-exclusive basis with OraSure. Abbott is focusing its sales efforts primarily on the hospital and physicians office markets.

OraSure® and Intercept®. OraSure® is the only collection device approved by the FDA for the detection of antibodies to HIV-1 in a sample of oral fluid. We have also obtained FDA clearance for the use of this product for detecting cocaine and cotinine (an indicator for the use of nicotine) in oral fluid. Samples collected with an OraSure® device are processed in a laboratory. If an oral fluid sample tests positive for antibodies to HIV-1, this result must be confirmed with our oral fluid Western blot confirmatory test, which is the only HIV-1 confirmatory test approved by the FDA for use with oral fluid. The OraSure® device is sold predominantly in the insurance market for the screening of life

insurance applicants, in physicians offices and in the public health market.

A collection device that is substantially similar to the OraSure® device is marketed under the name Intercept®. This device and the associated oral fluid immunoassays constitute the only laboratory-based

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oral fluid drug test that has been cleared by the FDA. The Intercept® device is used to collect oral fluid to be tested for various drugs, such as marijuana, cocaine, opiates, amphetamines, methamphetamines, phencyclidine (PCP), benzodiazepines, barbiturates, and methadone. Intercept® is used primarily by companies to test their employees and prospective employees, in the criminal justice system for testing prison inmates, arrestees and parolees, and in drug treatment and community/family service programs.

Histofreezer®. The Histofreezer® product is an alternative to liquid nitrogen treatment for the removal of warts and other benign skin lesions by freezing. We sell our Histofreezer® product through a dealer network in more than 20 countries worldwide, with most of our revenues coming from sales in the United States to family doctors, pediatricians and podiatrists. By using our Histofreezer® product, these medical professionals can treat warts and other skin lesions for patients that would otherwise need to be referred to a dermatologist for treatment.

We are expanding our Histofreezer® marketing and sales efforts in the professional markets through the engagement of specialized sales forces which will target obstetricians, gynecologists and family physicians. In addition, in April 2003, we entered into an agreement with the maker of the Compound W® line of wart removal products to distribute Histofreezer® under the trade name Freeze Off® into the over-the-counter market in the United States.

Other Information

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 220 East First Street, Bethlehem, Pennsylvania 18015. Our telephone number is (610) 882-1820, and our website address is http://www.orasure.com. Information contained on our website is not incorporated into this registration statement.

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RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones facing our Company. 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 or other securities could decline due to any of these risks, and you may lose all or part of your investment.

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 and described below or elsewhere in this prospectus.

Regulatory Risks

The Time Needed to Obtain Regulatory Approvals and Respond to Changes in Regulatory Requirements Could Adversely Affect Our Business.

Many of our proposed and existing products are subject to regulation by the FDA and other governmental or public health agencies. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products. In addition, we are often required to obtain approval or registration with foreign governments or regulatory bodies before we can import and sell our products in foreign countries.

The process of obtaining required approvals or clearances from governmental or public health agencies can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities and other costly, time-consuming procedures. For example, we are seeking FDA approval for the use of the OraQuick® rapid HIV-1 antibody test on venous whole blood samples and intend to pursue approval of claims for oral fluid and plasma samples. Approval of these claims will include the submission of clinical data and could require significant time to obtain. The submission of an application to the FDA or other regulatory authority for these or other claims does not guarantee that an approval or clearance to market the product will be received. Each authority may impose its own requirements and delay or refuse to grant approval or clearance, even though a product has been approved in another country.

Moreover, the approval or clearance process for a new product can be complex and lengthy. This time span increases our costs to develop new products and increases the risk that we will not succeed in introducing or selling them in the United States or other countries.

At the present time, we have received FDA clearance or approval for the OraSure® and Intercept® oral fluid collection devices, the OraQuick® rapid HIV-1 antibody test (for use with finger-stick whole blood samples only), the UP*link* drug testing system and opiates assay, the Histofreezer® portable cryosurgical system (in both the professional and over-the-counter markets), the Q.E.D.® saliva alcohol test, the OraSure® oral fluid Western blot HIV-1 confirmatory test, and various other tests.

Newly promulgated or changed regulations could also require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA), which is part of the U.S. Department of Health and Human Services, is in the process of drafting regulations for the use of oral fluid drug testing for federal workers. Although we believe the SAMHSA regulations, when issued in final form, will permit us to market and sell our oral fluid drug tests for use with federal workers, there is no guarantee that those regulations will do so, and our ability to sell those products in that market could be limited.

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The regulations in some states may restrict our ability to sell products in those states. For example, certain states restrict or do not allow the testing of oral fluid for drugs of abuse or the rapid, point-of-care testing for HIV. While we intend to work with state legislators and regulators to remove or modify any applicable restrictions, there is no guarantee we will be successful in these efforts.

In addition, all *in vitro* diagnostic products that are to be sold in the European Union (EU) must bear the CE mark indicating conformance with the essential requirements of the In Vitro Diagnostic Directive (IVDD). The deadline for meeting this requirement is December 7, 2003. We will not be permitted to sell our products in the EU without a CE mark after this date, which could lead to the termination of strategic alliances and agreements for sales of those products in the EU. While we intend to CE mark certain existing and future products, and are not aware of any material reason why we will be unable to do so, there can be no assurance that compliance with all provisions of the IVDD will be demonstrated and the CE mark obtained prior to the deadline. The OraSure® and Intercept® collection devices (collection pad only) and Histofreezer® product currently bear the CE mark.

Failure to Comply With FDA or Other Requirements May Require Us to Suspend Production of Our Products Which Could Result in a Loss of Revenues.

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

During 2000, the FDA issued warning letters with respect to our serum Western blot HIV-1 confirmatory test, stating that we were not in compliance with the FDA s regulations. We have responded to each of these letters and voluntarily discontinued this product. The concerns raised by the FDA also applied to the production of our oral fluid Western blot HIV-1 confirmatory test, which we still manufacture in Oregon. Although we believe that we have satisfactorily addressed the points raised by the FDA, the FDA could force us to stop manufacturing products at our Oregon facility if the FDA concludes that we remain out of compliance with applicable regulations. In addition, if the FDA were to find that we are not in compliance with applicable regulations at our manufacturing facilities in Bethlehem, Pennsylvania, we could be forced to stop manufacturing products at those locations as well. 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.

Risks Relating to Our Financial Results, Structure and Need for Financing

We Have a History of Losses.

We have not achieved full-year profitability. We incurred net losses of approximately $3.3 million, $3.7 million, $12.7 million and $1.6 million, in 2002, 2001 and 2000 and for the six months ended June 30, 2003, respectively. As of June 30, 2003, the Company had an accumulated deficit of approximately $131.1 million.

Our limited combined operating history makes it difficult to forecast our future operating results. In order to achieve sustainable profitability, our revenues will have to continue to grow at a significant rate. However, our revenues have remained essentially flat during the past two years.

Our ability to achieve revenue growth, and therefore profitability, will be dependent upon a number of factors including, without limitation, the following:

- Creating market acceptance for and selling increasing volumes of the OraSure® collection device, the Intercept® and UP*link* drug testing products, and the OraQuick® rapid HIV-1 antibody test;

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The degree to which certain of our new products may replace sales of our existing products and the financial impact of that change, including the degree to which our OraQuick® test will replace our OraSure® collection device for HIV-1 testing or sales of the Freeze Off® wart removal product in the over-the-counter market will replace sales of our Histofreezer® product to physicians offices or other professional markets;

Achieving growth in sales of the Freeze Off® wart removal product in the over-the-counter market;

Achieving growth in international markets with our OraQuick® rapid HIV-1 antibody test and other products; and

Commercially developing, and obtaining regulatory approval and creating market acceptance for, our Up-converting Phosphor Technology, (UPT), the UP*link* drugs-of-abuse rapid detection system, and other new products in a time frame consistent with our objectives.

We have not yet fully achieved these objectives and there can be no assurance that we will be able to do so. Moreover, even if we achieve our objectives and become profitable, there can be no assurance that we will be able to sustain such profitability in the future.

Our Reported Financial Results May be Adversely Affected by Changes in Accounting Principles Generally Accepted in the United States.

We prepare our financial statements in conformity with accounting principles generally accepted in the United States. These accounting principles are subject to interpretation by the Financial Accounting Standards Board (FASB), the American Institute of Certified Public Accountants, the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change.

For example, while current accounting rules allow us to exclude the expense of stock options granted to our employees from our financial statements, influential legislators and business policy groups have suggested that the rules be changed to require those options to be expensed. We rely on stock options as an important component of our employee compensation packages. As of April 22, 2003, the FASB had decided to require companies to expense the value of employee stock options and is expected to issue formal guidance on this matter later in 2003 that could become effective in 2004.

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

We May Require Future Additional Capital to Fund Our Operations.

Although we have made significant progress in the past toward controlling expenses and increasing product revenue, we have historically depended, to a substantial degree, on capital raised through the sale of equity securities and bank borrowings to fund our operations.

Our future liquidity and capital requirements will depend on numerous factors, including, but not limited to, the following:

- The costs and timing of the expansion of our manufacturing capacity;
- The success of our research and product development efforts;
- The scope and results of clinical testing;

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The magnitude of capital expenditures;

Changes in existing and potential relationships with business partners;

The time and cost of obtaining regulatory approvals;

The costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses;

The costs and timing of expansion of sales and marketing activities;

The timing of the commercial launch of new products;

The extent to which existing and new products gain market acceptance;

Competing technological and market developments; and

The scope and timing of strategic acquisitions.

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

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, 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 us 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 our ability to obtain regulatory approvals required to manufacture, market or sell our products in the United States and other countries.

Risks Relating to Our Industry, Business and Strategy

Our Ability to Sell Products Could be Affected by Competition From New and Existing Diagnostic Products and by Treatment or Other Non-Diagnostic Products Which May be Developed.

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point of care and is highly competitive and rapidly changing. Our principal competitors often have considerably greater financial, technical and marketing resources. As new products enter the market, our products may become obsolete or a competitor s products may be more effective or more effectively marketed and sold than ours. If we fail to maintain and enhance our competitive position, our customers may decide to use products developed by competitors which could result in a loss of revenues.

In addition, the development and commercialization of products outside of the diagnostics industry could adversely affect sales of our product. For example, the development of a safe and effective vaccine

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to HIV or treatments for other diseases or conditions that our products are designed to detect, could reduce, or eventually eliminate, the demand for our HIV or other diagnostic products and thereby result in a loss of revenues.

Our Research, Development and Commercialization Efforts May Not Succeed or Our Competitors May Develop and Commercialize More Effective or Successful Diagnostic Products.

In order to remain competitive, we must regularly commit substantial resources to research and development and the commercialization of new products.

The research and development process generally takes a significant amount of time from inception to commercial product launch. This process is conducted in various stages. During each stage there is a substantial risk that we will not achieve our goals on a timely basis, if at all, and we may have to abandon a product in which we have invested substantial amounts.

During 2002, 2001 and 2000, we incurred approximately $8.3 million, $9.4 million and $10.4 million, respectively, in research and development expenses. During the six months ended June 30, 2003, we incurred approximately $4.0 million in research and development expenses. We expect to continue to incur significant costs from our research and development activities.

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

Successful products require significant development and investment, including testing, to demonstrate their cost-effectiveness or other benefits prior to commercialization. In addition, regulatory approval must be obtained before most products may be sold. Additional development efforts on these products will be required before any regulatory authority will review them. Regulatory authorities may not approve these products for commercial sale. In addition, even if a product is developed and all applicable regulatory approvals are obtained, there may be little or no market for the product. Accordingly, if we fail to develop commercially successful products, or if competitors develop more effective products or a greater number of successful new products, customers may decide to use products developed by our competitors. This would result in a loss of revenues and adversely affect our results of operations, cash flows and business.

If We Lose Our Key Personnel or Are Unable to Attract and Retain Qualified Personnel as Necessary, Our Business Could be Harmed.

Our success will depend to a large extent upon the contributions of our executive officers, management, and sales, marketing, operations and scientific staff. We may not be able to attract or retain qualified employees in the future due to the intense competition for qualified personnel among medical products businesses.

If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively manufacture, sell and market our products, to meet the demands of our strategic partners in a timely

fashion, or to support internal research and development programs. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms.

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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 we bring new products to market, we may need to increase our product liability coverage. We have obtained the required regulatory approvals to sell our Histofreezer® portable cryosurgical system in the consumer or over-the-counter market. We believe the sale of this or other products in the over-the-counter market could increase the risk of potential product liability exposure and the required level of insurance coverage that we will need to maintain. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could affect our decision to commercialize new products.

Efforts to Consolidate or Restructure Could Adversely Affect Our Business.

We may from time to time restructure and consolidate various aspects of our operations in order to achieve cost savings and other efficiencies. For example, during 2001 we began a restructuring of our manufacturing operations which included the transfer of OraQuick® manufacturing from our Beaverton, Oregon facility to Bethlehem, Pennsylvania. In addition, we plan to close our Oregon facility and transfer all remaining manufacturing operations and research and development activities in that facility related to the oral fluid Western blot HIV-1 confirmatory test, along with our contract manufacturing operations for the OraSure® and Intercept® collection devices, to our facilities in Pennsylvania. We must obtain FDA approval to transfer certain operations to another location. This transfer and the need to obtain FDA approval could interfere with or delay our manufacturing processes and disrupt continued operations. Any delay in or disruption of operations, and in particular manufacturing operations, could result in increased costs or could delay or prevent us from selling certain products and thereby result in a loss of revenue.

Future Acquisitions or Investments Could Disrupt Our Ongoing Business, Distract Our Management, Increase Our Expenses and Adversely Affect Our Business.

We may consider strategic acquisitions or investments as a way to expand our business in the future. These activities, and their impact on our business, are subject to the following risk factors:

- Suitable acquisitions or investments may not be found or consummated on terms that are satisfactory to us;
- We may be unable to successfully integrate an acquired company s personnel, assets, management systems and technology into our business;
- Acquisitions may require substantial expense and management time and could disrupt our business;
- An acquisition and subsequent integration activities may require greater capital resources than originally anticipated at the time of acquisition;

An acquisition may result in the incurrence of unexpected expenses, the dilution of our earnings or our existing stockholders percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business;

An acquisition may result in the loss of existing key personnel or customers or the loss of the acquired company s key personnel or customers;

The benefits to be derived from an acquisition could be affected by other factors, such as regulatory developments, general economic conditions and increased competition; and

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An acquisition of a foreign business may involve additional risks, including not being able to successfully assimilate differences in foreign business practices or overcome language barriers.

The incurrence of one or more of the above or other factors may prevent us from achieving all or a significant part of the benefits expected from an acquisition or investment. This may adversely affect our financial condition, results of operations and ability to grow our business.

Risks Relating to Collaborators

Our Failure to Maintain Existing Distribution Channels, or Develop New Distribution Channels, May Result in Lower Revenues.

We have marketed many of our products by collaborating with laboratories, diagnostic companies and distributors. For example, our OraSure® oral fluid collection device is distributed to the insurance industry through major insurance testing laboratories. Our sales depend to a substantial degree on our ability to sell products to these customers and develop new product distribution channels, and on the marketing abilities of the companies with which we collaborate.

Some of our distributors have recently consolidated, and such consolidation has had, and may continue to have, an adverse impact on the level of orders for our products. One of these laboratories, Lab*One*, Inc., acquired another large insurance laboratory customer, Osborne Group, Inc., in 2001. These customers together accounted for approximately 26%, 29% and 30% of our revenues for the years 2002, 2001, and 2000, respectively. As a result of efficiencies gained following this acquisition, Lab*One* purchased approximately $1 million less of our insurance assays in 2002 than both companies purchased in 2001.

In addition, some distributors have experienced, and may continue to experience, pressure from their customers to reduce the price of their products and testing services. For example, Lab*One* and our other insurance testing laboratories are facing this pressure and are using lower cost insurance testing assays that they have developed internally or purchased from our competitors. This has reduced our sales of insurance assays and is expected to lower sales of these products in 2003 and beyond.

Although we will try to maintain and expand our business with our distributors, there can be no assurance that such companies will continue to purchase or distribute our products or maintain historic order volumes, or that new distribution channels will be available on satisfactory terms.

The Use of Sole Supply Sources For Critical Components of Our Products Could Adversely Affect Our Business.

We currently purchase certain critical components of our products from sole supply sources. For example, all of the HIV-1 antigen used to make our oral fluid Western blot HIV-1 confirmatory test is purchased from bioMerieux, Inc. (BMX), and all of the HIV antigen and nitrocellulose required to make our OraQuick® rapid HIV-1 antibody test is purchased from sole source suppliers. If these suppliers are unable or unwilling to supply the required component, we would need to find another source, and perform additional development work and obtain FDA approval for the use of the alternative component for our products. Completing that development and obtaining such FDA approval could require significant time to complete and may not occur at all. These events could either disrupt our ability to manufacture and sell certain of our products or completely prevent us from doing so. Either event would have a material adverse effect on our results of operations, cash flows and business.

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

In testing an oral fluid sample collected with an OraSure® device for HIV-1 in the United States, our customers must use an HIV-1 screening test approved by the FDA for use with our OraSure® device.

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Where an oral fluid sample screens positive for HIV-1, our customers must then use our oral fluid Western blot HIV-1 confirmatory test, which has also been approved by the FDA for use with our OraSure® device, to confirm that positive indication.

BMX (bioMerieux, Inc.) manufactures and sells the only oral fluid HIV-1 screening test that has received FDA approval for use in detecting HIV-1 in an oral fluid specimen collected with our OraSure® collection device. BMX has developed a new HIV-1 screening test, and has indicated that this new test will eventually replace its existing FDA-approved HIV-1 screening test. We are working with BMX to obtain FDA approval for use of the new screening test with our OraSure® device. BMX also supplies the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and is the exclusive world-wide distributor of that product.

If BMX ceases to manufacture or sell an HIV-1 screening test approved by the FDA for use with our OraSure® collection device, or if our oral fluid Western blot HIV-1 confirmatory test is not made available to our customers (because BMX either fails to supply the HIV-1 antigen required to make this product or fails to distribute this product), we would need to find alternate suppliers for these products, which would require additional development work and FDA approval. These activities would likely require significant time to complete. If our customers cannot obtain an HIV-1 screening test or Western blot HIV-1 confirmatory test that has been approved by the FDA for use in connection with our OraSure® collection device, these customers would likely stop purchasing our OraSure® device. Sales of the OraSure® device were approximately $12.7 million and $11.5 million, or 40% and 35% of our total revenues, in 2002 and 2001, respectively.

We Are Dependent Upon Strategic Partners to Assist in Developing and Commercializing Some of Our Diagnostic Products.

Although we intend to pursue some product opportunities independently, opportunities that require a significant level of investment for development and commercialization or a distribution network beyond our existing sales force may necessitate involving one or more strategic partners. In particular, our strategy for development and commercialization of UPT, including the UP*link* rapid detection system, and certain other products may entail entering into additional arrangements with distributors or other corporate partners, universities, research laboratories, licensees and others. We may be required to transfer material rights to such strategic partners, licensees and others. While we expect that our current and future partners, licensees and others have and will have an economic motivation to succeed in performing their contractual responsibilities, the amount and timing of resources to be devoted to these activities will be controlled by others. Consequently, there can be no assurance that any revenues or profits will be derived from such arrangements.

Risks Relating to Intellectual Property

Our Success Depends on Our Ability to Protect Our Proprietary Technology.

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

As appropriate, we intend to file patent applications and obtain patent protection for our proprietary technology. These patent applications and patents will cover, as applicable, compositions of matter for our products, methods of making those products, methods of using those products, and apparatus relating to the use or manufacture of those products. We will also rely on trade secrets, know-how, and continuing technological advancements to protect our proprietary technology.

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We have entered, and will continue to enter, into confidentiality agreements with our employees, consultants, advisors and collaborators. However, these parties may not honor these agreements and we may not be able to successfully protect our rights to unpatented trade secrets and know-how. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know-how.

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

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

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

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

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

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

The importance of HIV-2 differs by country, and can be affected by both regulatory requirements and by competitive pressures. Because the competitive situation in each country will be affected by the availability of other testing products as well as the country s regulatory environment, we may be at a competitive disadvantage in some markets without an HIV-2 product. In particular, our ability to sell a product that does not include an HIV-2 test may be limited, or a competitor s product that includes an HIV-2 test may be preferred and have a competitive advantage over an HIV-1 only test that we sell.

Another factor that may affect the specific countries in which we will be able to sell an OraQuick® rapid HIV-1 or HIV-2 test, and therefore the overall sales potential, concerns whether we can arrange a

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sublicense or distribution agreement related to any patents which claim lateral flow assay methods and devices covering the OraQuick® rapid HIV antibody tests or their use. OraQuick® is a lateral flow assay device that tests for specific antibodies or other substances. The term lateral flow generally refers to a test strip through which a sample flows and which provides a test result on a portion of the strip downstream from where the sample is applied. There are numerous patents in the United States and other countries which claim lateral flow assay methods and devices. Some of these patents may broadly cover the technology used in the OraQuick® test and are in force in the United States and other countries. We may not be able to make the OraQuick® test in the United States and sell it in countries where there is no patent on the device. We have obtained licenses under several lateral flow patents, which we believe should be sufficient to permit the manufacturing and sale of the OraQuick® device as currently contemplated. However, licenses under additional patents may be required.

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

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

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

Risks Relating to Product Marketing and Sales

A Market for Our Products May Not Develop.

Our future success will depend, in part, on the market acceptance, and the timing of such acceptance, of new products such as the Intercept® drug test, the OraQuick® rapid HIV-1 antibody test, products currently under development such as the UP*link* drugs of abuse rapid detection system and other products using the UPT 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 perceived benefits of these products. We currently have limited evidence on which to evaluate the market reaction to products that may be developed, and there can be no assurance that any products will meet with market acceptance and fill the market need that is perceived to exist.

If Acceptance and Adoption of Our Oral Fluid Testing in the Market Does Not Continue, Our Future Results May Suffer.

We have made significant progress in gaining acceptance of oral fluid testing for HIV in the insurance and public health markets. We have also made significant progress in gaining acceptance of oral fluid testing for drugs of abuse in the workplace and criminal justice testing markets.

However, the ultimate degree of acceptance in these markets is uncertain, and other markets may resist the adoption of oral fluid HIV testing as a replacement for other testing methods in use today. In addition, certain

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state laws prohibit or restrict the use of oral fluid testing for drugs of abuse in certain markets. As a result, there can be no assurance that we will be able to expand the use of our oral fluid testing products in these or other markets.

Our Increasing International Presence May be Affected by Regulatory, Cultural or Other Restraints.

We intend to increase international sales of our products. Our international sales accounted for approximately $3.9 million or 12% of total revenues for 2002, approximately $5.3 million or 16% of total revenues for 2001, and approximately $4.0 million or 14% of total revenues for 2000.

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;
- The unavailability of licenses to certain patents in force in a foreign country which cover our products may restrict our ability to sell into that country;
- Our inability to obtain the CE mark on our products in a timely manner may preclude or delay our ability to sell products to the European Union;
- Cultural and political differences may make it difficult to effectively market, sell and gain acceptance of products in foreign jurisdictions;
- Inexperience in international markets may slow or limit our ability to sell products in foreign countries;
- Exchange rates, currency fluctuations, tariffs and other barriers, extended payment terms and dependence on and difficulties in managing international distributors or representatives may affect our revenues even when product sales occur;
- The creditworthiness of foreign entities may be less certain and foreign accounts receivable collection may be more difficult;
- Economic conditions, the absence of available funding sources, terrorism, civil unrest and war may slow or limit our ability to sell our products in foreign countries;
- International markets often have long sales cycles, especially sales to foreign governments, quasi-governmental agencies and international public health agencies, thereby delaying or limiting our ability to sell our products; and
- We may be at a disadvantage if competitors in foreign countries sell competing products at prices at or below such competitors or our cost.

In February 2000, we entered into an agreement for the distribution of our OraQuick® rapid HIV antibody test in a number of African countries. Because of the lack of funding sources in those countries for the purchase of our product and other factors, our distributor failed to meet its minimum purchase commitments under our agreement. As a result, we were forced to write-off approximately $0.6 million of OraQuick® inventory initially manufactured in contemplation of sales to this distributor.

In addition, we have entered into a contract for the manufacture and supply of the OraQuick® rapid HIV antibody test 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 and distribution of our products in countries other than the United States. Interruption of the supply of our products could reduce revenues or cause us to incur significant additional expenses in finding an alternative source of supply.

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Risks Related to this Offering

Applicable law, our charter, our bylaws and preferred stock purchase rights may delay or prevent a change in control or the removal of our current management.

Our board has the authority to issue up to 25,000,000 shares of preferred stock and to determine the price, privileges and other terms of such shares. Our board may exercise this authority without the approval of, or notice to, our stockholders. Accordingly, the rights of the holders of our common stock may be adversely affected by the rights of the holders of any preferred stock that may be issued in the future. In addition, the issuance of preferred stock may make it more difficult for a third party to acquire a majority of our outstanding voting stock in order to effect a change in control or replace our current management.

We are also subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. The application of Section 203 could also delay or prevent a third party or a significant stockholder of ours from acquiring control of us or replacing our current management. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder, unless the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns 15% or more of a corporation s voting stock.

In May 2000, our board of directors adopted a plan that grants each holder of our common stock the right to purchase shares of our series A preferred stock. This plan is designed to help insure that all our stockholders receive fair value for their shares of common stock in the event of a proposed takeover of us, and to guard against the use of partial tender offers or other coercive tactics to gain control of us without offering fair value to the holders of our common stock.

In addition, there are provisions in our charter and bylaws, such as a staggered board and significant notice provisions for nominations of directors and proposals for consideration at a meeting of our stockholders. The stockholder rights plan and our charter and bylaws may make it more difficult for a third party to acquire a majority of our outstanding voting stock in order to effect a change in control or replace our current management.

Our stock price could continue to be volatile.

Our stock price has been volatile. For example, since July 1, 2001, the market price of our common stock has fluctuated between $15.00 and $3.33, and since July 1, 2002, the market price of our common stock has fluctuated between $8.85 and $3.33.

The following factors, among others, could have a significant impact on the market for our common stock:

- future announcements concerning us;

future announcements concerning our competitors or industry;

governmental regulation;

clinical results with respect to our products in development or those of our competitors;

developments in patent or other proprietary rights;

litigation or public concern as to the safety of products that we or others have developed;

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the relatively low trading volume for our common stock;

period to period fluctuations in our operating results;

changes in estimates of our performance by securities analysts;

general market and economic conditions; and

terrorist attacks, civil unrest and war.

The issuance of additional equity securities may have a dilutive effect on our existing stockholders and could lead to a decline in the price of our common stock.

Any additional sale of equity securities may have a dilutive effect on our existing stockholders. In addition, the perceived risk associated with the possible sale of a large number of shares could cause some of our stockholders to sell their stock, thus causing the price of our stock to decline. Subsequent sales of our common stock in the open market or the private placement of our common stock or securities convertible into common stock could also have an adverse effect on the market price of the shares. If our stock price declines, it may be more difficult or we may be unable to raise additional capital.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in the Sections entitled, Who We Are and Risk Factors, and elsewhere in this prospectus, constitute forward-looking statements. These statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry s results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, those listed under the Section entitled, Risk Factors, and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terminology such as may, will, should, intend, expect, plan, anticipate, believe, estimate, predict, potential, or continue or the negative of such terms or other comparable terminology.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance, or achievements. We do not assume responsibility for the accuracy and completeness of the forward-looking statements. We do not intend to update any of the forward-looking statements after the date of this prospectus to conform them to actual results, except as required by the federal securities laws.

RATIO OF EARNINGS TO FIXED CHARGES

Earnings were insufficient to cover fixed charges by approximately the following amounts for the periods ended as set forth below (in thousands):

	Six Months Ended	Fiscal Year Ended December 31,			Three Months Ended December 31,	Fiscal Year Ended September 30,	
	June 30, 2003	2002	2001	2000	1999	1999	1998
Deficiency of earnings to cover fixed charges	$ 1,607,670	$ 3,342,473	$ 3,699,000	$ 12,722,187	$ 421,287	$ 4,183,264	$ 2,374,146

Fixed charges consists of interest expense plus the portion of rent expense under operating leases deemed by us to be representative of the interest factor.

Our Company was formed in May 2000, for the purpose of combining two companies, STC Technologies, Inc. (STC) and Epitope, Inc. (Epitope). On September 29, 2000, STC and Epitope were merged into our Company. The merger was accounted for as a pooling of interests and, accordingly, all prior period financial statements of Epitope have been restated to include the results of STC. The above financial data for each of the years ended September 30, 1999 and 1998 include Epitope s previous September 30 fiscal year amounts and STC s December 31 calendar year amounts. On September 29, 2000, the Company changed its fiscal year-end from September 30 to December 31, effective with the calendar year beginning January 1, 2000. A three-month transition period from October 1, 1999 through December 31, 1999 preceded the start of the 2000 fiscal year. As a result of the merger, financial statements for the three-month period ended December 31, 1999 include amounts for Epitope and STC for the three months ended December 31, 1999. Accordingly, STC s results of operations for the three months ended December 31, 1999 are included in both the financial statements for the year ended September 30, 1999 and for the three-month transition period ended December 31, 1999.

We would have had to generate additional earnings of approximately $1,608,000 for the six-month period ended June 30, 2003 to achieve an earnings to fixed charges ratio of 1:1.

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USE OF PROCEEDS

Except as otherwise described in the applicable prospectus supplement, the net proceeds from the sale of the securities offered hereunder will be added to our general funds and used for general corporate purposes, which may include, but are not limited to:

- ongoing research and development activities;
- commercialization of new products;
- potential acquisitions;
- capital expenditures;
- patent license fees;
- debt service and retirement; and
- general working capital.

The amounts and timing of our actual expenditures for each purpose may vary significantly depending upon numerous factors, including the status of our research and product development efforts, regulatory approvals, competition, marketing and sales activities, the market acceptance of any products introduced by us and economic or other conditions. Pending such uses, we intend to invest the net proceeds of this offering in short-term, investment grade, interest-bearing securities.

THE SECURITIES WE MAY OFFER

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. We will also include in the prospectus supplement information, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange or market, if any, on which the securities will be listed.

We may sell from time to time, in one or more offerings:

- common stock;

preferred stock; and/or

debt securities.

In this prospectus, we will refer to the common stock, preferred stock and debt securities collectively as securities. The total dollar amount of all securities that we may issue will not exceed $75,000,000.

If we issue debt securities at a discount from their original stated principal amount, then, for purposes of calculating the total dollar amount of all securities issued under this prospectus, we will treat the initial offering price of the debt securities as the total original principal amount of the debt securities.

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DESCRIPTION OF COMMON STOCK AND PREFERRED STOCK

The following description of our common stock and preferred stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future common stock or preferred stock that we may offer, we will describe the particular terms of any series of these securities in more detail in the applicable prospectus supplement.

Under our certificate of incorporation, our authorized capital stock consists of 120,000,000 shares of common stock, par value $0.000001 per share, and 25,000,000 shares of preferred stock, par value $0.000001 per share. As of July 28, 2003, we had 38,518,540 shares of common stock outstanding and no shares of preferred stock outstanding. As of July 28, 2003, we had reserved for issuance 120,000 shares of series A preferred stock in connection with our stockholder rights plan (described below). As of the date of this prospectus, we have not issued any shares of our series A preferred stock.

Common Stock

Voting. For all matters submitted to a vote of stockholders, each holder of common stock is entitled to one vote for each share registered in his or her name. Subject to applicable law and any preferential rights we may grant to the holders of preferred stock, if any is outstanding, holders of our common stock will have all voting power. Our common stock does not have cumulative voting rights. As a result, subject to the voting rights of any outstanding preferred stock, of which there currently is none, persons who hold more than 50% of the outstanding common stock entitled to elect members of our board of directors can elect all of the directors who are up for election in a particular year.

Dividends. If our board of directors declares a dividend, holders of common stock will receive payments from our funds that are legally available to pay dividends. However, this dividend right is subject to any preferential dividend rights we may grant to the holders of preferred stock, if any is outstanding.

Liquidation and Dissolution. If we are liquidated or dissolve, the holders of our common stock will be entitled to share ratably in all the assets that remain after we pay our liabilities and any amounts we may owe to the holders of preferred stock, if any is outstanding.

Other Rights and Restrictions. Holders of our common stock do not have preemptive rights, and they have no right to convert their common stock into any other securities. Our common stock is not subject to redemption by us. The rights, preferences and privileges of holders of our common stock are subject to the rights of the holders of any series of preferred stock which we may designate in the future. Our certificate of incorporation and bylaws do not restrict the ability of a holder of common stock to transfer his or her shares of common stock. When we issue shares of common stock under this prospectus, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

Listing. Our common stock is listed on the Nasdaq National Market under the symbol OSUR.

Transfer Agent and Registrar. The transfer agent and registrar for our common stock is Mellon Investor Services LLC.

Preferred Stock

General. Our certificate of incorporation authorizes the issuance of up to 25,000,000 shares of preferred stock, par value $0.000001 per share. We have reserved for issuance 120,000 shares of series A preferred stock in connection with our stockholder rights plan. We may issue, from time to time in one

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or more series, up to 24,880,000 shares of preferred stock, the terms of which may be determined at the time of issuance by our board of directors, without further action by our stockholders, and may include voting rights, preferences as to dividends and liquidation, conversion rights, redemption rights and sinking fund provisions. The shares of each series of preferred stock shall have preferences, limitations and relative rights, including voting rights, identical with those of other shares of the same series and, except to the extent provided in the description of such series, of those of other series of preferred stock.

The issuance of any preferred stock could adversely affect the rights of the holders of common stock and, therefore, reduce the value of the common stock. The ability of our board of directors to issue preferred stock could discourage, delay or prevent a takeover or change in control.

The description of the terms of a particular series of preferred stock in the applicable prospectus supplement will not be complete. You should refer to the applicable certificate of designation for complete information regarding a series of preferred stock. The prospectus supplement will also contain a description of U.S. federal income tax consequences relating to the preferred stock, if material.

The terms of any particular series of preferred stock will be described in the prospectus supplement relating to that particular series of preferred stock, including, where applicable:

- the series designation, stated value and liquidation preference of such preferred stock and the number of shares offered;
- the offering price;
- the dividend rate or rates (or method of calculation), the date or dates from which dividends shall accrue, and whether such dividends shall be cumulative or noncumulative and, if cumulative, the dates from which dividends shall commence to cumulate;
- any redemption or sinking fund provisions;
- the amount that shares of such series shall be entitled to receive in the event of our liquidation, dissolution or winding-up;
- the terms and conditions, if any, on which shares of such series shall be exchangeable for shares of our stock of any other class or classes, or other series of the same class;
- the voting rights, if any, of shares of such series in addition to those set forth in the Section entitled, Voting Rights, below;
- the status as to reissuance or sale of shares of such series redeemed, purchased or otherwise reacquired, or surrendered to us on conversion or exchange;
- the conditions and restrictions, if any, on the payment of dividends or on the making of other distributions on, or the purchase, redemption or other acquisition by us, of our common stock or of any other class of our stock ranking junior to the shares of such series as to dividends or upon liquidation;

the conditions and restrictions, if any, on the creation of indebtedness of us, or on the issue of any additional stock ranking on a parity with or prior to the shares of such series as to dividends or upon liquidation; and

any additional dividend, liquidation, redemption, sinking or retirement fund and other rights, preferences, privileges, limitations and restrictions of such preferred stock.

If we issue shares of preferred stock under this prospectus, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

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Voting Rights. The General Corporation Law of Delaware provides that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of that preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Other. Our issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of common stock or could adversely affect the rights and powers, including voting rights, of the holders of common stock. The issuance of preferred stock could have the effect of decreasing the market price of our common stock.

Certain Effects of Authorized But Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, facilitating corporate acquisitions or paying a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, if we issue preferred stock, the issuance could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation.

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law, or the DGCL, which, subject to certain exceptions and limitations, prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that such stockholder became an interested stockholder, unless:

(i) prior to such date, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

(ii) upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced (for the purposes of determining the number of shares outstanding under the DGCL, those shares owned (x) by persons who are directors and also officers and (y) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer are excluded from the calculation); or

(iii) on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

For purposes of Section 203, a business combination includes:

(i) any merger or consolidation involving the corporation and the interested stockholder;

(ii) any sale, lease, exchange, mortgage, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

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(iii) subject to certain exceptions, any transaction which results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

(iv) any transaction involving the corporation which has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

(v) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

For purposes of Section 203, an interested stockholder is defined as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

Selected Certificate of Incorporation and Bylaw Provisions

Our certificate of incorporation provides that the number of directors shall be as determined by the board of directors from time to time, but shall be at least three and not more than twelve. It further provides that directors may be removed only for cause, and then only by the affirmative vote of the holders of at least a majority of all outstanding voting stock entitled to vote in an election of directors. These provisions, in conjunction with the provision of the certificate of incorporation authorizing the board of directors to fill vacant directorships, will prevent stockholders from removing incumbent directors without cause and filling the resulting vacancies with their own nominees.

Our certificate of incorporation further provides that the board of directors will be divided into three classes, with each class containing as nearly as possible one-third of the total number of directors and the members of each class serving for staggered three-year terms. At each annual meeting of our stockholders, the number of directors equal to the number of the class whose term expires at the time of such meeting will be elected to hold office until the third succeeding annual meeting of stockholders. This provision could make it more difficult for stockholders to take control of the board of directors.

Our certificate of incorporation provides that stockholders may act only at an annual or special meeting of stockholders and may not act by written consent unless such consent is unanimous. Special meetings of the stockholders can be called only by our Chairman of the Board, Chief Executive Officer, President, or board of directors pursuant to a resolution approved by a majority of the whole board of directors. This provision will prevent stockholders from removing board members by calling a special meeting of stockholders without the consent of the Chairman of the Board, the Chief Executive Officer, the President or the board of directors.

Our bylaws contain provisions (i) requiring that advance notice be delivered to us of any business to be brought by a stockholder before any meeting of stockholders and (ii) establishing procedures to be followed by stockholders in nominating persons for election to the board of directors. Generally, such advance notice provisions provide that written notice must be given to us by a stockholder, with respect to director nominations or stockholder proposals, not less than 90 nor more than 120 days prior to the meeting (except that if less than 100 days notice or prior public disclosure of the date of the meeting is given or made to stockholders, then notice by the stockholder, to be timely, must be received within 10 days of the date on which notice of the date of the meeting was mailed or such public disclosure was made, whichever first occurs). Such notice must set forth specific information regarding such stockholder and such business or director nominee, as described in the bylaws.

Our certificate of incorporation authorizes the board of directors to take into account (in addition to any other considerations which the board of directors may lawfully take into account) in determining whether to take or to refrain from taking corporate action on any possible acquisition proposals, including proposing any related matter to our stockholders, the long-term as well as short-term interests

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of our company and its stockholders, including the possibility that these may be best served by the continued independence of our company, customers, employees and other constituencies and any subsidiaries, as well as the effect upon communities in which we do business. In considering the foregoing and other pertinent factors, the board of directors is not required, in considering our best interests, to regard any particular corporate interest or the interest of any particular group affected by such action as a controlling interest.

Certain provisions of the certificate of incorporation and bylaws, including those described above, may only be amended by stockholders upon the affirmative vote of the holders of at least two-thirds of the outstanding voting capital stock entitled to vote on such amendment.

The preceding provisions could have the effect of discouraging, delaying or making more difficult certain attempts to acquire us or to remove incumbent directors even if a majority of our stockholders believe the attempt to be in their or our best interests. The foregoing summaries are qualified in their entirety by reference to our certificate of incorporation and bylaws, copies of which are incorporated by reference into the registration statement of which this prospectus is a part.

Stockholder Rights Plan

In May 2000, our board of directors adopted a stockholder rights plan. Pursuant to the rights plan, we distributed a dividend of one right to purchase shares of our capital stock under certain circumstances specified in the rights plan, for each outstanding share of common stock. We refer to these purchase rights as the Rights. The Rights trade with the common stock and will detach and become exercisable only if, in a transaction not approved by our board of directors, ten business days elapse after either a person (together with that person s affiliates or associates) acquires 15% or more of the outstanding shares of our common stock, or announces a tender offer the completion of which would result in ownership by a person (together with such person s affiliates or associates) of 15% or more of those shares.

If the Rights detach and become exercisable as a result of the commencement of a tender offer, unless subsequently redeemed, each Right then would entitle its holder to purchase one one-thousandth of a share of the series A preferred stock for an exercise price specified in the rights plan (which is intended to equal the estimated value of our common stock at the end of the ten-year life of the Rights). If we were to be involved in a merger or other business combination transaction after the Rights become exercisable, each Right would entitle its holder to purchase, for the Right s exercise price, a number of the acquiring or surviving company s shares of common stock having a market value equal to twice the exercise price. If, in a transaction not approved by our board of directors, a person (together with such person s affiliates or associates) acquires 15% or more of the outstanding shares of our common stock, each Right would entitle its holder (other than the acquiring person and its affiliates and associates, all of whose Rights become automatically void) to purchase, for the Right s exercise price, a number of shares of our common stock having a market value equal to twice the exercise price. At any time after a person (together with such person s affiliates or associates) acquires at least 15%, but not more than 50%, of the outstanding shares of our common stock, our board of directors can elect to exchange one share of common stock for each Right (other than Rights held by such acquiring person and its affiliates and associates). We would be entitled to redeem the Rights at $.01 per Right at any time until ten business days following a public announcement that a person (together with such person s affiliates or associates) has acquired beneficial ownership of 15% or more of the outstanding shares of common stock. Following such an announcement, or, subject to certain exceptions specified in the rights plan, the acquisition of beneficial ownership of 15% or more of the outstanding shares of common stock by the acquirer (together with such person s affiliates or associates), the Rights acquired by such person or persons would be null and void. Prior to the date upon which the Rights detach, the terms of the rights plan could be amended by our board of directors without the consent of the holders of the Rights. The Rights expire on May 6, 2010, unless earlier redeemed by us.

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The rights plan may deter takeover bids for our Company. To the extent an acquirer would be discouraged by the rights plan from acquiring an equity position in us, stockholders may be deprived from receiving a premium for their shares. The issuance of additional shares of common stock prior to the time the Rights become exercisable would result in an increase in the number of Rights outstanding.

We anticipate that the series A preferred stock, if issued, would rank junior to all other series of preferred stock as to the payment of dividends and the distribution of assets in liquidation, unless the terms of any such other series provide otherwise. Each share of series A preferred stock would have a quarterly dividend rate per share equal to 1,000 times the per share amount of any dividend (other than a dividend payable in shares of common stock or a subdivision of the common stock) declared from time to time on the common stock, subject to certain adjustments. The holders of series A preferred stock would be entitled to receive a preferred liquidation payment per share of $1,000 (plus accrued and unpaid dividends) or, if greater, an amount equal to 1,000 times the payment to be made per share of common stock. Generally, the holder of each share of series A preferred stock would vote together with the common stock (and any other series of preferred stock entitled to vote on such matter) on any matter as to which the common stock is entitled to vote, including the election of directors. The holder of each share of series A preferred stock would be entitled to 1,000 votes, or one vote for each one one-thousandth of a share. In the event of any merger, consolidation, combination or other transaction in which shares of common stock are exchanged for or changed into other stock or securities, cash and/or property, the holder of each share of series A preferred stock would be entitled to receive 1,000 times the aggregate amount of stock, securities, cash and/or property into which or for which each share of common stock is changed or exchanged.

The foregoing dividend, voting and liquidation rights of the series A preferred stock would be protected against dilution in the event that additional shares of common stock are issued pursuant to a stock split or stock dividend. Because of the nature of the series A preferred stock s dividend, voting, liquidation and other rights, the value of the one one-thousandth of a share of series A preferred stock purchasable with each Right is intended to approximate the value of one share of common stock.

Stock Option Plan

As of July 28, 2003, a total of 4,417,633 options to purchase shares of our common stock had been granted and remained outstanding and unexercised under our stock option plan.

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we may offer, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement.

The debt securities will be our direct unsecured general obligations and may include debentures, notes, bonds and/or other evidences of indebtedness. The debt securities will be either senior debt securities or subordinated debt securities. The debt securities will be issued under one or more separate indentures. Senior debt securities will be issued under a senior indenture, and subordinated debt securities will be issued under a subordinated indenture. We use the term indentures to refer to both the senior indenture and the subordinated indenture. We have filed forms of the indentures as exhibits to the registration statement which includes this prospectus.

The indentures will be qualified under the Trust Indenture Act of 1939. We use the term debenture trustee to refer to either the senior trustee or the subordinated trustee, as applicable.

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The following summaries of material provisions of the debt securities and indentures are subject to, and qualified in their entirety by reference to, all the provisions of the indenture and any relevant indenture supplement applicable to a particular series of debt securities. Except as we might otherwise indicate, the terms of the senior indenture and subordinated indenture are identical.

General

We will describe in each prospectus supplement the following terms relating to a series of debt securities:

- the title;
- the principal amount being offered, and if a series, the total authorized amount and the total amount outstanding;
- any limit on the amount that may be issued;
- whether or not we will issue the series of debt securities in global form, the terms and who the depository will be;
- the maturity date;
- the annual interest rate, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- whether and under what circumstances, if any, we will pay additional amounts on any debt securities held by a person who is not a United States person for tax purposes, and whether we can redeem the debt securities if we have to pay such additional amounts;
- the place where payments will be payable;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;
- the date, if any, after which, and the price at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;
- the date, if any, on which, and the price at which, we are obligated, pursuant to any mandatory sinking fund provisions or otherwise, to redeem, or at the holder s option to purchase, the series of debt securities;
- whether the indenture will restrict our ability to pay dividends, or will require us to maintain any asset ratios or reserves;

whether we will be restricted from incurring any additional indebtedness or issuing additional securities;

a discussion on any material or special United States federal income tax considerations applicable to the debt securities;

information describing any book-entry features;

the denominations in which we will issue the series of debt securities, if other than denominations of $1,000 and any integral multiple thereof;

material changes in the amount of outstanding debt that is secured, and/or senior debt ranking equally with the senior debt that may be issued under the senior indenture and senior to the subordinated debt that may be issued under the subordinated indenture;

any provisions for payment of additional amounts for taxes and any provision for redemption, if we must pay such additional amount with respect to any debt security;

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whether the debt securities are to be offered at a price such that they will be deemed to be offered at an original issue discount as defined in paragraph (a) of Section 1273 of the Internal Revenue Code; and

any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities including any additional events of default or covenants provided with respect to the debt securities, and any terms which may be required by us or advisable under applicable laws or regulations.

Conversion or Exchange Rights

We will set forth in the prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for common stock or other securities of ours. We will include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of common stock or other securities of ours that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

The indentures do not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of all or substantially all of our assets. However, any successor to or acquirer of such assets must assume all of our obligations under the indentures or the debt securities, as appropriate.

Redemption

The indentures contain a provision which allow us to redeem all or a portion of the debt securities on and after the dates specified in the applicable prospectus supplement and in accordance with the terms established for such debt securities as specified in the applicable prospectus supplement. We are required to send a notice to all debt securities holders no less than 30 days and no more than 90 days prior to the redemption date which shall specify:

the redemption date;

the redemption price; and

the particular debt securities to be redeemed if such redemption is not for the entire debt security.

If less than all of the debt securities of a series are to be redeemed, we must give the debenture trustee at least 45 days notice in advance of the redemption date as to the aggregate principal amount of debt securities of the series to be redeemed. Upon receipt of the notice, the debenture trustee shall select, by lot or in such other manner as it shall deem appropriate and fair in its discretion, the debt securities to be redeemed and shall thereafter promptly notify us in writing of the numbers of the debt securities to be redeemed, in whole or in part. In any event, the debenture trustee s determination shall provide for the selection of a portion or portions (equal to one thousand U.S. dollars ($1,000) or any

integral multiple thereof) of the principal amount of such debt securities of a denomination larger than $1,000.

Events Of Default Under The Indenture

The following are events of default under the indentures with respect to any series of debt securities that we may issue:

if we fail to pay interest when due and our failure continues for 90 days and the time for payment has not been extended or deferred;

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if we fail to pay the principal, or premium, if any, when due and the time for payment has not been extended or delayed;

if we fail to observe or perform any other covenant or agreement contained in the debt securities or the indentures, other than a covenant or agreement specifically relating to another series of debt securities, and our failure continues for 90 days after we receive notice from the debenture trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and

if specified events of bankruptcy, insolvency or reorganization occur as to us.

If an event of default with respect to debt securities of any series occurs and is continuing, the debenture trustee or the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the debenture trustee if notice is given by such holders, may declare the unpaid principal of all debt securities of that series due and payable immediately.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indentures, if an event of default under an indenture shall occur and be continuing, the debenture trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the debenture trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the debenture trustee, or exercising any trust or power conferred on the debenture trustee, with respect to the debt securities of that series, provided that:

the direction so given by the holder is not in conflict with any law or the applicable indenture; and

subject to its duties under the Trust Indenture Act of 1939, the debenture trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders of debt securities of any other series.

A holder of the debt securities of any series will only have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

the holder has given written notice to the debenture trustee of a continuing event of default with respect to that series;

the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity, to the debenture trustee to institute the proceeding as trustee; and

the debenture trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions, within 90 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

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We will periodically file statements with the debenture trustee regarding our compliance with specified covenants in the indentures.

Modification of Indenture; Waiver

We and the debenture trustee may change an indenture without the consent of any holders with respect to specific matters, including:

- to fix any ambiguity, defect or inconsistency in the indenture;
- to comply with the provisions described above under the Section entitled, Consolidation, Merger or Sale;
- to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act of 1939;
- to evidence and provide for the acceptance of appointment by a successor trustee;
- to provide for uncertificated debt securities and to make all appropriate changes for such purpose;
- to add to our covenants such new covenants, restrictions, conditions or provisions for the protection of the holders, or to surrender any right or power conferred on us under the indenture; and
- to change anything that does not materially adversely affect the interests of any holder of debt securities of any series.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the debenture trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, we and the debenture trustee may only make the following changes with the consent of each holder of any outstanding debt securities affected:

- extending the fixed maturity of the series of debt securities;
- reducing the principal amount, reducing the rate of or extending the time for payment of interest, or any premium payable upon the redemption of any debt securities; or
- reducing the percentage of debt securities, the holders of which are required to consent to any amendment.

Discharge

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for obligations to:

register the transfer or exchange of debt securities of the series;

replace stolen, lost or mutilated debt securities of the series;

maintain paying agencies;

hold monies for payment in trust;

compensate and indemnify the trustee; and

appoint any successor trustee.

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In order to exercise our rights to be discharged, we must deposit with the trustee money or government obligations sufficient to pay all the principal of, premium, if any, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we otherwise specify in the applicable prospectus supplement, in denominations of $1,000 and any integral multiple thereof. The indentures provide that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company or another depository named by us and identified in a prospectus supplement with respect to that series. See Section entitled, Legal Ownership of Securities, for a further description of the terms relating to any global or book-entry securities.

At the option of the holder, subject to the terms of the indentures and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indentures and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will make no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If we elect to redeem the debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or

- register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Information Concerning the Debenture Trustee

The debenture trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the debenture trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the debenture trustee is under no obligation to exercise any of the powers given it by the indentures at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

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Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest payment.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless otherwise indicated in the applicable prospectus supplement, we will we make interest payments by check which we will mail to the holder. Unless we otherwise indicate in a prospectus supplement, we will designate the corporate trust office of the debenture trustee in the City of New York as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the debenture trustee for the payment of the principal of or any premium or interest on any debt securities which remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the security thereafter may look only to us for payment thereof.

Governing Law

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act of 1939 is applicable.

Subordination of Subordinated Notes

The subordinated notes will be unsecured and will be subordinate and junior in priority of payment to certain of our other indebtedness to the extent described in a prospectus supplement. The subordinated indenture does not limit the amount of subordinated notes which we may issue. It also does not limit us from issuing, assuming or guaranteeing any other secured or unsecured debt, nor does the indenture limit the amount of indebtedness or other liabilities that any subsidiary can create, incur, assume or guarantee. As of June 30, 2003, we had $4,145,545 of outstanding indebtedness that would have constituted senior indebtedness under the subordinated indenture.

LEGAL OWNERSHIP OF SECURITIES

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee maintain for this purpose as the holders of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as indirect holders of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depositary on behalf of other financial institutions that

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participate in the depositary s book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Securities issued in global form will be registered in the name of the depositary or its participants. Consequently, for securities issued in global form, we will recognize only the depositary as the holder of the securities, and we will make all payments on the securities to the depositary. The depositary passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depositary and its participants do so under agreements they have made with one another or with their customers and are not obligated to do so under the terms of the securities.

As a result, investors in a book-entry security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depositary s book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not holders, of the securities.

Street Name Holders

We may terminate a global security or issue securities in non-global form. In these cases, investors may choose to hold their securities in their own names or in street name. Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

Legal Holders

Our obligations, as well as the obligations of any applicable trustee and of any third parties employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the holder, we have no further responsibility for the payment or notice even if that holder is required, under agreements with depositary participants or customers or by law, to pass it along to the indirect holders but does not do so. Similarly, we may want to obtain the approval of the holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of the indenture or for other purposes. In such an event, we would seek approval only from the holders, and not the indirect holders, of the securities. Whether and how the holders contact the indirect holders is up to the holders.

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Special Considerations For Indirect Holders

If you hold securities through a bank, broker or other financial institution, either in book-entry form or in street name, you should check with your own institution to find out:

- how it handles securities payments and notices;
- whether it imposes fees or charges;
- how it would handle a request for the holders consent, if ever required;
- whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;
- how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and
- if the securities are in book-entry form, how the depositary s rules and procedures will affect these matters.

Global Securities

A global security is a security held by a depositary which represents one or any other number of individual securities. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depositary. Unless we specify otherwise in the applicable prospectus supplement, The Depository Trust Company, New York, New York, known as DTC, will be the depositary for all securities issued in book-entry form.

A global security may not be transferred to or registered in the name of anyone other than the depositary, its nominee or a successor depositary, unless special termination situations arise. We describe those situations below under the Section entitled, Special Situations When a Global Security Will Be Terminated. As a result of these arrangements, the depositary, or its nominee, will be the sole registered owner and holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depositary or with another institution that does. Thus, an investor whose security is represented by a global security will not be a holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement for a particular security indicates that the security will be issued in global form only, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

Special Considerations For Global Securities

As an indirect holder, an investor s rights relating to a global security will be governed by the account rules of the investor s financial institution and of the depositary, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depositary that holds the global security.

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If securities are issued only in the form of a global security, an investor should be aware of the following:

- An investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations we describe below;
- An investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe under the Section entitled, Legal Ownership of Securities, above;
- An investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;
- An investor may not be able to pledge his or her interest in a global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;
- The depositary s policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor s interest in a global security. We and any applicable trustee have no responsibility for any aspect of the depositary s actions or for its records of ownership interests in a global security. We and the trustee also do not supervise the depositary in any way;
- The depositary may, and we understand that DTC will, require that those who purchase and sell interests in a global security within its book-entry system use immediately available funds, and your broker or bank may require you to do so as well; and
- Financial institutions that participate in the depositary s book-entry system, and through which an investor holds its interest in a global security, may also have their own policies affecting payments, notices and other matters relating to the securities. There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations When A Global Security Will Be Terminated

In a few special situations described below, the global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own name, so that they will be direct holders. We have described the rights of holders and street name investors above.

The global security will terminate when the following special situations occur:

- if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;
- if we notify any applicable trustee that we wish to terminate that global security; or

if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

The prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the prospectus supplement. When a global security terminates, the depositary, and not we or any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

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PLAN OF DISTRIBUTION

We may sell the securities being offered hereby in one or more of the following ways from time to time:

- through agents to the public or to investors;
- to underwriters for resale to the public or to investors;
- directly to investors; or
- through a combination of any of these methods of sale.

We will set forth in a prospectus supplement the terms of the offering of securities, including:

- the name or names of any agents or underwriters;
- the purchase price of the securities being offered and the proceeds we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts and other items constituting agents or underwriters compensation;
- any initial public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchanges or markets on which such securities may be listed.

Agents

We may designate agents who agree to use their reasonable efforts to solicit purchases for the period of their appointment or to sell securities on a continuing basis.

Underwriters

If we use underwriters for a sale of securities, the underwriters will acquire the securities for their own account. The underwriters may resell the securities in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. The underwriters will be obligated to purchase all the securities of the series offered if they purchase any of the securities of that series. We may change from time to time any initial public offering price and any discounts or concessions the underwriters allow or reallow or pay to dealers. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement naming the underwriter the nature of any such relationship.

Direct Sales

We may also sell securities directly to one or more purchasers without using underwriters or agents. Underwriters, dealers and agents that participate in the distribution of the securities may be underwriters as defined in the Securities Act of 1933, as amended (the Securities Act), and any discounts or commissions they receive from us and any profit on their resale of the securities may be treated as underwriting discounts and commissions under the Securities Act. We will identify in the applicable prospectus supplement any underwriters, dealers or agents and will describe their compensation. We may have agreements with the underwriters, dealers and agents to indemnify them against specified civil

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liabilities, including liabilities under the Securities Act. Underwriters, dealers and agents may engage in transactions with or perform services for us in the ordinary course of their businesses.

Trading Markets and Listing Of Securities

Unless otherwise specified in the applicable prospectus supplement, each class or series of securities will be a new issue with no established trading market, other than our common stock, which is listed on The Nasdaq National Market. We may elect to list any other class or series of securities on any exchange or market, but we are not obligated to do so. It is possible that one or more underwriters may make a market in a class or series of securities, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We cannot give any assurance as to the liquidity of the trading market for any of the securities.

Stabilization Activities

Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934, as amended (the Exchange Act). Overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

Passive Market Marking

Any underwriters who are qualified market markers on The Nasdaq National Market may engage in passive market making transactions in the securities on The Nasdaq National Market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security. If all independent bids are lowered below the passive market maker s bid, however, the passive market maker s bid must then be lowered when certain purchase limits are exceeded.

LEGAL MATTERS

The validity of the securities we are offering by this prospectus will be passed upon for us by Pepper Hamilton LLP, Philadelphia, Pennsylvania. Jeffrey P. Libson, Esq., a partner at Pepper Hamilton LLP, owns options to purchase 21,184 shares of our common stock.

EXPERTS

The financial statements of OraSure Technologies, Inc. as of December 31, 2002 and for the year then ended, have been incorporated by reference herein and in the registration statement of which this prospectus forms a part, in reliance upon the report of KPMG LLP, independent accountants, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

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The financial statements incorporated by reference in this registration statement of which this prospectus forms a part as of December 31, 2001 and for the years ended December 31, 2001 and 2000 have been incorporated by reference in reliance on the report of Arthur Andersen LLP, independent public accountants, given on the authority of said firm as experts in auditing and accounting.

Effective May 21, 2002, the Company s audit committee approved the dismissal of Arthur Andersen LLP as the Company s independent auditors and the appointment of KPMG LLP to serve as the Company s independent auditors. After reasonable efforts, the Company has not been able to obtain the written consent of Arthur Andersen LLP to the incorporation by reference of its report into this registration statement. The Company has dispensed with the requirement to file the written consent of Arthur Andersen LLP in reliance on Rule 437a promulgated under the Securities Act. Since the Company has not been able to obtain the written consent of Arthur Andersen LLP, you will not be able to recover against Arthur Andersen LLP under Section 11 of the Securities Act for any untrue statements of material fact contained in the financial statements audited by Arthur Andersen LLP incorporated by reference herein or any omissions to state a material fact required to be stated therein.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the information requirements of 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 statements and all of their exhibits, at the SEC public reference room located at:

450 Fifth Street, N.W.

Judiciary Plaza

Room 1024

Washington, D.C. 20549

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 have filed or may file with the SEC (but we do not incorporate by reference any documents or portions of documents that we furnish to or are otherwise not deemed filed with the SEC):

1. Our Annual Report on Form 10-K for the year ended December 31, 2002;

2. Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2003;

3. Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2003;

4. Our Current Reports on Form 8-K filed on January 31, 2003, February 6, 2003 and June 27, 2003;

5. Our Definitive Proxy Statement filed April 11, 2003;

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6. The description of our capital 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 shares of preferred stock contained in the Registration Statement on Form 8-A filed on June 11, 2001;

8. All documents filed by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the initial registration statement and prior to the effectiveness of the registration statement; and

9. All documents filed by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act on or after the date of this prospectus and prior to the termination of the offering of securities under this prospectus or any prospectus supplement.

If you request, either orally or in writing, we will provide you with a copy of any or all documents which are incorporated by reference. We will provide such documents to you free of charge, but will not include any exhibits, unless those exhibits are incorporated by reference into the document. You should address written requests for documents as follows:

Corporate Secretary

OraSure Technologies, Inc.

220 East First Street

Bethlehem, Pennsylvania 18015

(610) 882-1820

Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our 10-Q, 8-K and 10-K reports to the SEC. Also note that we provide a cautionary discussion of risks and uncertainties relevant to our business in the Risk Factors section of this prospectus. These are factors that we think could cause our actual results to differ materially from expected results. Other factors besides those listed here could also adversely affect us. This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995.

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PROSPECTUS SUPPLEMENT

(To Prospectus dated August 8, 2003)

5,000,000 Shares

Common Stock

Thomas Weisel Partners LLC

SG Cowen

Wells Fargo Securities, LLC