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	