SIMPLE. RAPID. ACCURATE.

Delivering advanced diagnostic solutions for global needs

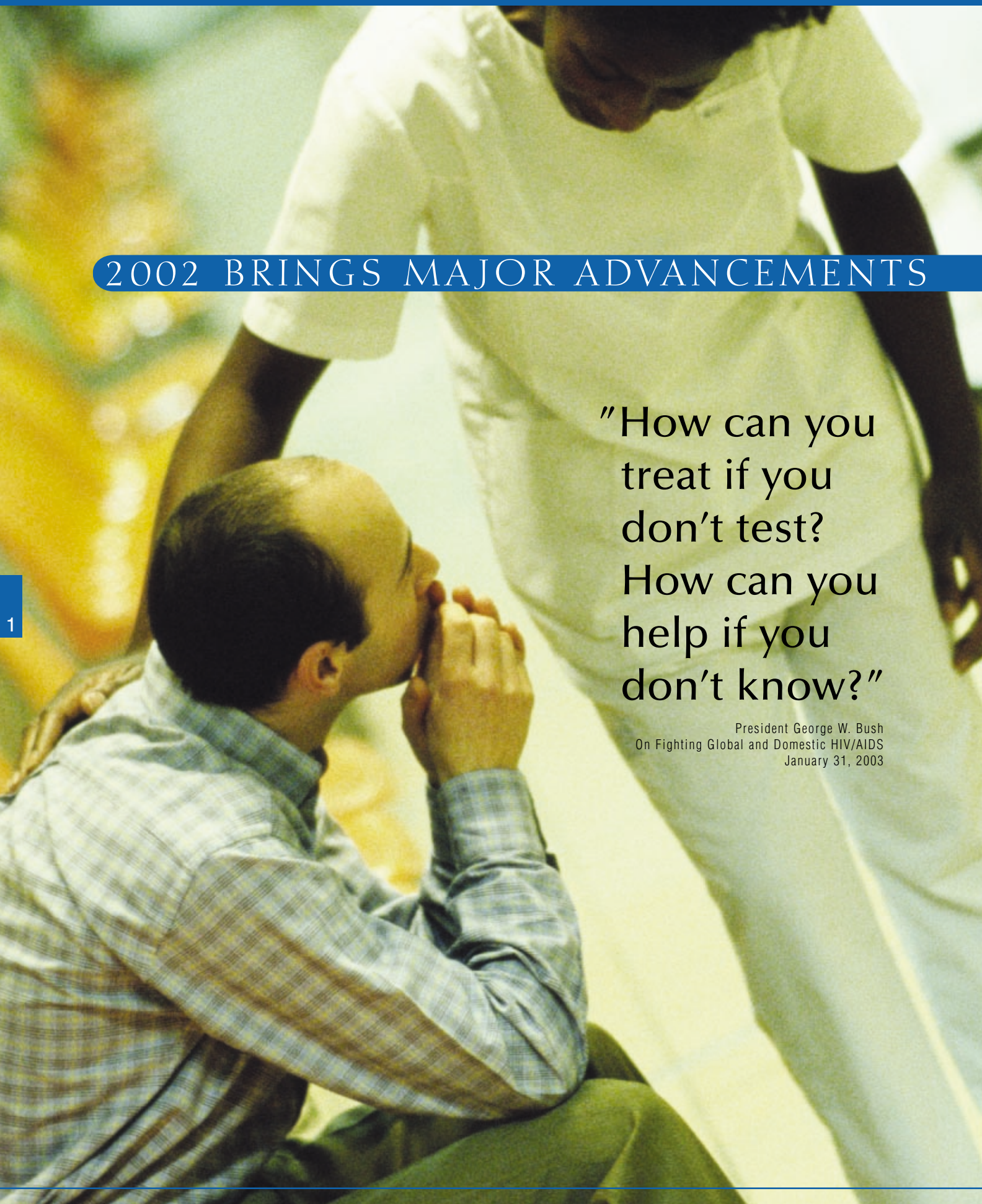
2002

ANNUAL REPORT

OraSure Technologies, Inc.

diagnostic solutions for the new millennium

2002 BRINGS MAJOR ADVANCEMENTS



"How can you treat if you don't test? How can you help if you don't know?"

President George W. Bush
On Fighting Global and Domestic HIV/AIDS
January 31, 2003

OraQuick® is the first FDA-approved, rapid point-of-care HIV-1 antibody test with a CLIA waiver.

IN HIV-1 TESTING

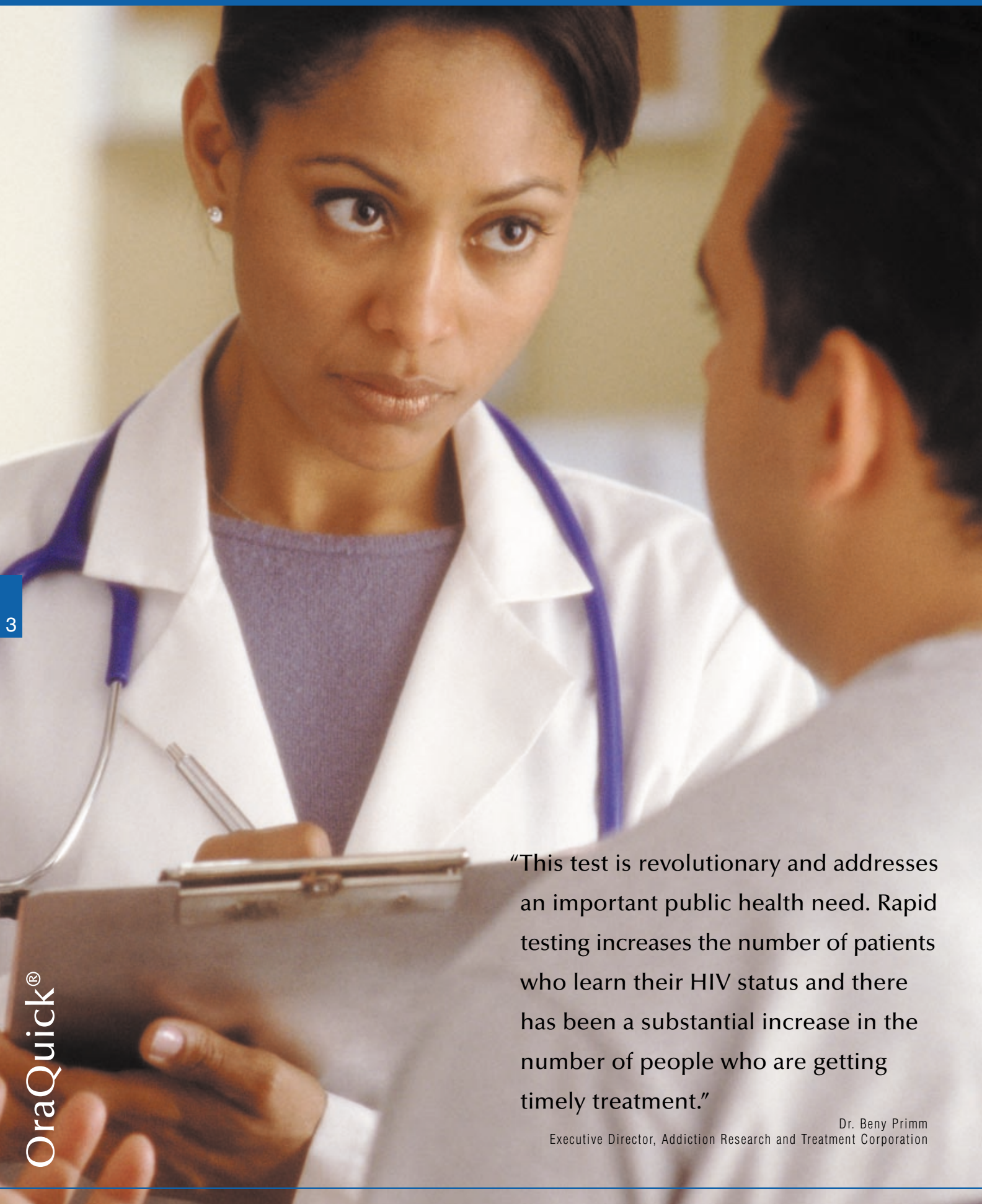
A waiver under the Clinical Laboratory Improvements Amendments of 1988 ("CLIA") enables HIV-1 testing with the OraQuick® test in nearly 180,000 sites within the U.S., including hospitals, physicians' offices, outreach clinics, and community-based organizations.

- Simple fingerstick test, using less than a drop of blood.
- Results in 20 minutes.
- Greater than 99% accurate.
- Testing results and counseling can now be provided in one visit.

"The OraQuick® Test can provide test results in one visit and in less than half an hour. By virtue of its speed, simplicity, and its portability, countless more Americans will be able to find out their HIV status immediately."

HHS Secretary Tommy G. Thompson
FDA Press Conference - November 7, 2002

OraQuick®
Rapid HIV-1 Antibody Test

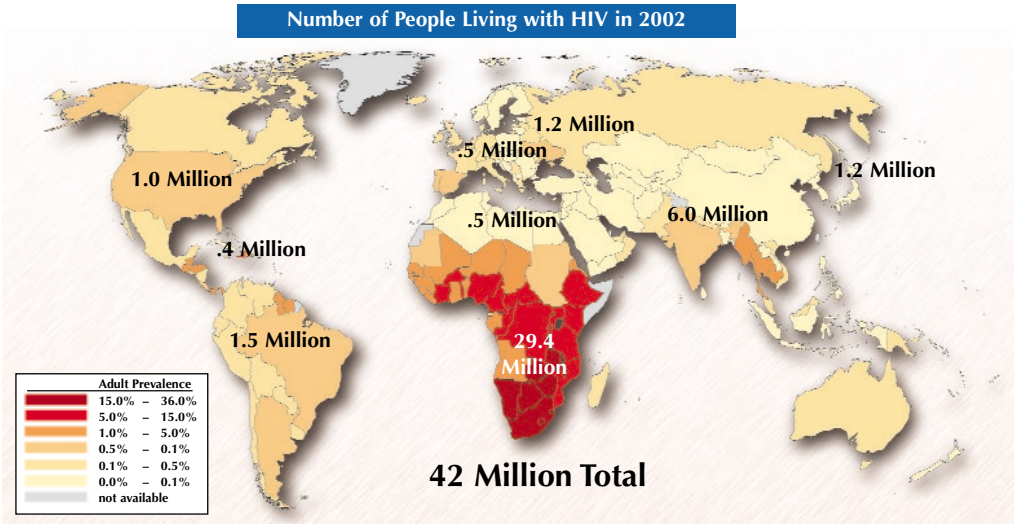


"This test is revolutionary and addresses an important public health need. Rapid testing increases the number of patients who learn their HIV status and there has been a substantial increase in the number of people who are getting timely treatment."

Dr. Beny Primm
Executive Director, Addiction Research and Treatment Corporation

CLIA-waived OraQuick® will have an immediate impact on public health, hospital, and military settings.

- **Public Health**
  - ♦ More than one-third of all individuals tested for HIV in public health settings did not return for their results last year. More than 8,000 of these people were HIV positive. OraQuick® provides accurate screening results and permits immediate counseling at the point-of-care.
- **Hospitals**
  - ♦ 20% of pregnant woman are not aware of their HIV status. OraQuick® can be used to quickly test women in labor to help identify and prevent mother-to-infant transmission of the HIV virus.
  - ♦ Nearly one million needle-stick injuries occur per year, 16,000 of which result in possible HIV exposure. OraQuick® can be used in these cases to identify infections more quickly, leading to immediate treatment.
- **Physicians' Offices**
  - ♦ There are 97,363 licensed physician office laboratories in the United States conducting CLIA waived testing today. OraQuick® allows physicians to perform HIV testing in their offices with or without the need for a laboratory.
- **Military**
  - ♦ The U.S. Navy began using OraQuick® in January 2003 for screening its personnel participating in the smallpox vaccination program directed by the Federal government.
- **Centers for Disease Control and Prevention ("CDC") Studies**
  - ♦ OraQuick® is being used as part of the on-going Mother-Infant Rapid Intervention at Delivery (MIRIAD) and Pediatric AIDS Clinical Trial Group (PACTG) clinical trials conducted by the CDC.
- **International**
  - ♦ There are 42 million people in the world living with HIV today. OraQuick® is being sold internationally to several countries around the world.



"We learned that when an employee went for a urine-based drug test, we lost between two and two-and-a half hours of an employee's productive time and of the HR staff member's time. Intercept® allows us to simply test the employee in the HR office, and within 15 minutes, the employee is back on the job."

T. Jeff Stone,
Vice President of Industrial Relations,
Georgia-Pacific

ORAL FLUID

GROWING MARKET SHARE

Intercept® Oral Fluid Drug Testing Service

Intercept® is the only FDA-cleared oral fluid collection device used with lab-based enzyme immunoassay ("EIA") screening tests to detect drugs of abuse. In 2002, the Company sold more than 600,000 devices and 2 million related EIA tests to the workplace, criminal justice, and drug rehabilitation markets.

OraSure® HIV-1 Oral Specimen Collection Device

OraSure® is the only FDA-approved oral fluid collection device used with a lab-based EIA screening test for HIV-1 antibody detection. In 2002, the Company sold nearly 4 million OraSure® devices into the insurance risk assessment and public health testing markets.

UPlink™ UP-Converting Phosphor Technology (UPT™)

UP*link*™ is the Company's rapid, point-of-care system utilizing a collector, lateral flow test cassettes, software, and an analyzer, and is designed to provide lab-quality results on a variety of samples, including oral fluid, blood, serum, urine, and stool samples. In April 2002, the Company received FDA clearance for an UP*link*™ Test System to detect opiates in oral fluid. While this opiates-only test will not be sold as a stand-alone product, the Company is completing development of a system for the full NIDA-5 panel of assays and intends to market a NIDA-5 UP*link*™ oral fluid rapid detection system once FDA clearance is obtained.

ORASURE TECHNOLOGIES, INC.

OraSure Technologies (Nasdaq: OSUR), Bethlehem, Pennsylvania, develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies and other enzyme immunoassay tests for insurance risk assessment, infectious disease, and drugs of abuse testing. The Company also manufactures and sells a cryosurgical removal system to the physicians' office therapy market.

The Company's products are sold in the United States and certain foreign countries to various distributors, clinical laboratories, government agencies, physicians' offices, hospitals, and commercial and industrial entities.

Headquartered in Bethlehem, Pennsylvania, the Company also has a sales office in The Netherlands. There were 187 full-time employees at December 31, 2002.

For the year-ending December 31, 2002, the Company had annual revenues of $32.0 million, a net loss of $3.3 million, working capital of $18.9 million, and cash and short-term investments of $14.9 million.

To Our Stockholders

The highlight of this past year undoubtedly was the receipt of FDA approval for our OraQuick® rapid HIV-1 fingerstick whole blood test.

This approval was announced on November 7, 2002, by Tommy Thompson, Secretary of the Department of Health and Human Services at a news conference in Washington, D.C. During his speech, he called OraQuick® an innovative and revolutionary new product that would satisfy an unmet need to help curb the spread of HIV-1 in the United States. He also encouraged the Company to apply for a CLIA waiver as soon as possible. The immense pride and sense of accomplishment we felt after hearing these kind words were almost indescribable.

For the next several days after the FDA approval, the Company's visibility and credibility soared, with feature spots on virtually every major news station and publication in the country. But after a weekend of celebrating this major milestone event, we began the hard work of scaling up manufacturing and we shipped the first 54,000 units of product to Abbott Laboratories, our co-exclusive distribution partner, by year-end.

The regulatory team also took Secretary Thompson's request to apply for a CLIA waiver very seriously, and worked virtually non-stop to fulfill that request. With a great deal of help and collaboration from the FDA, we submitted the data for this waiver on January 30, 2003. Amazingly, in less than 24 hours after our official submission, we were alerted to tune into a special news conference with President George W. Bush where he was to announce his initiatives to fight the global HIV/AIDS pandemic. In what will undoubtedly go down in the folklore of medical device approvals, President Bush stated these incredibly powerful words:

> ***"We must move quickly to increase the number of people who are tested for HIV. How can you treat if you do not test? How can you help if you don't know? And so the Food and Drug Administration recently approved a new HIV test which can provide results in less than 30 minutes, with 99.6% accuracy. So today, I've got an announcement to make. And it's this, that the Department of Health and Human Services, after a lot of careful review, has waived regulations so that the test will soon be available to doctors and public health facilities throughout the country."***
>
> ***President George W. Bush, 1/31/2003***

Was this all a dream, or had the President of the United States personally announced the approval of our waiver less than 24 hours after we had submitted the CLIA waiver application? It certainly was true, and it immediately more than quadrupled the number of potential customers for this product in the U.S. market. We obviously could not have scripted a better way to end 2002 and begin the new year.

However, despite this approval, when we reflect back on our overall results in 2002, it is fair to say that our financial and operating performance was mixed. We got off to a rough start in January 2002 when we announced that the revenues in the fourth quarter of 2001 would be well below expectations, and we experienced a sharp drop in our stock price. Shortly thereafter, Robert Thompson resigned as CEO of the Company, and on January 31, 2002, I was named as his replacement.

Throughout the balance of the year, I was determined to make the necessary tough decisions to streamline the organization, lower our costs, and consolidate our operations. In addition, I was fully committed to overhauling our sales and marketing team so that we would have the kind of firepower needed to shift the Company from its roots as a technology oriented company to a world-class market driven organization. I also felt that it was imperative that we evaluate all outstanding development projects, to ensure that we were putting our limited resources, both people and dollars, into those projects that could give us the highest long-term return on investment. At the same time, we focused on achieving our publicly stated business objectives over the course of the year. All in all, despite flat sales and some unforeseen delays in our product development activities, I believe that we did a very respectable job in 2002 and have laid the groundwork for a very promising future.

2002 Financial Results

Starting with our key financial results:

- Total revenues were $32 million, a 2% decrease over last year.
- Product revenues increased 2% to $31.7 million.
- Licensing and product development revenues decreased 78% to $300,000.
- Our gross margin decreased from 62% to 60% as a result of lower licensing and product development revenue and higher than anticipated inventory scrap levels.
- Sales and marketing expenses increased 1% to $8.1 million and included more than $500,000 in consulting fees for the development of our strategic marketing plans.
- Research and development expenses declined 12% to $8.3 million, primarily as a result of lower staffing expenses.
- General and administrative expenses declined 6% to $6.3 million and included $500,000 in severance for Mr. Thompson. Without this severance, general and administrative expenses would have decreased 14% in 2002.
- Our net loss improved 10% from $3.7 to $3.3 million.

However, if you dig a little deeper, the story begins to look better as cash flow from operations improved an impressive $4.7 million over 2001. Our liquidity remained strong with cash and short-term investments of $14.9 million and working capital of $18.9 million. We also entered into a new banking relationship with Comerica Bank, resulting in a new bank facility totaling $10.9 million, which will give us the resources to finance our future capital requirements.

We also made some difficult decisions to lower the Company's fixed costs when it became apparent that sales were lagging. During the year, we reduced headcount 17%, and we announced that we were going to shut down our Oregon facility and consolidate all operations into Bethlehem as soon as reasonably possible. We also carefully reevaluated each of our current development projects to ensure that there would be a reasonable return on invested capital. As a result of this analysis, we eliminated several marginal projects. One unexpected development was the level of inventory scrap, which equaled $1.4 million in 2002. This was totally unacceptable, and we are implementing programs to fix this problem in 2003.

While behind the scenes we were doing the things necessary to improve our cost structure and substantially improve our cash flow, we were achieving a series of important milestone events that will help to build a strong foundation for our future.

2002 – Major Milestone Events

The major 2002 milestone events were as follows:

- We struck a strategic partnership with Abbott Labs to maximize sales of OraQuick® to the hospital and physicians' office markets in the United States.
- We upgraded our quality systems and worked exhaustively to obtain FDA approval and CLIA waiver for our OraQuick® test.
- We expanded the number of independent reps selling Intercept® from 3 to 60, primarily through the addition of Quest Diagnostics, the market leader in workplace drug testing.
- We continued to convert the traditional urine drug testing market to our Intercept® oral fluid testing system as evidenced by the more than 50,000 oral fluid specimens processed per month by year-end, a 50 percent increase over the previous 12 months.
- The results of a the first large scale study of Intercept® (including more than 77,500 specimens) were published in the November 2002 issue of the *Journal of Analytical Toxicology*, indicating that oral fluid is as good as, if not better than, traditional urine drug testing.
- We secured FDA 510(k) clearance for the UP*link*™ rapid detection system for an opiates only test.
- We leased a 48,000 square foot world class manufacturing facility in Bethlehem, Pennsylvania, laying the groundwork to consolidate all manufacturing operations and expanding our capacity to facilitate rapid growth in the future.
- We are participating with the University of Pennsylvania in a four-year, $4.2 million NIH grant for research on oral fluid based diagnostic technologies using our UP*link*™ platform.
- We helped stabilize our stock price by meeting our announced financial targets for each quarter in 2002.
- We continued to work hard to restore the trust of our investors by being transparent and communicating our progress against our milestones in greater detail and more frequently.
- We added several highly qualified people to our senior management team, especially in the areas of sales and marketing.

Although I am quite proud of our accomplishments, there were two instances where we did not meet our originally stated objectives. First, we continued to experience unforeseen delays in meeting our stated research and development timelines with our UP*link*™ drugs of abuse rapid detection system. Second, despite a 50 percent increase in lab throughput over the last 12 months, sales of our Intercept® oral fluid drug test lagged expectations. We fully expect to improve in both of these important areas.

There were also a number of external factors that negatively influenced our business in 2002. These included, but were not limited to, a volatile stock market, weak economic conditions, a poor job market, the continuing prospect for terrorism and war, ever increasing pressure to lower our prices, and the difficulties encountered from the merger of our two largest insurance laboratory customers.

Despite these challenges, I am very proud to say that our team acted with tenacity, perseverance, and strong character. There was never any doubt in my mind that we would weather these storms, and would be better prepared to face the challenges and opportunities that lie ahead.

2003 – Major Business Objectives

As we look forward to 2003, we are targeting the following primary business objectives:

- We expect revenues to increase 25% for the year.
- We expect to be profitable in the second half of the year.
- We expect to retain a strong cash position.
- We intend to complete clinical trials for both an oral fluids and venous whole blood claim for OraQuick®.
- We will support Altrix, our European distributor for Intercept®, with an eye towards expanding more broadly into Europe.
- We intend to submit the UP*link*™ rapid detection system and the full NIDA-5 drug panel of assays for FDA clearance by mid-summer.
- We will work to increase Histofreezer® sales, with the addition of certain new specialized sales forces and expanded market reach.
- Subject to FDA approval, we will consolidate all manufacturing operations in Bethlehem, Pennsylvania.
- We will continue to build trust with our investors by being transparent and communicating frequently.

What an exciting position to be in! We begin 2003 with the only FDA approved, CLIA-waived rapid HIV-1 test in the United States and the only FDA cleared oral fluid laboratory based drug testing system. We have worked very hard to put ourselves in this formidable position, and we intend to pursue our objectives aggressively and are committed to making 2003 a major success story.

Final Thoughts

Finally, I want to express my deep appreciation to Bill Crouse, who retired as Chairman of our Board on March 3, 2003. For the past four years, Bill has been instrumental in shepherding the Company and has been a mentor and advisor to me. His contributions will be missed and we extend best wishes for his future endeavors.

I would also like to thank Doug Watson for stepping up to accept the Chairmanship role. Doug joined OraSure's Board in May 2002 after a distinguished career in the pharmaceutical industry, spanning 33 years. Doug brings a wealth of experience and proven success to the Company, and I look forward to working closely with him in the future.

And finally, to all our stakeholders, which include our customers, stockholders, employees, families, suppliers, and the community in which we live, thank you for your continued support and we look forward to a great year in 2003.

Sincerely,

Mike Gausling
President and CEO

Statements set forth above regarding future events or performance are "forward-looking statements," the Company's actual results could be quite different from those expressed or implied by such forward-looking statements. Factors that could affect results are discussed more fully in the sections entitled, "Forward-Looking Statements" and "Risk Factors," in the Company's Annual Report on Form 10-K for the year ended December 31, 2002, which accompanies this letter.

Selected Financial Information

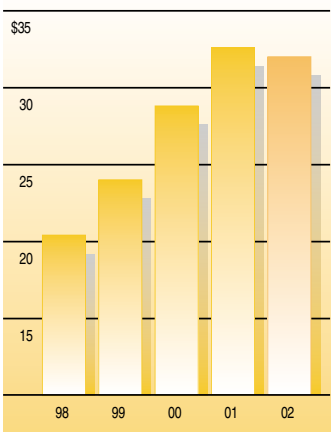
(In thousands, except share data, ratios, and number of employees)

	December 31,			September 30,	
	2002	2001	2000	1999	1998
Operating Results for the Year Ended					
Total revenue	$32,010	$32,573	$28,788	$24,046	$20,444
Net loss	$(3,342)	$(3,728)	$(12,747)	$(4,233)	$(2,374)
Net loss per share	$(0.09)	$(0.10)	$(0.36)	$(0.14)	$(0.09)
Weighted average shares outstanding	37,583	36,868	35,002	30,597	26,180
Financial Position as of:					
Working capital	$18,931	$19,764	$21,440	$16,773	$8,725
Total assets	$35,737	$37,285	$37,736	$30,251	$20,783
Long-term debt less current portion	$3,409	$3,586	$4,644	$5,820	$6,001
Total liabilities	$9,718	$10,744	$11,564	$11,659	$10,082
Total stockholders' equity	$26,019	$26,541	$26,172	$18,592	$10,701
Current ratio	4.1:1	3.8:1	4.2:1	4.2:1	3.2:1
Total liabilities to equity	0.4:1	0.4:1	0.4:1	0.6:1	0.9:1
Other Data					
Capital expenditures	$2,349	$2,764	$3,691	$1,829	$3,569
Full-time employees	187	221	210	171	163

As a result of the merger of STC Technologies, Inc. and Epitope, Inc. into OraSure Technologies, Inc., and the change in fiscal year-end of Epitope from September 30 to December 31, OraSure's financial position as of September 30, 1998 and 1999, and the operating results for each of the two years in the period ended September 30, 1999, reflect Epitope's previous September 30 fiscal year amounts and STC's December 31 calendar year amounts for the corresponding fiscal years of Epitope. This information should be read in conjunction with OraSure's Financial Statements and notes thereto included in Item 15 of the Company's Annual Report on Form 10-K for the year ended December 31, 2002.

REVENUE

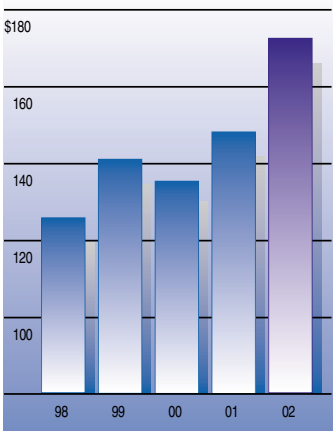
(Dollars in millions)



- Revenues were $32.0 million in 2002.

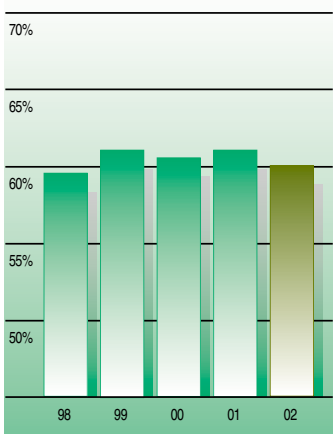
REVENUE PER FULL-TIME EMPLOYEE

(Dollars in thousands)



- Revenue per employee exceeded $171,000 in 2002.

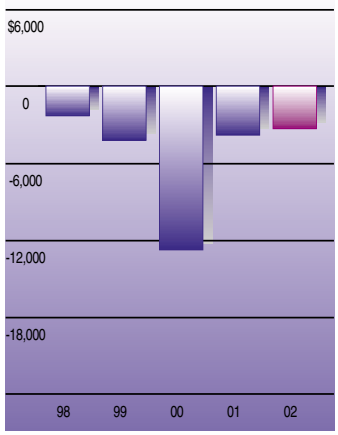
GROSS MARGIN PERCENTAGE



- Gross margin was 60% in 2002.

NET INCOME

(Dollars in thousands)



- Net loss of $3.3 million in 2002 represents a $386,000 improvement from 2001.

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

for the fiscal year ended December 31, 2002.

OR

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

for the transition period from _____ to _____.

Commission File No. 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
220 East First Street Bethlehem, Pennsylvania	**18015**
(Address of Principal Executive Offices)	**(Zip Code)**

(610) 882-1820

(Registrant's Telephone Number, Including Area Code)

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

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

Common Stock, $.000001 par value per share

(Title of Class)

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

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

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☒ No ☐

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the Registrant's most recently completed second fiscal quarter (June 28, 2002)**:** $200,531,507

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of March 26, 2003: 38,363,618 shares.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement for the 2003 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

TABLE OF CONTENTS

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

PART I

ITEM 1. Business.

Our Company was formed in May 2000 under Delaware law solely for the purposes of combining two companies, STC Technologies, Inc. ("STC" or "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 (the "Merger"). Our principal offices are located at 220 East First Street, Bethlehem, Pennsylvania 18015, and our telephone number is (610) 882-1820.

General

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 and certain foreign countries to various distributors, government agencies, clinical laboratories, physicians' offices, hospitals, and commercial and industrial entities.

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

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

Additional information about the Company can be found on our website. Our website address is www.orasure.com. We make available free of charge through a link provided at such website our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, as well as any amendments to those Reports. Such reports are made available as soon as reasonably practicable after they are filed or furnished to the Securities and Exchange Commission. Our Internet website and the information contained in or connected to that website are not intended to be incorporated by reference into this Report.

Products

Our principal products currently include the following:

- The OraSure® and Intercept® oral fluid collection devices;
- The OraQuick® rapid HIV-1 antibody test;
- The Histofreezer® wart removal system;

- Certain immunoassay tests and reagents for insurance risk assessment, substance abuse and forensic toxicology applications;
- An oral fluid Western Blot confirmatory test for the Human Immunodeficiency Virus Type 1 ("HIV-1"); and
- The Q.E.D.® saliva alcohol test.

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 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.

We have received premarket approval from the U.S. Food and Drug Administration (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 EIA screening test has been approved by the FDA for use with our OraSure® device and is manufactured and sold by another party.

HIV-1 antibody detection using the OraSure® collection device involves three steps:

- Collection of an oral fluid specimen using the OraSure® device;
- Screening of the specimen for HIV-1 antibodies at a laboratory with an EIA screening test approved by the FDA for use with the OraSure® device; and
- Laboratory confirmation of any positive screening test results with our oral fluid Western Blot HIV-1 confirmatory test (described below).

A trained health care professional then conveys test results and provides appropriate counseling to the individual who was tested. 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 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.

We believe that the Intercept® device has several advantages over certain competing drug testing products, including its lower total cost, its non-invasive nature, safety, mobility and accuracy, the ease of maintaining a chain-of-custody, the treatment of test subjects with greater dignity, no requirement for specially-prepared collection facilities, and difficulty of sample adulteration. The availability of an oral fluid test is intended to allow our customers to test for drug impairment on demand, eliminate scheduling costs and inconvenience, and streamline the testing process.

OraQuick® Rapid Test

OraQuick® is our rapid test platform designed to test an oral fluid, whole blood or serum/plasma sample for the presence of various antibodies or analytes. The device uses a porous flat pad to collect an oral fluid specimen. After collection, the pad is inserted into a vial containing a pre-measured amount of developer solution and allowed to develop. When whole blood is to be tested, a loop collection device is used to collect less than a drop of blood and mix it in the developer solution, after which the collection pad is inserted into the solution. The specimen and solution then flow through the testing device where test results are observable in approximately 20 minutes. The OraQuick® 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 FDA for detecting HIV-1 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.

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.

During 2003, we expect to submit an application to the FDA for approval of an OraQuick® test for use in detecting antibodies for HIV in oral fluid samples. We are also likely to pursue FDA approval of the use of the OraQuick® test for detecting HIV in venous whole blood and serum/plasma samples.

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

Histofreezer®

In 1991, we 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 we 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 family doctors, 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.

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.

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.

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.

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 market 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. (formerly Organon Teknika Corporation) ("BMX").

In January 2001, we suspended the production of EPIblot®, a serum-based Western Blot HIV-1 confirmatory test. The serum Western Blot product accounted for approximately 5% of the Company's 2000 revenues, but had been consistently unprofitable because of low production yields and the high cost of quality control. The discontinuation of this product had no effect on the manufacturing or sale of our oral fluid Western Blot HIV-1 confirmatory test.

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 1997, the product also received a CLIA waiver.

Each Q.E.D.® test kit contains a collection stick that is used to collect a sample of saliva and a disposable detection device that displays results in a format similar to a thermometer. The Q.E.D.® device is easy to operate and instrumentation is not required to read the result. The product has a testing range of 0 to 0.145% blood alcohol, and produces results in approximately two minutes.

Products Under Development

UPT™ and UP*link*™ *Development*

During 2002 and prior years, much of our research and development efforts were 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 drugs of abuse in oral fluid.

Up-Converting Phosphor Technology. 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™ overcomes some of the limitations of other diagnostic detection methods and offers features not commercially available today. The fact that UPT™ testing produces zero background interference dramatically increases the potential sensitivity of any test system. In addition, UPT™ offers 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 fully explored these potential UPT™ applications and have not determined which applications to pursue or the manner in which these opportunities will be pursued, if at all. We believe we will need to enter into partnering arrangements with other entities to exploit fully the potential of UPT™.

UP*link*™. UP*link*™ is our first product 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 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 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 mid-summer of 2003. Subject to receipt of this FDA clearance, we plan 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.

In March 2000, we signed a research and development agreement with Dräger Safety AG & Co. KGaA (formerly Dräger Sicherheitstechnik GmbH) ("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. (formerly Meridian Diagnostics, 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 the respiratory syncytial virus ("RSV"), has been substantially completed and this product is currently undergoing field trials. However, due to development delays and certain other events, we have agreed in principle with Meridian to terminate this agreement. Despite the expected termination of our agreement, we intend to complete development and pursue FDA 510(k) clearance and commercialization of the RSV test. In addition, we intend to seek other potential parties to help fund the development of 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™ technology 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 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 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 useful for the diagnosis of a variety of infectious diseases or conditions in addition to HIV-1, such as viral hepatitis.

OraQuick® Platform

We believe that OraQuick® has significant potential as a 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 other diseases.

We have received FDA premarket approval for the OraQuick® test for detecting HIV-1 in finger-stick whole blood samples. We are developing additional applications and will likely seek FDA approval for OraQuick® for use in testing oral fluid, venous whole blood and serum/plasma samples.

Research and Development

In 2002, our research and development activities focused on the continued development of the UP*link*™ analyzer, test cassette and collector, the development of the UP*link*™ drugs of abuse and RSV assays, DNA feasibility studies, clinical trials for the OraQuick® rapid HIV-1 antibody test, and improvements to certain of our existing products.

We supplement our own research and development activities by funding external research. We have funded research at Leiden University and certain other entities, and intend to continue funding external research.

Research and development expenses totaled approximately $8.3 million in 2002, $9.4 million in 2001, and $10.4 million in 2000.

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.

We market our products in the United States and internationally. Revenues attributable to customers in the United States amounted to $28.1 million, $27.3 million and $24.8 million in 2002, 2001 and 2000, respectively. Revenues attributable to international customers amounted to $3.9 million, $5.3 million and $4.0 million, or 12%, 16% and 14% of our total revenues, in 2002, 2001 and 2000, respectively.

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 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.

Our sales force continues to encourage additional insurance companies to use OraSure® and to extend the use of the product by existing customers. A small number of companies have expanded use of OraSure® to the $1 million and higher dollar policy amounts. This expansion is attributable to several factors, including increasing acceptance of the reliability of oral fluid testing, the high quality of test results, the low cost of oral fluid testing relative to blood tests, and the ease of use of the OraSure® device.

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, colleges and universities, correctional facilities and the military. There are also a number of organizations in the public health market such as AIDS service organizations and various community-based organizations set up primarily for the purpose of encouraging and enabling HIV-1 testing.

To better serve 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 Abbott Laboratories was appointed as the co-exclusive distributor of the OraQuick® rapid HIV-1 antibody test in the United States. We expect Abbott ultimately to focus primarily on the hospital and physician office market, while we intend to primarily target our direct sales to the public health and criminal justice markets, the military, the CDC and other agencies.

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.

Physicians' Offices

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. We are presently exploring ways to further penetrate the physicians' office market and we are considering expanding into potential new markets for Histofreezer®.

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, and laboratory testing.

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.

We currently have one customer, Lab*One*, that accounted for 26% of our total revenues during 2002.

In August 2001, Lab*One* acquired Osborne Group, Inc., our second largest laboratory customer in the insurance risk assessment market. As a result of this acquisition and other operating improvements, Lab*One* has achieved certain efficiencies and reduced its overall inventory levels, which in turn lowered their purchases of our insurance testing assays during 2002. We believe this is an indication that the market for our insurance testing assays will continue to come under pressure as Lab*One* and our other laboratory customers are expected to try to reduce their costs by improving their efficiencies or possibly using competing products. There can be no assurance that sales to Lab*One* will not decrease further or that this customer will not choose to replace our 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.

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 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 beginning later in 2003.

We manufacture the OraQuick® test in our Bethlehem, Pennsylvania facilities. 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 used in the test 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 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 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 our Bethlehem, Pennsylvania facility. 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.

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.

Histofreezer® is manufactured 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. We believe that additional manufacturers of the Histofreezer® product 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 the Histofreezer® product.

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.

Employees

As of December 31, 2002, we had 187 full-time employees, including 38 in sales, marketing, and client services; 44 in research and development; 87 in operations, manufacturing, quality control, purchasing and shipping; and 18 in administration and finance. Seventeen of our employees hold Ph.D. degrees. This compares to 225 employees as of December 31, 2001. Our employees are not currently represented by a collective bargaining agreement.

During 2002, we implemented a 17% headcount reduction primarily as a result of lower than anticipated sales levels during 2001 and the elimination of certain development projects. We intend to close our Oregon facilities and move these operations to Bethlehem, Pennsylvania beginning later in 2003.

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.

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;
- Access to adequate capital;
- The ability to develop and market products and processes;
- The ability to attract and retain qualified personnel; and
- The availability of patent protection.

A few large corporations produce a wide variety of diagnostic tests and other medical devices and equipment. A larger number of mid-size companies generally compete only in the diagnostic industry, and a significant number of small companies produce only a few diagnostic products. As a result, the diagnostic test industry is 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 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. In addition, Abbott Laboratories currently sells a competing rapid HIV test in the United States. We believe several other companies may seek FDA approval to sell competing rapid HIV tests in the United States.

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 IgG in oral fluid are the only assays available in the marketplace. However, we expect to face increasing competition from assays developed internally by our laboratory customers, which could be produced at a cost lower than the price typically paid for our products. In urine chemistries, our significant competitors include The Diagnostics Systems Group of Olympus America Inc. and DRI.

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 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 UP*link*™ product also 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.

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

The Histofreezer® product's delivery system and warmer operating temperature than 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.

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 sixteen 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 one patent and certain pending patent applications for the OraQuick® rapid HIV antibody test in the United States. We also intend to 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," 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 nine U.S. patents and numerous foreign patents for methods, compositions, and apparatuses relating to phosphor technologies. Several additional UPT™ patent applications remain pending in the United States and abroad. We expect to continue to expand our UPT™ patent portfolio in 2003. Several new patents were granted during 2002 in the U.S. for the design of the UP*link*™ rapid detection platform.

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

General

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.

Domestic Regulation

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

There are two review procedures by which medical devices can receive FDA clearance or approval. Some products may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act. To obtain this clearance, the manufacturer must provide a premarket notification that it intends to begin marketing the product, and show that the product is substantially equivalent to another legally marketed product (i.e., that it has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness). In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding substantial equivalence. An applicant must submit a 510(k) application at least 90 days before marketing of the affected product commences. Although FDA clearance may be granted within that 90-day period, in some cases as much as a year or more may be required before clearance is obtained, if at all.

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is required by statute and the FDA's regulations to have an approved application), the FDA must approve a premarket approval application ("PMA") before marketing can begin. PMAs must demonstrate, among other matters, that the medical device provides a reasonable assurance of safety and effectiveness. A PMA is typically a complex submission, including the results of preclinical and clinical studies. Preparing a PMA is a detailed and time-consuming process. Once a PMA has been submitted, the FDA is required to review the submission within 180 days. However, the FDA's review may, and often is, much longer, often requiring one year or more, and may include requests for additional data. The OraQuick® rapid HIV-1 antibody test received PMA approval in November 2002.

In 2002, Congress enacted the Medical Device User Fee and Modernization Act, which authorizes the FDA to assess and collect user fees for premarket notifications and premarket approval applications filed on or after October 1, 2002. Fees for fiscal year 2003 range from $2,187 for premarket notifications to $154,000 for premarket approval applications, although fee reductions are available for companies qualifying as small businesses. We do not currently qualify as a small business.

Biologic products must be the subject of an approved biologics license application before they can be marketed. The FDA approval process for a biologic product is similar to the PMA approval process, involving a demonstration of the product's safety and effectiveness based in part on both preclinical and clinical studies. We currently do not manufacture or sell any biologic products.

Many of our insurance testing products are used for non-medical purposes and many of our drugs-of-abuse products sold to state crime labs are for forensic use. The FDA does not currently regulate products used for these purposes.

Every company that manufactures medical devices distributed in the United States must comply with the FDA's Quality System Regulations ("QSRs"). These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation and purchasing. In complying with QSRs, manufacturers must continue to expend time, money, and effort in the area of production and quality control to ensure full technical compliance. Companies are also subject to other post-market and general requirements, including restrictions imposed on marketed products, promotional standards, and requirements for recordkeeping and reporting of certain adverse reactions. If there are any modifications made to our marketed devices, a premarket notification or premarket approval application may be required to be submitted to, and cleared or approved by, the FDA, before the modified device may be marketed. The FDA regularly inspects companies to determine compliance with QSRs and other post-market requirements. Failure to comply with statutory requirements and the FDA's regulations can result in warning letters, monetary penalties, suspension or withdrawal of regulatory approvals, operating restrictions, total or partial suspension of production, injunctions, product recalls, seizure of products, and criminal prosecution.

Products that include electrical or light emitting equipment must also comply with the FDA's safety and performance standards applicable to such equipment. Our UP*link*™ analyzer is a piece of electrical equipment that uses a laser to read the test results and is, therefore, subject to these requirements. In addition, there is an industry safety and performance standard for electrical equipment established by Underwriters Laboratories, Inc., known as UL3101-1. Although a voluntary standard, compliance with UL3101-1 supported our 510(k) submission for the UP*link*™ analyzer. Underwriters Laboratories Inc. was retained to examine and test the UP*link*™ analyzer and has certified that this product meets the FDA requirements and UL3101-1.

The Clinical Laboratory Improvements Amendments of 1988, or CLIA, prohibit laboratories from performing *in vitro* tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings unless there is in effect for such laboratories a certificate issued by the U.S. Department of Health and Human Services applicable to the category of examination or procedure performed. We consider the applicability of the requirements of CLIA in the design and development of our products. We have obtained a waiver of the CLIA requirements for our OraQuick® rapid HIV-1 antibody test and Q.E.D.® alcohol saliva test and may seek similar waivers for certain other products. A CLIA waiver allows certain customers to use the waived products that may not have been able to use them without complying with certain quality control and other requirements.

Certain of our products may also be affected by state regulations in the United States. For example, there are several states that restrict or do not currently permit oral fluid drug testing in the workplace or other markets. In addition, several states prohibit or limit the use of rapid, point-of-care HIV testing. We are presently working with legislators or regulators in certain of these states in an effort to modify or remove any restrictions affecting our ability to sell products.

International

We are also subject to regulations in foreign countries governing products, human clinical trials and marketing, and may need to obtain approval from international public health agencies, such as the World Health Organization, in order to sell products in certain countries. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for U.S. governmental approvals. We generally pursue approval only in those countries that we believe have a significant market opportunity.

The International Organization for Standardization ("ISO") is a worldwide federation of national standards bodies from some 130 countries, established in 1947. The mission of ISO is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods

and services. ISO certification is evidenced by the CE mark and indicates that our quality system complies with standards applicable to activities ranging from initial product design and development through production and distribution. In addition, we must comply with the essential requirements of the In Vitro Diagnostic Directive in order to receive authorization to affix a CE mark to our products. A CE mark will be required for distribution of medical devices in the European common markets beginning in December 2003.

In the first quarter of 1999, we received authorization to use the CE mark for the OraSure® and Intercept® collection devices based on meeting ISO standards at our Beaverton facility. In December 2000, our Bethlehem facility received final certification for the European Medical Device Directive (93/42/EEC), ISO 9001, ISO 13485, and EN 46001. We have also received authorization to use the CE mark for our Histofreezer® product line.

Prior to international sale of a product containing electrical and light-emitting equipment, the safety and performance of such a product must be demonstrated. We retained Underwriters Laboratories, Inc. and Laird Technologies to examine and test the UP*link*™ analyzer, and they certified that this product meets the following international standards and directives: IEC 60825-1, IEC/EN 61010-1, CAN/CSA 22.2 No. 1010.1-92, IEC 1010-1, EN 61000 (in part), and EN 55022, EMC Directive 89/336/EEC.

We must also submit evidence of marketing approval or clearance by the FDA to Health Canada's Therapeutic Products Programme, and we must comply with certain registration requirements, prior to commencing sales in Canada. We have completed this process for several of our current products that require FDA review and may do so with respect to other products in the future.

Environmental Regulation

Because of the nature of our current and proposed research, development, and manufacturing processes, we are subject to stringent federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge and handling and disposal of materials and wastes. We believe that we have complied with these laws and regulations in all material respects. We have not been required to take any action to correct any environmental noncompliance.

Forward-Looking Statements

This Report contains certain "forward-looking statements," within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings, expenses or other financial performance, future product performance or development, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words "believes," "expects," "anticipates," "intends," "plans," "estimates," "may," "will," "should," "could," or similar expressions.

Forward-looking statements are not guarantees of future performance or results. Known and unknown factors could cause actual performance or results to be materially different from those expressed or implied in these statements. Some of these factors are: ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties; ability to obtain and timing of obtaining necessary regulatory approvals; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to

international marketing and manufacturing of products; ability to sell products internationally; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; ability to complete consolidation or restructuring activities; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in the Section entitled, "Risk Factors," and elsewhere in this Report.

Although forward-looking statements help to provide complete information about future prospects, they may not be reliable. The forward-looking statements are made as of the date of this Report and we undertake no duty to update these statements.

Risk Factors

The following is a discussion of certain significant risk factors that could potentially negatively impact our financial condition, performance and prospects.

We Face Intense Competition From New and Existing Diagnostic Products.

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

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

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

During 2002, 2001 and 2000, we incurred $8.3 million, $9.4 million and $10.4 million, respectively, in research and development expenses. We expect to continue to incur significant costs from our research and development activities. A primary focus of our efforts has been, and is expected to continue to be, the development of our UPT™ technology and the related UP*link*™ rapid detection system. However, there can be no assurance that we will succeed in our research and development efforts with respect to UPT™, UP*link*™ or other technologies or products. If we fail to develop commercially successful products, or if competitors develop more effective products or a greater number of successful new products, customers may decide to use products developed by our competitors. This would result in a loss of revenues and adversely affect our results of operations, cash flows and business.

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

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

drugs of abuse in the workplace and criminal justice testing markets. Other markets, particularly the physicians' office market, may resist the adoption of oral fluid testing as a replacement for other testing methods in use today. In addition, certain state laws prohibit or restrict the use of oral fluid testing for drugs of abuse in certain markets. There can be no assurance that we will be able to expand the use of our oral fluid testing products in these or other markets.

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

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

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

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

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

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

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

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

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

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

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

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

As described more fully above under the Section entitled, "Government Regulation," many of our proposed and existing products are subject to regulation by the FDA and other governmental or public health agencies. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products.

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

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

Newly promulgated or changed regulations could also require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. For example, the Substance Abuse and Mental Health Services Administration ("SAMHSA"), which is part of the U.S. Department of Health and Human Services, is in the process of drafting regulations for the use of oral fluid drug testing for federal workers. Although we believe the SAMHSA regulations, when issued in final form, will permit us to market and sell our oral fluid drug tests for use with federal workers, there is no guarantee that those regulations will do so, and our ability to sell those products in that market could be limited. Other changes in government regulations, such as the adoption of the FDA's Quality System Regulation, may also adversely affect our results of operations by requiring that we incur the expense of changing or implementing new manufacturing and control procedures.

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

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

At the present time, we have received FDA clearance or approval for the OraSure® and Intercept® oral fluid collection devices, the OraQuick® rapid HIV-1 antibody test (for use with finger-stick whole blood samples), the UP*link*™ drug testing system and opiates assay, the Histofreezer® wart removal system, the Q.E.D.® saliva alcohol test, the OraSure® oral fluid Western Blot HIV-1 confirmatory test, and various other tests. The OraSure® and Intercept® collection devices (collection pad only) and Histofreezer® product currently bear the CE mark. See the Sections entitled, "Products" and "Government Regulation," for a further discussion of regulatory approvals and clearances obtained for our products.

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

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

During 2000, the FDA issued warning letters with respect to our Serum Western Blot product, stating that we were not in compliance with the FDA's regulations. We have responded to each of these letters and voluntarily discontinued this product. Although we believe that we have satisfactorily addressed the points raised by the FDA, the FDA could force us to stop manufacturing products at our Oregon facility if the FDA concludes that we remain out of compliance with applicable regulations. The FDA could also require us to recall products if we fail to comply with applicable regulations, which could force us to stop manufacturing such products. See the Section entitled, "Government Regulation," for a further discussion of regulatory requirements.

We Have a History of Losses.

We have not achieved full-year profitability. We incurred net losses of approximately $3.3 million, $3.7 million and $12.7 million in 2002, 2001 and 2000 respectively. As of December 31, 2002, the Company had an accumulated deficit of approximately $129.4 million.

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

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

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

- The degree to which certain of our new products (i.e., the OraQuick® rapid HIV-1 antibody test) may replace sales of our existing products (i.e., the OraSure® device for HIV-1 testing) and the financial impact of that change;
- Achieving growth in international markets with our OraQuick® rapid HIV-1 antibody test and other products; and
- Commercially developing, and obtaining regulatory approval and creating market acceptance for, UPT™, the UP*link*™ drugs-of-abuse rapid detection system, and other new products in a time frame consistent with our objectives.

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

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

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

For example, while current accounting rules allow us to exclude the expense of stock options from our financial statements, influential legislators and business policy groups have suggested that the rules be changed to require those options to be expensed. We rely on stock options as an important component of our employee compensation packages. If we are required to expense options, we may be less likely to achieve profitability, or we may have to decrease or eliminate option grants. Decreasing or eliminating option grants may adversely impact our ability to attract and retain qualified employees.

Volatility and Other Factors May Affect Our Stock Price.

Our stock price may be volatile, and could experience substantial declines. The market price of our common stock has historically experienced and might continue to experience volatility in the future in response to a number of factors, including quarter-to-quarter variations in operating results, analysts' reports, the relatively low trading volume for our stock, market conditions in the industry, regulatory and other developments affecting our products, changes in governmental regulations, changes in general conditions in the economy or in the financial or stock markets, and terrorist attacks, civil unrest and war.

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

A Market for Our Products May Not Develop.

Our future success will depend, in part, on the market acceptance, and the timing of such acceptance, of new products such as the Intercept® drug testing service, the OraQuick® rapid HIV-1 antibody test, products currently under development such as the UP*link*™ drugs of abuse rapid detection system and other products using the UPT™ technology, and other new products or technologies that may be developed or acquired and introduced in the future. To achieve market acceptance, we must make substantial marketing efforts and spend significant funds to inform potential customers and the public of the perceived benefits of these products. We currently have limited evidence on which to evaluate the market reaction to products that may be developed, and there can be no assurance that any products will meet with market acceptance and fill the market need that is perceived to exist.

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

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

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

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

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

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

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

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

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

There are several factors that will affect the specific countries in which we will be able to sell our OraQuick® rapid HIV antibody test and therefore the overall sales potential of the test. One factor is whether we can arrange a sublicense or distribution agreement related to patents for detection of the HIV-2 virus. HIV-2 is a type of the HIV virus estimated to represent a small fraction of the known HIV cases worldwide. Nevertheless, HIV-2 is considered to be an important component in the testing regimen for HIV in many markets. HIV-2 patents are in force in most of the countries of North America and Western Europe, as well as in Japan, Korea, South Africa, and Australia. Access to a license for one or more HIV-2 patents may be necessary to sell HIV-2 tests in countries where such patents are in force, or to manufacture in countries where such patents are in force and then sell into non-patent markets. Since HIV-2 patents are in force in the United States, we may be restricted from manufacturing an OraQuick® rapid HIV-2 antibody test in the United States and selling into other countries, even if there were no HIV-2 patents in those other countries.

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

We have obtained licenses to HIV-1 patents held by the manufacturer of the HIV-1 antigen used in the OraQuick® device and by the National Institutes of Health. We are not aware of any other HIV-1 patents which would need to be licensed in order to manufacture and sell the OraQuick® rapid HIV-1 antibody test.

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

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

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

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

If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively sell and market our products, to meet the demands of our strategic partners in a timely fashion, or to support internal research and development programs. In particular, product development programs depend on the ability to attract and retain highly skilled scientists, including molecular biologists, biochemists and engineers, and sales and marketing efforts depend on the ability to attract and retain skilled and experienced sales and marketing representatives. Recruiting qualified personnel can be an intensely competitive and time-consuming process. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms.

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

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

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

We intend to increase international sales of our products. Our international sales accounted for approximately $3.9 million or 12% of total revenues for 2002, approximately $5.3 million or 16% of total revenues for 2001, and approximately $4 million or 14% of total revenues for 2000.

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

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

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

In addition, we have entered into a contract for the manufacture and supply of the OraQuick® rapid HIV antibody test in Thailand. However, we do not have significant direct experience with the use of international manufacturers. Factors such as economic and political conditions and foreign regulatory requirements may slow or prevent the manufacture of our products in countries other than the United States. Interruption of the supply of our products could reduce revenues or cause us to incur significant additional expenses in finding an alternative source of supply.

We May be Sued for Product Liabilities for Injuries Resulting From the Use of Our Diagnostic Products.

We may be held liable if any of our products, or any product which is made with the use or incorporation of any of our technologies, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. Although we have obtained product liability insurance, this insurance may not fully cover potential liabilities. As we bring new products to market, we may need to increase our product liability coverage. If we decide to obtain the required regulatory approvals and sell any of our products in the consumer or over-the-counter market, the risk of potential product liability exposure and the required level of insurance coverage could increase. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could affect our decision to commercialize new products.

*We May Not be Able to Commercialize Our UPT™, UP*link*™ or Other New Products Which Could Negatively Affect Our Future Revenues.*

Our UPT™ technology and the UP*link*™ rapid detection system are still under development. Commercial development of the UP*link*™ system or the UPT™ technology for certain other applications and other new products may not be successful. Successful products require significant development and investment, including testing, to demonstrate their cost-effectiveness or other benefits prior to commercialization. In addition, regulatory approval must be obtained before most products may be sold. Additional development efforts on these products will be required before any regulatory authority will review them. Regulatory authorities may not approve these products for commercial sale. In addition, even if a product is developed and all applicable regulatory approvals are obtained, there may be little or no market for the product. Accordingly, because of these uncertainties, the UP*link*™ rapid detection system, other applications of UPT™ or other new products may not be successfully commercialized, which could negatively affect our results of operations, cash flows and business.

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

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

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

We have licensed the worldwide rights to up-converting phosphor compositions, methods and apparatuses for use in diagnostic applications, which are the subject of numerous United States patents and several pending United States applications. Corresponding patents and patent applications have been granted, issued or filed in

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

We May Require Future Additional Funding to Stay in Business.

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

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

- The costs and timing of the expansion of our manufacturing capacity;
- The success of our research and product development efforts;
- The scope and results of clinical testing;
- The magnitude of capital expenditures;
- Changes in existing and potential relationships with business partners;
- The time and cost of obtaining regulatory approvals;
- The costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses;
- The costs and timing of expansion of sales and marketing activities;
- The timing of the commercial launch of new products;
- The extent to which existing and new products gain market acceptance;
- Competing technological and market developments; and
- The scope and timing of strategic acquisitions.

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

The Recent Economic Downturn and Terrorist Attacks May Adversely Affect Our Business.

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

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

Efforts to Consolidate or Restructure Could Adversely Affect Our Business.

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

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

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

- Suitable acquisitions or investments may not be found or consummated on terms that are satisfactory to us;
- We may be unable to successfully integrate an acquired company's personnel, assets, management systems and technology into our business;
- Acquisitions may require substantial expense and management time and could disrupt our business;
- An acquisition and subsequent integration activities may require greater capital resources than originally anticipated at the time of acquisition;
- An acquisition may result in the incurrence of unexpected expenses, the dilution of our earnings or our existing stockholders' percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business;
- An acquisition may result in the loss of existing key personnel or customers or the loss of the acquired company's key personnel or customers;
- The benefits to be derived from an acquisition could be affected by other factors, such as regulatory developments, general economic conditions and increased competition; and
- An acquisition of a foreign business may involve additional risks, including not being able to successfully assimilate differences in foreign business practices or overcome language barriers.

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

The previous discussion of our business should be read in conjunction with the Financial Statements and accompanying notes included in Item 15 of this Annual Report on Form 10-K.

ITEM 2. Properties.

In October 2002, we leased an approximate 48,000 square foot facility, which is our new primary corporate office and manufacturing facility, on property in Bethlehem, Pennsylvania. The lease has a ten-year initial term ending in October 2012 and base rental rate starting at $780,000 and increasing to $858,000 per year over that initial term. The lease also has a five-year renewal option at an annual base rental rate of $975,000 and a ten-year purchase option.

In April 1999, we signed a five-year lease to rent 25,845 square feet of space at the John M. Cook Technology Center in Bethlehem, Pennsylvania, which we use for our sales and marketing and research and development offices. Annual base rent for the initial five-year term of this lease ending in March 2005 is approximately $244,000. The lease also includes a five-year renewal option at an annual base rental rate of $271,000 and a ten-year purchase option.

We own a 33,500 square foot building in Bethlehem, Pennsylvania, which is used for manufacturing, engineering and information systems activities.

We lease approximately 30,500 square feet of office, manufacturing, and laboratory space in Beaverton, Oregon, under a lease that expires in January, 2005. We have annual base lease obligations under the lease starting at $351,000 and increasing to $395,000 during the term of the lease. We expect to consolidate the research and development and manufacturing operations currently performed in Oregon with our Bethlehem operations beginning later in 2003.

We rent additional warehouse space on an as-needed basis. We also lease space for small sales offices in Chicago, Illinois and Reeuwijk, The Netherlands.

We believe that the facilities described above are adequate for our current requirements.

ITEM 3. Legal Proceedings.

From time to time we are involved in legal proceedings arising in the ordinary course of business. In our opinion, based on the advice of counsel, these proceedings are not expected to have a material adverse effect on our financial position or results of operations.

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

No matters were submitted to a vote of security holders during the fourth quarter of the year ended December 31, 2002.

PART II

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

Our Common Stock is listed for trading on the National Market tier of The Nasdaq Stock Market ("NASDAQ") under the symbol OSUR. High and low sales prices reported by NASDAQ during the periods indicated are shown below.

	Year ended December 31,			
	2002		2001	
	High	Low	High	Low
First Quarter	$12.280	$4.750	$10.000	$5.875
Second Quarter	8.350	5.500	12.640	6.688
Third Quarter	6.820	3.330	15.000	7.260
Fourth Quarter	8.150	3.700	12.880	8.890

On March 21, 2003, there were 522 holders of record and approximately 12,500 holders in street name of the Common Stock, and the closing price of the Common Stock was $7.17 per share. We have never paid any cash dividends, and the Board of Directors does not anticipate paying cash dividends in the foreseeable future. We are generally not permitted to pay dividends or make other distributions to our stockholders under the terms of our credit facilities with Comerica Bank, without first obtaining Comerica's consent. We intend to retain any future earnings to provide funds for the operation and expansion of our business.

ITEM 6. Selected Financial Data.

The following table sets forth selected financial data of the Company. On September 29, 2000, STC and Epitope were merged into the Company (the "Merger"). The Merger was accounted for as a pooling of interests and, accordingly, all prior period financial statements of Epitope have been restated to include the results of operations, financial position and cash flows of STC. The selected financial data as of September 30, 1999 and 1998 and for each of the years then ended, include Epitope's previous September 30 fiscal year amounts and STC's December 31 calendar year amounts. On September 20, 2000, the Company changed its fiscal year-end from September 30 to December 31, effective with the calendar year beginning January 1, 2000. A three-month transition period from October 1, 1999 through December 31, 1999 (the "Transition Period") precedes the start of the 2000 fiscal year. As a result of the Merger, financial statements for the Transition Period include amounts for Epitope and STC for the three months ended December 31, 1999. Accordingly, STC's results of operations for the three months ended December 31, 1999 are included in both the financial statements for the year ended September 30, 1999 and for the Transition Period.

This information should be read in conjunction with the Financial Statements and notes thereto included in Item 15 and the information set forth in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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

	Year ended December 31,			Three months ended December 31,		Year ended September 30,	
	2002	2001	2000	1999	1998	1999	1998
Operating Results:					(Unaudited)		
Revenues	$ 32,010	$ 32,573	$ 28,788	$ 6,822	$ 5,138	$ 24,046	$20,444
Costs and expenses	35,550	36,906	42,917	7,105	5,857	28,138	22,721
Other income (expense), net	198	634	1,407	(138)	(159)	(91)	(98)
Net loss	(3,342)	(3,728)	(12,747)	(471)	(878)	(4,233)	(2,374)
Basic and diluted net loss per share	$ (0.09)	$ (0.10)	$ (0.36)	$ (0.02)	$ (0.03)	$ (0.14)	$ (0.09)
Weighted average number of shares outstanding	37,583	36,868	35,002	30,887	26,246	30,597	26,180

	December 31,					September 30,	
	2002	2001	2000	1999	1998	1999	1998
Financial position:							
Working capital	$ 18,931	$ 19,764	$ 21,440	$ 16,314	$ 8,255	$ 16,773	$ 8,725
Total assets	35,737	37,285	37,736	29,626	20,075	30,251	20,783
Long-term debt, excluding current portion	3,409	3,586	4,644	5,820	6,001	5,820	6,001
Accumulated deficit	(129,435)	(126,092)	(122,365)	(109,618)	(105,603)	(109,104)	(104,903)
Stockholders' equity	26,019	26,541	26,172	18,238	10,264	18,592	10,701

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

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

The following discussion should be read in conjunction with the financial statements contained herein and the notes thereto, along with the Section entitled, "Critical Accounting Policies and Estimates" set forth below.

Results of Operations—2002 Compared to 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.

	Dollars		Percentage Change	Percentage of Total Revenues (%)	
	2002	2001	Inc. (Dec.)	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
Physicians' office therapies	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. We expect that Abbott will purchase at least $4.0 million of OraQuick® devices during the first 15 months of our agreement, which is the minimum purchase commitment required to retain co-exclusive distribution rights. Additionally, we expect that sales of the OraQuick® device in the public health and military markets will increase throughout the year as acceptance of this product grows. 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 $200,000 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 physicians' office therapies market, which consisted solely of our Histofreezer® wart removal system, 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. This increase in inventory levels in advance of the price increase is expected to reduce Histofreezer® product sales during the first quarter of 2003. However, we believe that Histofreezer® sales levels in the U.S. will return to a more normal pattern beginning in the second and third quarters of 2003. We are evaluating distribution channel expansion for our Histofreezer® product line in order to expand our penetration of the physicians' offices therapies market, and are considering selling Histofreezer® in certain other markets not covered by our current distribution partners.

As a percentage of total revenues, international revenues decreased to approximately 12% in 2002 from approximately 16% in 2001, with Histofreezer® accounting for approximately 48% 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 $300,000 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 $200,000 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 $0.5 million 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.

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.

Results of Operations—2001 Compared to 2000

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

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

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

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

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

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

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

As a percentage of total revenues, international revenues increased to approximately 16% in 2001 from approximately 14% in 2000, with Histofreezer® accounting for approximately 39% of 2001 international revenues. Lab*One*, our largest customer, and Osborne Group, which was acquired by Lab*One* in 2001, together accounted for approximately 29% and 30% of total revenues in 2001 and 2000, respectively.

Licensing and product development revenues increased 113% to approximately $1.5 million in 2001 from approximately $0.7 million in 2000, reflecting a different mix of development work performed in 2001. During 2001, licensing and product development revenues were primarily from the continued development of the UP*link*™ drugs-of-abuse rapid detection system under an agreement with Dräger Safety, development of infectious disease applications for UP*link*™ under an agreement with Meridian, and the second phase of a grant from the NIH for the development of an oral fluid syphilis test.

During 2000, licensing and product development revenues consisted primarily of income from a collaboration with Lab*One* related to the Intercept® drug testing service, development work with Dräger Safety on the UP*link*™ drugs-of-abuse rapid detection system, and the first phase of the NIH grant.

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

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

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

Sales and marketing expenses increased 15% to approximately $8.0 million in 2001 from approximately $6.9 million in 2000. This increase was primarily the result of additional costs associated with increased staffing levels and related expenses, and the expansion of our customer service functions.

General and administrative expenses remained flat at approximately $6.8 million in 2001 and $6.9 million in 2000. Higher professional fees associated with certain partnering activities in 2001 were offset by cost savings from the elimination of duplicative overhead structures as a result of the Merger of STC and Epitope into the Company.

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

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

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

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

Gain on the sale of securities was $100,000 in 2001 as a result of the sale of Lab*One* common stock that we received as part of an Intercept® distribution arrangement with Lab*One,* entered into in 1999. In 2000, we recorded a gain on the sale of securities of $600,000, as a result of the sale of Andrew & Williamson Sales Company ("A&W") preferred stock we had received as part of a settlement with A&W in 1997.

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

Liquidity and Capital Resources

	December 31, 2002	December 31, 2001
	(In thousands)	
Cash and cash equivalents	$ 4,364	$ 2,426
Short-term investments	10,544	12,765
Working capital	18,931	19,764

The Company's cash, cash equivalents and short-term investments decreased approximately $283,000 during 2002 to approximately $14.9 million at December 31, 2002, primarily as a result of the Company's net loss for 2002, an increase in inventories, a decrease in accounts payable, and capital expenditures. Offsetting these uses of cash were an increase in accounts receivable collections and proceeds from stock option exercises. At December 31, 2002, the Company's working capital was approximately $18.9 million.

Net cash used in operating activities was approximately $0.5 million in 2002, a decrease of approximately $4.7 million from the $5.3 million used in operations in 2001. The $0.5 million of cash used in operating activities resulted primarily from the Company's net loss for the year of $3.3 million and a reduction in accounts payable, offset by $2.3 million in depreciation and amortization and by a significant improvement in our collection of accounts receivable.

Net cash used in investing activities during 2002 was $231,000. We purchased approximately $1.6 million of property and equipment and expended $0.7 million on licenses, product supply and distribution agreements. These expenditures were funded through net proceeds of approximately $2.2 million generated from the sale of short-term investments.

Capital expenditures are anticipated to increase during 2003 to approximately $3.0 million as a result of additional commitments we have made for the purchase and installation of manufacturing and research and development equipment for UP*link*™ and OraQuick®. We also expect to purchase additional information systems equipment to support our new corporate and manufacturing facility in Bethlehem, Pennsylvania and to upgrade certain older equipment.

Net cash provided by financing activities was approximately $2.7 million, reflecting the proceeds received from the exercise of stock options of approximately $2.8 million, offset by $169,000 of net loan principal repayments.

In September 2002, we entered into a new $10.9 million credit facility ("New Credit Facility") with Comerica Bank, pursuant to which we refinanced substantially all of our previously outstanding mortgage and term debt and increased our equipment and working capital lines of credit. The New 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.

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 December 31, 2002 was $874,186.

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 December 31, 2002 was $2,785,714.

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 December 31, 2002, we had an outstanding balance of approximately $423,658 under this facility consisting of two individual loans of (i) $179,786 with a fixed annual interest rate of 5.07% and (ii) $243,872 with a floating annual interest rate equal to Comerica's prime rate of 4.25% at December 31, 2002. We also had $2,564,356 available for future borrowings under this facility as of December 31, 2002.

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 shall accrue 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 December 31, 2002.

All borrowings under the New 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 New Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth and that require that we achieve positive net income for the year ending December 31, 2003 and for each year thereafter. The New 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.

In October 2002, we entered into new agreements with bioMérieux, Inc. ("BMX"), which replaced existing agreements between the parties, for the supply by BMX of HIV-1 antigen required to manufacture our oral fluid Western Blot HIV-1 confirmatory test, and for the distribution by BMX of the oral fluid Western Blot product on an exclusive worldwide basis. These agreements have an initial term ending December 31, 2005, which may be extended until December 31, 2007 under certain circumstances. As consideration for BMX entering into the new agreements, we have agreed to pay BMX $750,000 in installments through March 31, 2003.

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 (See "Certain Relationships and Related Transactions," included herein). 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 $852,240 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 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.

Contractual Obligations and Commercial Commitments. The following sets forth our approximate aggregate obligations at December 31, 2002 for future payments under contracts and other contingent commitments, for the years 2003 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2003**	**2004**	**2005**	**2006**	**2007**	**Thereafter**
Long-term debt(1)	$ 4,475,328	$1,065,966	$1,073,633	$1,077,085	$ 425,817	$ 118,313	$ 714,514
Operating leases(2)	9,357,185	1,467,879	1,460,066	887,585	780,000	783,108	3,978,547
Employment contracts(3)	1,503,780	1,503,780	—	—	—	—	—
Purchase obligations(4)	2,097,460	2,097,460	—	—	—	—	—
Minimum commitments under contracts(5)	1,950,000	300,000	300,000	225,000	225,000	225,000	675,000
Total contractual obligations	$19,383,753	$6,435,085	$2,833,699	$2,189,670	$1,430,817	$1,126,421	$5,368,061

(1) Represents principal repayments required under notes payable to our lenders. See Note 8 to the financial statements included herein.

(2) Represents payments required under our operating leases. See Notes 11 and 12 to the financial statements included herein.

(3) Represents salary, retention bonus or severance payments payable under the terms of employment agreements executed by us with certain officers and employees. See Note 11 to the financial statements included herein.

(4) Represents payments required by non-cancelable purchase orders related to inventory, services and capital expenditures. See Note 11 to the financial statements included herein.

(5) Represents payments required pursuant to certain research, licensing and royalty agreements executed by the Company. See Note 11 to the financial statements included herein.

Off-Balance Sheet Arrangements. We do not have any off-balance sheet arrangements, as defined in Item 304(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934, as amended.

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 Item 15 of this Report. 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"). This bulletin 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 recognize this revenue ratably 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 $292,146 at December 31, 2002. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period ($213,188, $5,193 and $4,269 in 2002, 2001 and 2000, respectively). Furthermore, there is no assurance that we will experience credit losses at the same rates as we have in the past. Also, at December 31, 2002, approximately $1.0 million or 19% 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 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 $10.6 million or 30% of our total assets at December 31, 2002. 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 December 31, 2002. Any unanticipated significant impairment in the future, however, could have a material adverse impact to our balance sheet and future operating results.

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 NOLs 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 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 5"). SFAS 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.

Certain Relationships and Related Transactions

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

The Lease, as amended, has an initial ten-year term ending in October 2012 and a base rent starting at $780,000 and increasing to $858,240 per year over that term. The base rental rate may be increased after the fifth year of the initial term in order to reflect changes in the interest rate on debt incurred by Tech Partners to finance construction of the leased facilities. 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.

Prior to deciding to enter into the Lease and an amendment increasing the base rental to reflect the cost of certain tenant fit-out improvements, our Board of Directors retained Imperial Realty Appraisal LLC, an independent commercial real estate appraisal firm, to evaluate the proposed base rental rate. Imperial Realty issued opinions indicating that the annual base rent set forth in the Lease, as amended, is below the market rental rate we could otherwise expect to pay to lease a comparable commercial property in the same general geographic market. The terms of the Lease are otherwise substantially similar to a commercial lease we entered into with a third party for our existing Bethlehem, Pennsylvania headquarters.

In January 2002, we terminated the employment agreement with Robert D. Thompson, our former Chief Executive Officer, and Mr. Thompson entered into a severance agreement pursuant to which Mr. Thompson will receive approximately $480,000. We also held a $75,000 note receivable previously made to Mr. Thompson in connection with his relocation from Portland, Oregon, which was repaid during 2002.

Recent Accounting Pronouncements

SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143"), which was released in August 2001, addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and their associated asset retirement costs. SFAS 143 requires an enterprise to record the fair value of an asset retirement obligation as a liability in the period in which it incurs a legal obligation associated with the retirement of intangible long-lived assets that result from the acquisition, construction, development, or normal use of the asset. The enterprise is also required to record a corresponding increase to the carrying amount of the related long-lived asset (i.e. the associated asset retirement cost) and to depreciate that

cost over the life of the asset. The liability is changed at the end of each period to reflect the passage of time (i.e. accretion expense) and changes in the estimated future cash flows underlying the initial fair value measurement. Because of the extensive use of estimates, most enterprises will record a gain or loss when they settle the obligation. We are required to adopt SFAS 143 for our fiscal year beginning January 1, 2003. We do not expect the adoption of SFAS 143 to have a material impact on our financial position or results of operations.

In April 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections" ("SFAS 145"). SFAS 145 amends existing guidance on reporting gains and losses on the extinguishment of debt to prohibit the classification of the gain or loss as extraordinary, as the use of such extinguishments have become part of the risk management strategy of many companies. SFAS 145 also amends SFAS 13 to require sale-leaseback accounting for certain lease modifications that have economic effects similar to sale-leaseback transactions. The provisions of SFAS 145 related to the rescission of SFAS 4 are applied in fiscal years beginning after May 15, 2002. Earlier application of these provisions is encouraged. The provisions of SFAS 145 related to SFAS 13 were effective for transactions occurring after May 15, 2002. The adoption of SFAS 145 is not expected to have a material effect on our financial statements.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). SFAS 146 addresses significant issues regarding the recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities. SFAS 146 also addresses recognition of certain costs related to terminating a contract that is not a capital lease, costs to consolidate facilities or relocate employees, and termination benefits provided to employees that are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract. SFAS 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 is not expected to have any impact on our financial position or results of operations.

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others, an interpretation of FASB Statements No. 5, 57 and 107 and a rescission of FASB Interpretation No. 34." This Interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees issued. The Interpretation also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of the Interpretation are applicable to guarantees issued or modified after December 31, 2002, and are not expected to have a material effect on our financial statements.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure ("SFAS 148"), an amendment of FASB Statement No. 123." SFAS 148 amends SFAS 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of Statement 123 to require prominent disclosures in both annual and interim financial statements. The disclosure modifications are required for fiscal years ending after December 15, 2002, and are included in the notes to our financial statements.

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities, an interpretation of ARB No. 51." This Interpretation addresses the consolidation by business enterprises of variable interest entities as defined in the Interpretation. The Interpretation applies immediately to variable interests in variable interest entities created after January 31, 2003, and to variable interests in variable interest entities obtained after January 31, 2003. Because we have no involvement with any variable interest entities, the application of this Interpretation is not expected to have a material effect on our financial statements.

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

We do not hold any amounts of derivative financial instruments or derivative commodity instruments. Therefore, we have no material market risk related to derivatives to report under this Item.

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

We do not currently have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in The Netherlands which are subject to foreign currency fluctuations. As currency rates change, translation of income statements of these operations from Euros to U.S. dollars affects year-to-year comparability of operating results. Our operations in The Netherlands represented approximately $1.7 million or 5% of our revenues for the year ended December 31, 2002. We do not expect the risk of foreign currency fluctuations to be material.

ITEM 8. Financial Statements and Supplementary Data.

Information with respect to this Item is contained in our Financial Statements included in Item 15 of this Annual Report on Form 10-K.

Arthur Andersen LLP (“Andersen”) audited the Company’s financial statements as of December 31, 2001 and for each of the years in the two-year period ended December 31, 2001 included in this Report. Because our former engagement team leaders have since left Andersen, Andersen did not reissue its report on those financial statements, and a copy of a previously issued report is included herein. Andersen has not consented to the use of such report or to any reference made to their firm in this Report. Andersen was convicted on June 15, 2002 of federal obstruction of justice arising from the government’s investigation of Enron Corp. You may have no effective remedy against Andersen in connection with a material misstatement or omission in the financial statements audited by Andersen, particularly in the event that Andersen ceases to exist or becomes insolvent as a result of the conviction or other proceedings against Andersen.

Additionally, as a result of the departure of our former engagement team leaders, Andersen is no longer in a position to consent to the inclusion or incorporation by reference in any prospectus of their report on the above-referenced financial statements, and investors in any offerings for which the Company uses their audit report will not be entitled to recovery against them under Section 11 of the Securities Act of 1933, as amended, for any material misstatements or omissions in those financial statements.

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

On May 21, 2002, we dismissed Arthur Andersen LLP and retained KPMG LLP as our independent accountants. Disclosure of this action is set forth in our Current Report on Form 8-K dated May 21, 2002.

PART III

We have omitted from Part III the information that will appear in our Definitive Proxy Statement for our 2003 Annual Meeting of Stockholders (the "Proxy Statement"), which will be filed within 120 days after the end of our fiscal year pursuant to Regulation 14A.

ITEM 10. Directors and Executive Officers of the Registrant.

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

ITEM 11. Executive Compensation.

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

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

The information required by this item with respect to the securities ownership of certain beneficial owners and management, and equity compensation plan information, is incorporated by reference to the information under the captions, "Principal Stockholders" and "Equity Compensation Plan Information," respectively, in the Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions.

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

ITEM 14. Controls and Procedures.

(a) *Evaluation of Disclosure Controls and Procedures*. Within the 90 days preceding the filing of this Report, an evaluation was performed under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company, which is required to be included in its periodic filings with the Securities and Exchange Commission.

(b) *Changes in Internal Controls*. There have been no significant changes in the Company's internal controls or in other factors that could significantly affect internal controls (including any corrective actions with regard to significant deficiencies or material weaknesses) subsequent to the date of the evaluation referred to in paragraph (a) of this Item.

PART IV

ITEM 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.

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

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

(b) *Reports on Form 8-K.*

1. Current Report on Form 8-K dated November 7, 2002, attaching a press release that announced the receipt of U.S. Food and Drug Administration approval of our OraQuick® Rapid HIV-1 Antibody Test for the detection of HIV-1 in finger-stick whole blood samples.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 31, 2003.

ORASURE TECHNOLOGIES, INC.

By: /s/ MICHAEL J. GAUSLING

Michael J. Gausling
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on March 31, 2003, by the following persons on behalf of the Registrant and in the capacities indicated.

Signature	Title
/s/ MICHAEL J. GAUSLING **Michael J. Gausling**	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ RONALD H. SPAIR **Ronald H. Spair**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)
/s/ MARK L. KUNA **Mark L. Kuna**	Vice President and Controller (Principal Accounting Officer)
/s/ *CARTER H. ECKERT **Carter H. Eckert**	Director
/s/ *FRANK G. HAUSMANN **Frank G. Hausmann**	Director
/s/ *RICHARD J. LANE **Richard J. Lane**	Director
/s/ *GREGORY B. LAWLESS **Gregory B. Lawless**	Director
/s/ *ROGER L. PRINGLE **Roger L. Pringle**	Director
/s/ *DOUGLAS G. WATSON **Douglas G. Watson**	Director

*By: /s/ RONALD H. SPAIR

Ronald H. Spair
(Attorney-in-Fact)

Certification

I, Michael J. Gausling, certify that:

1. I have reviewed this annual report on Form 10-K of OraSure Technologies, Inc;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/s/ MICHAEL J. GAUSLING

Michael J. Gausling
President and Chief Executive Officer
(Principal Executive Officer)

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this annual report on Form 10-K of OraSure Technologies, Inc;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses

Date: March 31, 2003

/s/ RONALD H. SPAIR

Ronald H. Spair
Executive Vice President and
Chief Financial Officer
(Principal Financial Officer)

INDEX TO FINANCIAL STATEMENTS

INDEPENDENT AUDITOR'S REPORT

The Board of Directors and Stockholders
OraSure Technologies, Inc.:

We have audited the accompanying balance sheet of OraSure Technologies, Inc. as of December 31, 2002 and the related statements of operations, stockholders' equity and comprehensive loss, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements of OraSure Technologies, Inc. as of December 31, 2001 and for each of the years in the two-year period ended December 31, 2001 were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated January 31, 2002, except for the facility lease discussed in Note 12 as to which the date was March 21, 2002.

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

In our opinion, the 2002 financial statements referred to above present fairly, in all material respects, the financial position of OraSure Technologies, Inc. as of December 31, 2002, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

Philadelphia, Pennsylvania
January 27, 2003

The following is a copy of a report issued by Arthur Andersen LLP and included in the Company's 2001 Annual Report on Form 10-K. This report has not been reissued by Arthur Andersen LLP, and Arthur Andersen LLP has not issued a consent to its use in this filing.

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To OraSure Technologies, Inc.:

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

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

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

ARTHUR ANDERSEN LLP

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

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31, 2002	December 31, 2001
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,364,308	$ 2,426,346
Short-term investments	10,543,876	12,764,903
Accounts receivable, net of allowance for doubtful accounts of $292,146 and $209,492	5,197,787	6,057,927
Note receivable from officer	—	75,000
Inventories	4,088,474	4,444,772
Prepaid expenses and other	925,707	1,038,511
Total current assets	25,120,152	26,807,459
PROPERTY AND EQUIPMENT, net	7,427,950	7,800,137
PATENTS AND PRODUCT RIGHTS, net	2,543,519	2,042,533
OTHER ASSETS	645,626	634,546
	$ 35,737,247	$ 37,284,675
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,065,966	$ 1,057,572
Accounts payable	1,801,952	2,874,061
Accrued expenses	3,321,509	3,111,886
Total current liabilities	6,189,427	7,043,519
LONG-TERM DEBT	3,409,362	3,586,458
OTHER LIABILITIES	119,546	114,025
COMMITMENTS AND CONTINGENCIES (Note 11)		
STOCKHOLDERS' EQUITY:		
Preferred stock, par value $.000001; 25,000,000 shares authorized, none issued	—	—
Common stock, par value $.000001; 120,000,000 shares authorized, 38,100,557 and 37,403,269 shares issued and outstanding	38	37
Additional paid-in capital	155,638,314	152,758,591
Accumulated other comprehensive loss	(184,676)	(125,664)
Accumulated deficit	(129,434,764)	(126,092,291)
Total stockholders' equity	26,018,912	26,540,673
	$ 35,737,247	$ 37,284,675

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

	For the year ended December 31,		
	2002	**2001**	**2000**
REVENUES:			
Product	$31,691,495	$31,095,850	$ 28,095,408
Licensing and product development	318,272	1,477,494	692,808
	32,009,767	32,573,344	28,788,216
COST OF PRODUCTS SOLD	12,888,556	12,333,695	11,102,096
Gross profit	19,121,211	20,239,649	17,686,120
OPERATING EXPENSES:			
Research and development	8,274,351	9,389,313	10,399,120
Sales and marketing	8,068,879	7,980,496	6,932,068
General and administrative	6,318,513	6,752,326	6,876,516
Merger-related	—	—	7,607,158
Restructuring-related	—	450,000	—
	22,661,743	24,572,135	31,814,862
Operating loss	(3,540,532)	(4,332,486)	(14,128,742)
INTEREST EXPENSE	(284,678)	(402,686)	(490,415)
INTEREST INCOME	483,431	933,050	1,315,666
FOREIGN CURRENCY GAIN (LOSS)	(694)	3,122	(18,696)
GAIN ON SALE OF SECURITIES	—	100,000	600,000
Loss before income taxes	(3,342,473)	(3,699,000)	(12,722,187)
INCOME TAXES	—	28,789	24,363
NET LOSS	$ (3,342,473)	$ (3,727,789)	$(12,746,550)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.09)	$ (0.10)	$ (0.36)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	37,582,780	36,868,101	35,002,283

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 1999	32,632,911	$ 33	$128,115,489	$(259,218)	$(109,617,952)	$18,238,352
Common stock issued upon exercise of options	1,319,624	1	5,720,997	—	—	5,720,998
Common stock issued upon exercise of warrants	2,405,907	2	13,865,364	—	—	13,865,366
Common stock issued under Employee Stock Purchase Plan and Savings Plan	75,562	—	273,254	—	—	273,254
Compensation expense for stock option grants	—	—	792,685	—	—	792,685
Comprehensive loss:						
Net loss	—	—	—	—	(12,746,550)	(12,746,550)
Currency translation adjustment	—	—	—	(61,140)	—	(61,140)
Net unrealized gain on marketable securities	—	—	—	89,111	—	89,111
Total comprehensive loss						(12,718,579)
Balance at December 31, 2000	36,434,004	36	148,767,789	(231,247)	(122,364,502)	26,172,076
Common stock issued upon exercise of options	968,729	1	3,851,805	—	—	3,851,806
Common stock issued under Employee Stock Purchase Plan	536	—	2,123	—	—	2,123
Compensation expense for stock option grants	—	—	136,874	—	—	136,874
Comprehensive loss:						
Net loss	—	—	—	—	(3,727,789)	(3,727,789)
Currency translation adjustment	—	—	—	(75,670)	—	(75,670)
Net unrealized gain on marketable securities	—	—	—	181,253	—	181,253
Total comprehensive loss						(3,622,206)
Balance at December 31, 2001	37,403,269	37	152,758,591	(125,664)	(126,092,291)	26,540,673
Common stock issued upon exercise of options	688,454	1	2,793,742	—	—	2,793,743
Common stock issued under Employee Stock Purchase Plan	8,834	—	35,042	—	—	35,042
Compensation expense for stock option grants	—	—	50,939	—	—	50,939
Comprehensive loss:						
Net loss	—	—	—	—	(3,342,473)	(3,342,473)
Currency translation adjustment	—	—	—	(6,481)	—	(6,481)
Net unrealized loss on marketable securities	—	—	—	(52,531)	—	(52,531)
Total comprehensive loss						(3,401,485)
Balance at December 31, 2002	38,100,557	$ 38	$155,638,314	$(184,676)	$(129,434,764)	$26,018,912

The accompanying notes are an integral part of these statements

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

	For the year ended December 31,		
	2002	**2001**	**2000**
OPERATING ACTIVITIES:			
Net loss	$ (3,342,473)	$ (3,727,789)	$(12,746,550)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock based compensation expense	50,939	136,874	792,685
Common stock issued as compensation for services	—	—	62,409
Amortization of deferred revenue	(107,500)	(179,167)	(143,334)
Depreciation and amortization	2,286,682	2,175,055	2,243,001
Gain on sale of securities and disposition of investment in affiliated company	—	(116,853)	(600,000)
Loss on disposition of property and equipment	2,553	173,975	10,844
Provision for excess and obsolete inventories	1,373,614	600,000	1,141,351
Changes in assets and liabilities-			
Accounts receivable	860,140	(1,118,408)	(1,853,514)
Notes receivable	75,000	100,649	
Inventories	(1,017,316)	(3,549,168)	(231,516)
Prepaid expenses and other	112,804	75,180	(153,631)
Accounts payable	(884,594)	443,050	308,789
Accrued expenses and other	72,644	(269,248)	1,125,020
Net cash used in operating activities	(517,507)	(5,255,850)	(10,044,446)
INVESTING ACTIVITIES:			
Purchases of property and equipment	(1,649,129)	(2,763,639)	(3,071,565)
Proceeds from the sale of property and equipment	2,393	33,231	—
Purchase of patents, licenses and product rights	(700,000)	—	(619,589)
Purchase of short-term investments	(9,306,439)	(21,297,303)	(24,869,468)
Proceeds from sale of short-term investments	11,474,935	23,420,432	22,339,595
Proceeds from sale of securities	—	637,500	600,000
Proceeds from disposition of investment in affiliated company	—	106,102	—
Investment in affiliated companies	—	—	(20,404)
(Increase) decrease in other assets	(52,660)	(202,819)	50,000
Net cash used in investing activities	(230,900)	(66,496)	(5,591,431)
FINANCING ACTIVITIES:			
Borrowings of term debt	4,322,854	—	—
Repayment of term debt	(4,491,556)	(1,125,206)	(1,054,194)
Net proceeds from issuance of common stock	2,828,785	3,853,929	19,797,206
Net cash provided by financing activities	2,660,083	2,728,723	18,743,012
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	26,286	(75,670)	(61,140)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,937,962	(2,669,293)	3,045,995
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	2,426,346	5,095,639	2,049,644
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 4,364,308	$ 2,426,346	$ 5,095,639

The accompanying notes are an integral part of these statements.

1. BACKGROUND:

The Company

We develop, manufacture and market oral specimen collection devices using our proprietary oral fluid technologies, diagnostic products including *in vitro* diagnostic tests, and other medical devices. These products are sold in the United States and certain foreign countries to various distributors, government agencies, clinical laboratories, physicians' offices, hospitals, and commercial and industrial entities.

Merger

On September 29, 2000, STC Technologies, Inc. ("STC") and Epitope, Inc. ("Epitope") were merged (the "Merger") into OraSure Technologies, Inc., a newly formed company, incorporated under Delaware law solely for the purposes of combining the two companies and changing the state of incorporation of Epitope from Oregon to Delaware. The Merger was accounted for as a pooling of interests. There were no material adjustments required to conform the accounting policies of the two companies. In connection with the Merger, during the year ended December 31, 2000, we recorded merger-related expenses of $7.6 million, which were comprised of the following:

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

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

We consider all highly liquid investments purchased with a purchased maturity of ninety days or less to be cash equivalents. As of December 31, 2002 and 2001, cash equivalents consisted of certificates of deposit, commercial paper and U.S. government and agency obligations.

Short-term Investments

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

The following is a summary of our available-for-sale securities at December 31, 2002 and 2001:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2002				
Certificates of deposit	$ 3,581,734	$ —	$ —	$ 3,581,734
Commercial paper	399,017	88	—	399,105
Government and agency bonds	1,974,734	—	(3,321)	1,971,413
Corporate bonds	4,570,558	22,041	(975)	4,591,624
Total available-for-sale securities	$10,526,043	$ 22,129	$ (4,296)	$10,543,876
December 31, 2001				
Certificates of deposit	$ 2,398,963	$ 709	$ —	$ 2,399,672
Government and agency bonds	5,027,637	70,200	—	5,097,837
Corporate bonds	5,267,939	37,109	(37,654)	5,267,394
Total available-for-sale securities	$12,694,539	$108,018	$(37,654)	$12,764,903

Supplemental Cash Flow Information

For 2002, 2001 and 2000, we paid interest of $268,340, $402,686 and $490,410, respectively.

For 2002, 2001 and 2000, we recorded provisions for bad debts of $295,842, $100,000, and $0, respectively. We had deductions of $213,188, $5,193 and $4,269 against the allowance for doubtful accounts in 2002, 2001 and 2000, respectively.

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

Inventories

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

Property and Equipment

Property and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method

over the estimated useful lives of the related assets or the lease term, whichever is shorter. Buildings are depreciated over 20 years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over three to ten years. Leasehold improvements are generally amortized over the shorter of the estimated useful lives or the terms of the related leases. When assets are sold or otherwise disposed of, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the statement of operations.

Patents and Product Rights

Patents and product rights consist of costs associated with the acquisition of patents and product distribution rights and direct costs associated with patent submissions. Patents and product rights are amortized using the straight-line method over estimated useful lives of five to ten years. Amortization expense for 2002, 2001 and 2000 was $416,247, $359,853 and $816,111, respectively.

Other Assets

Included in other assets is a $337,253 investment, representing a 9.4% ownership interest in a privately-held nonaffiliated company. We do not have a controlling interest in this company, nor do we have an ownership or voting interest which allows us to exert significant influence over the operating and financial policies of this investee company. Accordingly, we have accounted for this investment using the cost method of accounting.

Impairment of Long-Lived Assets

In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", if indicators of impairment exist, we assess the recoverability of the affected long-lived assets, which include property and equipment, patents and product rights, by determining whether the carrying value of such assets can be recovered through the sum of the undiscounted future operating cash flows and eventual disposition of the asset. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the assets to the fair value of these assets, generally determined based on the present value of the expected future cash flows associated with the use of the asset. We believe the future cash flows to be received from our long-lived assets will exceed the assets' carrying value, and accordingly we have not recognized any impairment losses through December 31, 2002.

Revenue Recognition

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. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

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

In accordance with Emerging Issues Task Force ("EITF") Issue No. 00-10, "Accounting for Shipping and Handling Fees and Costs," we record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold.

Significant Customer Concentration

In 2002, 2001 and 2000, one customer accounted for approximately 26 percent, 29 percent and 30 percent, respectively, of our total revenues. The same customer accounted for approximately 19 percent and 21 percent of accounts receivable as of December 31, 2002 and 2001, respectively.

Research and Development

Research and development costs are charged to expense as incurred.

Restructuring-related Expenses

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

Stock-Based Compensation

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

We have elected to adopt the disclosure provisions of SFAS 123, as amended by SFAS 148 "Accounting for Stock-Based Compensation — Transition and Disclosure" ("SFAS 148"). Under SFAS 123, compensation expense related to stock options granted to employees and directors is computed based on the fair value of the stock option at the date of grant using an option valuation methodology, typically the Black-Scholes option pricing model. Pursuant to the disclosure requirements of SFAS 123, had compensation expense for our common stock option plan been determined based upon the fair value of the options at the date of grant, our net loss for 2002, 2001 and 2000 would have increased as follows:

	Year ended December 31,		
	2002	2001	2000
Net loss:			
As reported	$(3,342,473)	$(3,727,789)	$(12,746,550)
Add: stock-based employee compensation expense included in net loss	—	—	792,685
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards	(3,359,281)	(2,913,149)	(5,657,257)
Pro forma	$(6,701,754)	$(6,640,938)	$(17,611,122)
Basic and diluted net loss per share:			
As reported	$ (0.09)	$ (0.10)	$ (0.36)
Pro forma	$ (0.18)	$ (0.18)	$ (0.50)

Income Taxes

We follow SFAS No. 109, "Accounting for Income Taxes", pursuant to which the liability method is used in accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future

tax consequences of operating loss and credit carryforwards and differences between the financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates that are expected to be in effect when the items reverse.

Foreign Currency Translation

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

Gain on Sale of Securities

In December 2001, we recognized a gain of $100,000 on the sale of 50,000 shares of Lab*One*, Inc. common stock received in connection with a distribution agreement we entered into with Lab*One*, Inc. in April 1999. Our original investment associated with these shares was $537,500. We no longer hold any common shares or warrants of Lab*One*, Inc.

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

Net Loss Per Common Share

We have presented basic and diluted net loss per share pursuant to SFAS No. 128, "Earnings per Share" ("SFAS 128"). In accordance with SFAS 128, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is generally computed assuming the conversion or exercise of all dilutive securities such as common stock options and warrants; however, outstanding common stock options and warrants to purchase 3,999,608, 3,915,233 and 4,677,357 shares were excluded from the computation of diluted net loss per common share for 2002, 2001 and 2000, respectively, because they were anti-dilutive due to our losses.

Other Comprehensive Income (Loss)

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

Fair Value of Financial Instruments

As of December 31, 2002, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, accounts payable, and accrued expenses approximate their respective fair values based on their short-term nature. In addition, we believe the carrying value of our debt instruments, which do not have readily ascertainable market value, approximates their fair values, given that the interest rates on outstanding borrowings approximate market rates.

Recent Accounting Pronouncements

SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143"), which was released in August 2001, addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and their associated asset retirement costs. SFAS 143 requires an enterprise to record

the fair value of an asset retirement obligation as a liability in the period in which it incurs a legal obligation associated with the retirement of intangible long-lived assets that result from the acquisition, construction, development, or normal use of the asset. The enterprise is also required to record a corresponding increase to the carrying amount of the related long-lived asset (i.e. the associated asset retirement cost) and to depreciate that cost over the life of the asset. The liability is changed at the end of each period to reflect the passage of time (i.e. accretion expense) and changes in the estimated future cash flows underlying the initial fair value measurement. Because of the extensive use of estimates, most enterprises will record a gain or loss when they settle the obligation. We are required to adopt SFAS 143 for our fiscal year beginning January 1, 2003. We do not expect the adoption of SFAS 143 to have a material impact on our financial position or results of operations.

In April 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections" ("SFAS 145"). SFAS 145 amends existing guidance on reporting gains and losses on the extinguishment of debt to prohibit the classification of the gain or loss as extraordinary, as the use of such extinguishments have become part of the risk management strategy of many companies. SFAS 145 also amends SFAS 13 to require sale-leaseback accounting for certain lease modifications that have economic effects similar to sale-leaseback transactions. The provisions of SFAS 145 related to the rescission of SFAS 4 are applied in fiscal years beginning after May 15, 2002. Earlier application of these provisions is encouraged. The provisions of SFAS 145 related to SFAS 13 were effective for transactions occurring after May 15, 2002. The adoption of SFAS 145 is not expected to have a material effect on our financial statements.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). SFAS 146 addresses significant issues regarding the recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities. SFAS 146 also addresses recognition of certain costs related to terminating a contract that is not a capital lease, costs to consolidate facilities or relocate employees, and termination benefits provided to employees that are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract. SFAS 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 is not expected to have any impact on our financial position or results of operations.

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others, an interpretation of FASB Statements No. 5, 57 and 107 and a rescission of FASB Interpretation No. 34." This Interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees issued. The Interpretation also clarifies that a guarantor is required to recognize, at inception of a guarantee, a liability for the fair value of the obligation undertaken. The initial recognition and measurement provisions of the Interpretation are applicable to guarantees issued or modified after December 31, 2002, and are not expected to have a material effect on our financial statements.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure, an amendment of FASB Statement No. 123" ("SFAS 148"). SFAS 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements. The disclosure modifications are required for fiscal years ending after December 15, 2002, and are included in the notes to our financial statements.

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities, an interpretation of ARB No. 51." This Interpretation addresses the consolidation by business enterprises of variable interest entities as defined in the Interpretation. The Interpretation applies immediately to variable interests in

variable interest entities created after January 31, 2003, and to variable interests in variable interest entities obtained after January 31, 2003. Because we have no involvement with any variable interest entities, the application of this Interpretation is not expected to have a material effect on our financial statements.

Reclassifications

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

3. INVENTORIES:

	December 31,	
	2002	2001
Raw materials	$2,787,967	$2,918,825
Work in process	430,977	644,397
Finished goods	869,530	881,550
	$4,088,474	$4,444,772

4. PROPERTY AND EQUIPMENT:

	December 31,	
	2002	2001
Building and leasehold improvements	$ 5,893,702	$ 5,464,353
Machinery and equipment	10,104,511	9,935,897
Computer equipment	2,314,015	2,131,606
Furniture and fixtures	1,442,644	1,205,750
Construction in progress	656,061	698,675
	20,410,933	19,436,281
Less—Accumulated depreciation and amortization	(12,982,983)	(11,636,144)
	$ 7,427,950	$ 7,800,137

Depreciation expense was $1,828,855, $1,815,202 and $1,426,890 for 2002, 2001 and 2000, respectively.

5. PATENTS AND PRODUCT RIGHTS:

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

In October 2002, we entered into new supply and distribution agreements with bioMérieux, Inc. (“BMX”), which replaced existing agreements between the parties, for the supply by BMX of HIV-1 antigen required to manufacture our oral fluid Western Blot HIV-1 confirmatory test and for the distribution by BMX of the oral fluid Western Blot product on an exclusive worldwide basis. These agreements have an initial term ending December 31, 2005, which may be extended until December 31, 2007 under certain circumstances. As consideration for BMX entering into the new agreements, we agreed to pay BMX $750,000, of which $250,000 is included in our accompanying balance sheet at December 31, 2002 in accrued expenses and will be paid in March 2003. We recorded the $750,000 as additional Patent and Product Rights on our balance sheet and are amortizing this amount through December 2005, the initial term of the agreements.

6. ACCRUED EXPENSES:

	December 31, 2002	December 31, 2001
Payroll and related benefits	$1,387,834	$1,728,651
Laboratory testing fees	531,921	278,305
Professional fees	296,162	271,112
Deferred revenue	316,139	401,060
Other	789,453	432,758
	$3,321,509	$3,111,886

7. CREDIT FACILITIES:

In September 2002, we entered into a new $10.9 million credit facility ("New Credit Facility") with a new bank, pursuant to which we refinanced substantially all of our previously outstanding mortgage and term debt and increased our equipment and working capital lines of credit. The New 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 (see Note 8).

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 the bank'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 December 31, 2002, we had $2,564,356 available for future borrowings under the non-revolving equipment line of credit.

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 shall accrue at a rate, selected at our option, equal to the bank'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 December 31, 2002.

All borrowings under the New 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 New Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth and that require us to achieve positive net income for the year ending December 31, 2003 and for each year thereafter. The New 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 the bank.

8. LONG-TERM DEBT:

	December 31, 2002	December 31, 2001
Term loan payable to bank, interest at 4.99%, monthly principal installments of $71,429, plus interest, through March 2006, secured by a first priority security interest in all of our assets.	$ 2,785,714	$ —
Mortgage loan payable to bank, interest at an annual floating rate equal to the bank's prime rate (4.25% at December 31, 2002), fixed monthly installments of principal and interest of $7,426 through September 2007, at which time the interest rate and fixed monthly repayment amount is reset for the remaining sixty monthly installments, secured by our building.	874,186	—
Note payable to bank, interest at an annual floating rate equal to the bank's prime rate (4.25% at December 31, 2002), monthly principal installments of $5,081, plus interest, through December 2006, secured by certain equipment.	243,872	—
Note payable to bank, interest at 5.07%, monthly principal installments of $3,995, plus interest, through September 2006, secured by certain equipment.	179,786	—
Note payable to Pennsylvania Industrial Development Authority, interest at 2%, monthly installments of principal and interest of $4,895 through March 2010, secured by a second lien on our building.	391,770	442,285
Notes payable to bank, interest at 8%, refinanced in September 2002.	—	3,987,919
Note payable to bank, interest at 7.75%, monthly installments of principal and interest of $31,271 through July 2002, secured by certain property and equipment, inventory and intangible assets.	—	213,826
	4,475,328	4,644,030
Less—Current portion	(1,065,966)	(1,057,572)
	$ 3,409,362	$ 3,586,458

Long-term debt maturities as of December 31, 2002 are as follows:

2003	$1,065,966
2004	1,073,633
2005	1,077,085
2006	425,817
2007	118,313
Thereafter	714,514
	$4,475,328

These notes payable require, among other items, the maintenance of certain financial covenants (see Note 7).

9. INCOME TAXES:

At December 31, 2002, we had net operating loss carryforwards for federal income tax purposes of approximately $79.6 million that have begun to expire and will continue to expire through 2022. The Tax Reform Act of 1986 contains provisions that may limit the annual amount of net operating loss carryforwards available to be used in any given year in the event of significant changes in ownership. In connection with the Merger, a change in ownership occurred. We believe the annual limitation will not have a material effect on our ability to utilize our loss carryforwards. Given our losses in recent years, we believe a full valuation allowance is needed as of December 31, 2002.

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

	December 31	
	2002	2001
Deferred tax asset:		
Net operating loss carryforwards	$ 27,358,000	$ 26,949,000
Stock based compensation	—	2,643,000
Accruals and reserves currently not deductible	1,614,000	1,696,000
Patent costs	558,000	445,000
Research and development credit carryforwards	2,252,000	1,850,000
Valuation allowance on deferred tax assets	(31,782,000)	(33,583,000)
	$ —	$ —

10. STOCKHOLDERS' EQUITY:

Stock Options

We grant stock-based awards under the OraSure Technologies, Inc. 2000 Stock Award Plan (the "2000 Plan"). The 2000 Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the 2000 Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards.

Under the terms of the 2000 Plan, qualified incentive stock options for shares of our common stock may be granted to eligible employees, including our officers. To date, options generally have been granted with ten-year exercise periods and an exercise price not less than the fair market value on the date of grant. Options generally vest over four years, with one quarter of the options vesting one year after grant and the remainder vesting on a monthly basis over the next three years. The 2000 Plan also provides that nonqualified options may be granted at a price not less than 75 percent of the fair market value of a share of common stock on the date of grant. The option term and vesting schedule of such awards may either be unlimited or have a specified period in which to vest and be exercised.

We apply APB Opinion No. 25 and the related interpretations in accounting for stock options granted to employees and directors. Accordingly, compensation expense, if any, is recognized for the intrinsic value (the difference between the exercise price and the fair value of our common stock) on the date of grant. Compensation, if any, is deferred and charged to expense over the respective vesting period. In 2000, we issued an executive an option to purchase 375,000 shares of common stock for $4.59 per share. The fair market value of our common stock at the date of issuance was $6.13. We recorded deferred compensation of $577,500 on the date of grant to be amortized over the vesting period of three years. However, the options immediately vested upon the closing of the Merger in accordance with change in control rights contained in the stock option grant. As a result, we recorded $577,500 of compensation expense in 2000 related to these options. We also recorded an additional $215,185 of compensation expense in 2000 due to the amortization of deferred compensation related to other stock options, resulting from the change in control rights provided under the applicable stock option grants.

The weighted average fair value of the options granted during 2002, 2001 and 2000 is estimated at $3.45, $7.10 and $4.96 per share, respectively, using the Black-Scholes option pricing model, with the following assumptions: dividend yield of zero; volatility of 71 percent, 65 percent and 64 percent, respectively; weighted average risk-free interest rate of 2.89 percent, 4.86 percent and 6.13 percent, respectively; and an expected life of 5.0, 7.0 and 4.3 years, respectively.

We account for stock-based compensation to non-employees using the fair value method, in accordance with SFAS No. 123 and EITF No. 96-18. In 2002 and 2001, we recorded compensation expense of $50,939 and

$136,874 related to options to purchase 20,000 shares and 19,000 shares, respectively, of our common stock granted to outside consultants or members of a non-employee advisory board. No such awards were made in 2000. Compensation expense was computed based on the estimated fair value of the stock options at the date of grant, using the Black-Scholes option pricing model.

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

	Shares	Price per Share	Weighted Average Exercise Price per Share
Balance, December 31, 1999	4,369,905	$0.80–$18.17	$ 3.93
Granted	1,596,142	4.59 – 15.03	6.82
Exercised	(1,319,624)	0.80 – 6.00	4.32
Canceled	(139,066)	0.80 – 18.17	3.57
Balance, December 31, 2000	4,507,357	0.80 – 15.03	4.85
Granted	357,000	7.88 – 12.95	10.51
Exercised	(968,729)	0.80 – 9.47	3.98
Canceled	(150,395)	0.80 – 14.81	6.14
Balance, December 31, 2001	3,745,233	0.80 – 15.03	5.57
Granted	1,267,275	3.83 – 7.42	5.74
Exercised	(688,454)	0.80 – 7.09	4.06
Canceled	(444,446)	0.80 – 14.84	6.14
Balance, December 31, 2002	3,879,608	$0.80–$15.03	$ 5.83

At December 31, 2002, 2,218,019 shares were available for future grants under the 2000 Plan. The following table summarizes information about stock options outstanding at December 31, 2002:

Options outstanding				Options exercisable	
Range of exercise prices	Number outstanding	Weighted average remaining life, in years	Weighted average exercise price	Number exercisable	Weighted average exercise price
$ 0.80–$2.83	485,605	5.99	$ 1.29	368,991	$ 1.45
$ 3.22–$4.17	422,592	14.85	4.05	294,592	4.05
$ 4.18–$4.97	144,994	15.03	4.52	133,994	4.52
$ 5.04	471,573	13.05	5.04	471,573	5.04
$ 5.50–$5.81	35,313	5.15	5.77	35,313	5.77
$ 5.87	880,951	9.08	5.87	110,832	5.87
$ 6.00–$6.87	221,019	7.48	6.73	159,351	6.69
$ 7.09	688,581	7.95	7.09	399,050	7.09
$ 7.42–$10.71	415,980	8.42	9.77	202,097	9.59
$10.92–$15.03	113,000	8.00	12.68	56,123	12.72
	3,879,608	9.60	$ 5.83	2,231,916	$ 5.43

Employee Stock Purchase Plan

In 1993, Epitope's stockholders approved the adoption of the 1993 Employee Stock Purchase Plan ("1993 ESPP"). The 1993 ESPP, as subsequently amended by Epitope's stockholders, covered a maximum of 500,000 shares of common stock for subscription over established offering periods. As a result of the Merger, the 1993 ESPP was adopted and renamed by us. The Compensation Committee of the Board of Directors determines the number of offering periods, the number of shares offered, and the length of each period, provided that no more than three offering periods may be set during any given fiscal year. The purchase price for stock purchased under the 1993 ESPP for each subscription period is the lesser of 85 percent of the fair market value of a share of

common stock at the commencement of the subscription period and the fair market value at the close of the subscription period. An employee may also elect to withdraw at any time during the subscription period and receive the amounts paid plus interest at the rate of 6 percent.

As of December 31, 2002 and 2001, 0 and 8,834 shares of common stock, respectively, were subscribed for through one offering. These shares may be purchased over 24 months at an initial subscription price of $3.96. During the years ended December 31, 2002, 2001 and 2000, 8,834, 536 and 70,253 shares, respectively, were issued at prices ranging from $2.74 to $4.78 per share under the 1993 ESPP.

Common Stock Warrants

As of December 31, 2002, warrants to purchase 120,000 shares of common stock at $6.13 per share were outstanding. These warrants were issued on September 30, 1998 and expire on September 30, 2008.

11. COMMITMENTS AND CONTINGENCIES:

Phosphor Agreements

In April 1995, we entered into several research, licensing and royalty agreements (collectively the "Phosphor Agreements"), related to development and commercialization of our up-converting phosphor technology ("UPT™"). Under the terms of the Phosphor Agreements, as amended, we are obligated to make an annual license payment of $50,000 and an annual minimum royalty payment of $100,000 for usage of patented technology licensed to us. Upon the first commercial sale of a UPT™-based product or service, we are obligated to pay royalties based upon a percentage of the net sales of UPT™-based products, research and development fees and sublicensing revenues, for a period equal to the longer of ten years from the date of the first commercial sale of a UPT™-based product or service (which occurred in 2001) or the remaining life of the patents underlying the licensed technology, which expire through 2017. Royalties from the commercial sale of products or services can be credited against our minimum royalty obligation of $100,000 per year. In connection with the acquisition of certain technology related to UPT™, we are also required to pay sponsored research funds of $125,000 per year in 2003 and 2004, decreasing to $50,000 per year through 2008, as well as royalties of $25,000 per year, until 2008.

Leases

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

2003	$1,467,879
2004	1,460,066
2005	887,585
2006	780,000
2007	783,108
Thereafter	3,978,547
	$9,357,185

Rent expense for 2002, 2001 and 2000 was $1,070,510, $805,878 and $716,748, respectively.

Purchase Commitments

As of December 31, 2002, we had outstanding non-cancelable purchase commitments in the amount of $2,097,460, of which $688,626, $351,416 and $1,057,418 are related to inventory, services and capital expenditures, respectively.

Employment Agreements

Under terms of employment agreements with certain executive officers and other employees, extending through 2003, we are required to pay each individual a base salary and for some individuals, a retention bonus, for continuing employment with our Company. The agreements require payments of $1,503,780 in 2003, which includes the severance payments discussed below.

In January 2002, we terminated an employment agreement with our former chief executive officer. During the first quarter of 2002, we recorded $480,063 in severance expenses, of which, $215,113 is payable in 2003. These expenses include continued salary and benefit premium payments to this officer, related employment taxes, and the value of certain computer equipment transferred to this individual. We also held a $75,000 note receivable from this officer, which was repaid during 2002.

Litigation

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

12. RELATED-PARTY FACILITY LEASE:

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 ten-year term. The base rental rate may be increased after the fifth year of the initial term, in order to reflect changes in the debt incurred by Tech Partners to finance construction of the leased facilities. We have not guaranteed any debt incurred by Tech Partners. This lease also provides us with options to renew our 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 upon a formula set forth in the lease agreement.

13. RETIREMENT PLANS:

As a result of the Merger, during 2000 and a portion of 2001, we maintained two distinct retirement plans covering substantially all of our employees. Both plans permitted voluntary employee contributions to be excluded from the employees' current taxable income under the provisions of Internal Revenue Code Section 401(k) and the regulations thereunder. Generally, all employees of Epitope were eligible to participate in a profit sharing and deferred savings plan. The plan provided for us to make a matching contribution (either in cash, our common stock, or a combination of both) equal to 50 percent of an employee's contribution, not to exceed 2.5 percent of an employee's compensation. We contributed 5,309 shares valued at $62,409 during 2000 to this plan. Generally, all employees of STC were eligible to participate in a profit sharing plan. The plan provided for us, subject to the Board of Directors' discretion, to match employee contributions up to $3,000 or 8% of a participant's salary, whichever is less. Our contributions to the plan were $75,789 and $122,903 for 2001 and 2000, respectively.

On May 1, 2001, we merged the two aforementioned plans into the OraSure Technologies, Inc. 401(k) Plan (the "New Plan"). The New Plan permits voluntary employee contributions to be excluded from an employee's current taxable income under provisions of Internal Revenue Code Section 401(k) and the regulations thereunder. The New Plan also provides for us to match employee contributions up to the lesser of $4,000 or 10% of the employee's salary. Contributions to the New Plan were $443,280 and $239,402 in 2002 and 2001, respectively.

14. GEOGRAPHIC INFORMATION:

Under the disclosure requirements of SFAS No.131, "Segment Disclosures and Related Information," we operate within one segment, medical devices and products. Our products are sold principally in the United States and Europe. Segmentation of operating income and identifiable assets is not applicable since all of our revenues outside the United States are export sales.

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

	For the year ended December 31,		
	2002	2001	2000
United States	$28,124	$27,321	$24,763
Europe	2,726	3,510	2,507
Other regions	1,160	1,742	1,518
	$32,010	$32,573	$28,788

15. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2002 and 2001. These quarterly results are unaudited, but in the opinion of management, have been prepared on the same basis as our audited financial information and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information set forth herein (all amounts in thousands, except per share amounts).

	2002 Results				
	Three months ended				Year ended December 31, 2002
	March 31, 2002	June 30, 2002	September 30, 2002	December 31, 2002	
Revenues	$ 7,725	$ 7,930	$ 8,107	$ 8,248	$32,010
Costs and expenses	9,387	9,285	8,508	8,371	35,551
Operating loss	(1,662)	(1,355)	(401)	(123)	(3,541)
Other income, net	69	74	14	41	198
Net loss	$ (1,593)	$ (1,281)	$ (387)	$ (82)	$ (3,343)
Basic and diluted net loss per share	$ (0.04)	$ (0.03)	$ (0.01)	$ (0.00)	$ (0.09)
Weighted average number of shares outstanding	37,434	37,494	37,536	37,863	37,583

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

Board of Directors

Douglas G. Watson (3)
Chairman of the Board, OraSure Technologies, Inc. Founder, Pittengrieff Glen Associates

Carter H. Eckert (2, 3)
Chairman and Chief Executive Officer, IMPATH, Inc.

Michael J. Gausling
President and Chief Executive Officer, OraSure Technologies, Inc.

Frank G. Hausmann (2)
Chairman and Chief Executive Officer, CenterSpan Communications Corporation

Richard J. Lane (1, 3)
Chief Executive Officer, Andrx Corporation

Gregory B. Lawless (1)
Managing Partner, Collins Mabry & Co. LLC

Roger L. Pringle (1, 2)
President, The Pringle Company

Committees of the Board
1. *Compensation*
2. *Audit*
3. *Strategic Planning*

Executive Officers

Michael J. Gausling
President and Chief Executive Officer

Ronald H. Spair
Executive Vice President and Chief Financial Officer

R. Sam Niedbala, Ph.D.
Executive Vice President and Chief Science Officer

P. Michael Formica
Executive Vice President, Operations

Joseph E. Zack
Executive Vice President, Marketing and Sales

Jack E. Jerrett
Senior Vice President, General Counsel and Secretary

Mark L. Kuna
Vice President, Controller and Assistant Secretary

Independent Auditors

KPMG LLP
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Investor Relations

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Mission

To create, combine and collaborate to be the world's leading oral fluid diagnostics company.

To leverage our success with OraQuick® and UPlink™ to become the world's leading point-of-care diagnostics company.

To deliver superior diagnostic solutions through the use of the most user-friendly and technologically advanced sample collection, detection, information, and confirmation technologies.

To be entrepreneurial, build a culture based on our Core Values, and work to exceed stakeholder expectations.

Core Values

Trust *– Develop trust by delivering total quality, solving problems quickly, and resolving issues equitably.*

Agility *– Respond quickly and efficiently to capture opportunities, and adapt our operating plans to meet unpredictable and inevitable change.*

Innovation *– Encourage risk taking and create partnerships to achieve the most user-friendly and technologically advanced solutions possible.*

Quality *– Maintain the highest level of quality in every aspect of our business, always striving to exceed marketplace expectations.*

Transfer Agent

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Foreign Stockholders
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Stock Information

The Company's common stock is traded on the National Market tier of The Nasdaq Stock Market under the symbol OSUR.

Annual Report

A copy of the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission, is available without charge by writing the Investor Relations Department at OraSure Technologies, Inc.

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