2005 Annual Report

OraSure Technologies, Inc.

diagnostic solutions for the new millennium

Creating a path to a brighter future

Creating a path to a brighter future

Last year we began the execution of an aggressive business strategy to enable us to participate in larger and higher growth markets while leveraging our Company's strengths. Our strategy is focused on three main areas and I am pleased to report excellent progress.

First, we are growing our existing product lines and technologies by expanding our penetration into existing marketplaces and by launching into new global markets. Second, we are working to expand our infectious disease business with the identification and development of additional point-of-care tests. Third, we are taking steps to bring additional products over the counter into the retail marketplace.

At OraSure, we are creating a path to a brighter future for our customers, our stockholders, our corporate partners, our employees and the communities in which we live.

Delivering a banner year in 2005.

2005 was an outstanding year for OraSure. The Company realized record revenues of $69.4 million, a 28% increase over 2004, driven by significant growth across most product lines. We delivered our first full year of profitability in 2005 and continued to strengthen our cash and liquidity position. We had more than $77 million in cash and short-term investments and more than $90 million in working capital at the end of 2005.

Our outstanding team of employees is executing tactical initiatives that are critical to the success of the strategic plan we have in place. Here are a just few of the highlights:

- OraQuick® *ADVANCE*™ continues to be the main driver of our Company's growth as sales in our infectious disease testing business grew by 67% over 2004. Sales of OraQuick® *ADVANCE*™ to Abbott Laboratories for hospital distribution increased 149% over 2004. Furthermore, in 2005 two out of every three HIV tests conducted in public health settings were performed with an OraSure product.

- Intercept® sales during 2005 were also strong with revenues increasing 61% over 2004. Workplace testing grew 87% versus 2004 and the addition in 2005 of new large accounts, such as Lowe's Home Improvement and Seneca Foods Corporation, underscore the growing workplace acceptance of oral fluid drug testing as an alternative to urine drug testing. In the criminal justice marketplace, the award of a contract with The State of New Jersey Probation and Parole Department gives us a model to pursue with other large state agencies.

- Our products had significant success on the global front. A key part of that success was the launch of our over-the-counter cryosurgical product by SSL International in Europe. This product is being sold under SSL's Scholl tradename. The launch was initiated during the fourth quarter in a few select European countries and is expected to expand to other countries during 2006.

"Our outstanding team of employees is executing the tactical initiatives critical to the success of the strategic plan . . ."

“We look forward to the day . . . when millions of individuals will be empowered to know their HIV status . . .”

~ Sales growth in 2005 also provided an opportunity to decrease costs through increased utilization of our manufacturing facilities. Increased volume production across our product lines was an important driver of unit cost reduction and will continue to be so in the future.

~ In anticipation of significant capacity expansion, an automated manufacturing system for OraQuick® *ADVANCE*™ was installed in the fourth quarter. Validation of the system and submission for U.S. Food and Drug Administration (FDA) approval are key initiatives for 2006.

Expanding new horizons.

As I mentioned earlier, we are working to expand our infectious disease business with additional point-of-care tests.

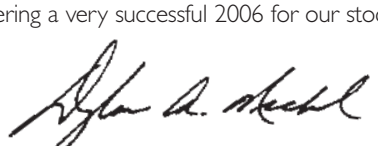
For example, the development of a rapid test for Hepatitis C, or HCV, on our OraQuick® platform is a high priority and is progressing nicely. Based on early performance data generated so far, we believe we will meet our design goals for this product. With an estimated 170 million people in the world chronically infected with HCV, and an estimated 3 to 4 million new infections each year, we believe a rapid HCV test will be an extremely important diagnostic tool for identifying those who are infected and enabling immediate treatment.

Progress against our strategy for growth in the over-the-counter diagnostic business continues as well. Our most immediate opportunity in the over-the-counter marketplace is the sale of our OraQuick® *ADVANCE*™ HIV-1/2 test, which we announced we would pursue at last year’s annual meeting. Since our announcement, the FDA, working with its Blood Products Advisory Committee, concluded that criteria for the approval of an over-the-counter rapid HIV test could be established and subsequently set forth clinical study requirements for approval of a home use HIV test kit. We are extremely encouraged by these developments and are aggressively moving forward with the planning and execution of the needed studies to obtain approval.

Building a bright future.

During the January 31, 2006, State of the Union address, President Bush called for a “nationwide effort, working closely with African-American churches and faith-based groups, to deliver rapid HIV tests to millions” in order to help end the stigma of AIDS and come closer to the day when there are no new infections in America. In a statement issued after the speech, the Administration indicated that the President is proposing to direct more than $90 million to the purchase and distribution of rapid HIV test kits in order to facilitate testing of more than 3 million people. We share the President’s vision and are fully supportive of this new initiative. We look forward to the day, hopefully in the near future, when millions of individuals will be empowered to know their HIV status through greater access to rapid testing.

I am extremely optimistic and enthusiastic about our growth opportunities across our different product lines in all geographies, as well as our ability to improve efficiencies, reduce our costs, and increase our margins in the year ahead. Our strategy is sound and our people are executing as we’ve promised. We remain committed to delivering a very successful 2006 for our stockholders.

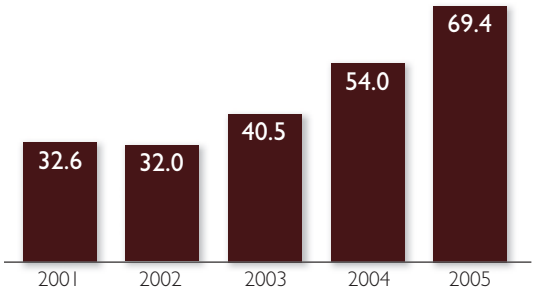


Douglas A. Michels
President and Chief Executive Officer

Statements set forth above regarding future events or performance are “forward-looking statements” and the Company’s actual results could be quite different from those expressed or implied by those statements. Factors that could affect results are discussed more fully in Section 1A, entitled, “Risk Factors,” in the accompanying Form 10-K for the year ended December 31, 2005.

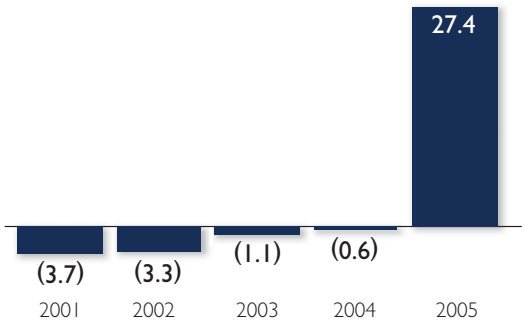
2005: A banner year

Revenue
(Dollars in millions)



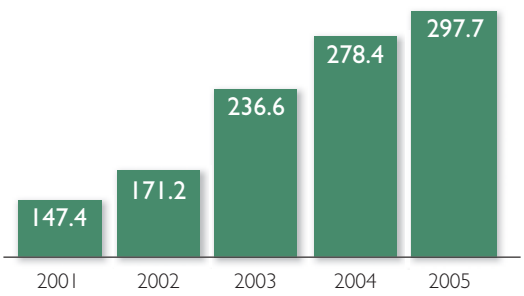
Revenues were $69.4 million in 2005, up 28.4% over 2004.

Net Income (Loss)
(Dollars in millions)



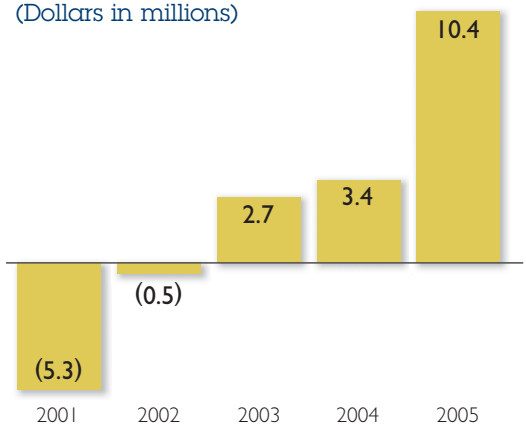
Excluding the $18.2 million income tax benefit recorded in 2005, net income in 2005 represents a $9.8 million improvement over 2004.

Revenue per Employee
(Dollars in thousands)



Revenue per employee exceeded $297,700 in 2005, up 7% over 2004.

Cash Flow from Operations
(Dollars in millions)



Cash flow from operations was $10.4 million in 2005, up $7.0 million over 2004.

Selected Financial Information

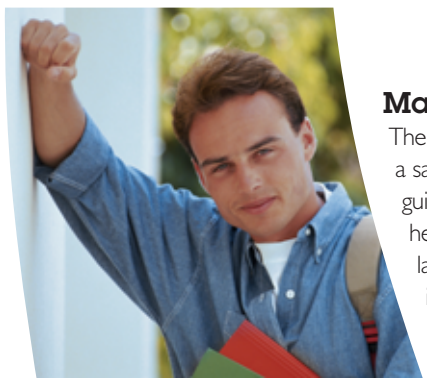
(In thousands, except per share data, ratios, and number of employees)

	December 31,				
	2001	**2002**	**2003**	**2004**	**2005**
Operating Results for the Year Ended:					
Total revenue	$32,573	$32,010	$40,451	$54,008	$69,366
Net income (loss)	$(3,728)	$(3,342)	$(1,136)	$(560)	$27,448
Earnings (loss) per share - diluted	$(0.10)	$(0.09)	$(0.03)	$(0.01)	$0.59
Shares used in computing earnings (loss) per share - diluted	36,868	37,583	39,794	44,464	46,147
Financial Position as of:					
Working capital	$19,764	$18,931	$67,171	$68,910	$90,670
Total assets	$37,285	$35,737	$86,151	$88,064	$130,747
Long-term debt less current portion	$3,586	$3,409	$2,456	$1,334	$884
Total liabilities	$10,744	$9,718	$12,642	$12,487	$11,828
Total stockholders' equity	$26,541	$26,019	$73,509	$75,577	$118,919
Current ratio	3.8:1	4.1:1	7.7:1	7.2:1	9.4:1
Total liabilities to equity	0.4:1	0.4:1	0.2:1	0.2:1	0.1:1
Other Data:					
Capital expenditures	$2,764	$1,649	$994	$912	$2,048
Full-time employees	221	187	171	194	233

OraQuick® *ADVANCE*™
Rapid HIV point-of-care testing

OraSure® HIV-1
Oral Specimen Collection Device

The most widely used rapid HIV test in public health and



Driving demand.

The continued strong demand for the OraQuick® *ADVANCE*™ Rapid HIV-1/2 Antibody Test, combined with our sales of the OraSure® HIV-1 Oral Specimen Collection Device in 2005, increased revenues for our infectious disease testing business by 67% over 2004.

Today, two out of every three HIV tests conducted in public health clinics are with an OraSure product. This is a clear indication that oral fluid is becoming the specimen of choice to detect antibodies to HIV in public health settings.

~ OraQuick® *ADVANCE*™ is being used in over 1,300 hospitals across the United States and is now the most widely used rapid HIV test in a hospital setting. Sales of OraQuick® *ADVANCE*™ to Abbott Laboratories in 2005 for hospital distribution increased 149% over 2004.

~ In 2005, we shipped nearly the entire $4 million OraQuick® *ADVANCE*™ bulk procurement by the Substance Abuse and Mental Health Services Administration (SAMHSA) to substance abuse, treatment and prevention sites throughout the United States.

~ On the international front, OraQuick® sales grew 30% over 2004. We also have been listed as a supplier by the World Health Organization and we continue active discussions with leaders of the President's Emergency Plan for AIDS Relief, The Global Fund, and the Global Business Coalition to access funding for testing.

Making routine HIV testing a reality.

The Centers for Disease Control and Prevention (CDC) hosted a satellite broadcast and public discussion on revised draft guidelines that would recommend routine HIV testing in healthcare settings. Final guidance is expected from the CDC later in 2006 and we believe these guidelines will have an immediate impact on the level of rapid HIV testing routinely performed in hospitals, physician offices and other medical facilities.

Empowering people to know their status.

We continue to aggressively pursue FDA approval to launch our OraQuick® *ADVANCE*™ test over-the-counter (OTC). Working with the FDA and its Blood Products Advisory Committee, the criteria and proposed clinical study requirements for OTC approval have been more clearly defined. We are forging ahead with the execution of the needed studies and look forward to empowering more individuals to know their HIV status in the near future.

hospitals.

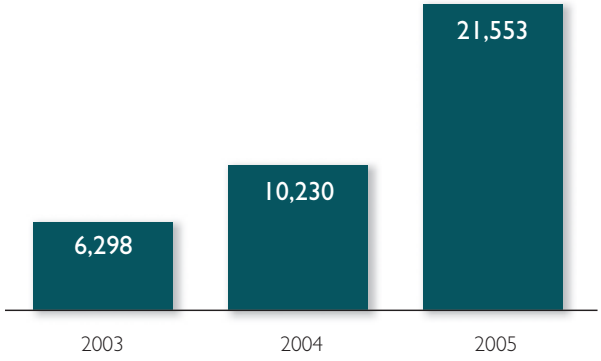
“ OraQuick® ADVANCE™ rapid HIV testing helps doctors make timely, better informed clinical decisions at the point of care. ”

Michael J. Collins
Corporate Vice President
U.S. Diagnostic Commercial Operations
Abbott

Abbott Diagnostics

OraQuick® Revenues

(Dollars in thousands)



Tackling Hepatitis C.

Preliminary data generated for our prototype Hepatitis C rapid test on our OraQuick® technology platform supports our belief that we will meet our design goals for this product. With an estimated 170 million people in the world chronically infected with HCV, and an estimated 3 to 4 million new infections each year, we believe a rapid HCV test will be a critical diagnostic tool.

Expanding around the globe.

We recently signed OraQuick® distribution agreements for South Korea and Singapore and we are finalizing an agreement for the Middle East. Active discussions also are continuing for distribution of OraQuick® in Japan and China. We have also made significant progress in our efforts to receive a CE mark for OraQuick® *ADVANCE*™, a requirement to sell this product in the European Union. All studies have been completed and all data required by the notifying body has been submitted for review. Upon approval we will move to obtain necessary country-specific registrations and would expect to launch OraQuick® *ADVANCE*™ in Europe in 2006.

Taking a bold stand.

During the January 2006 State of the Union address, President Bush called for a “nationwide effort, working closely with African-American churches and faith-based groups, to deliver rapid HIV tests to millions” in order to help end the stigma of AIDS and come closer to the day when there are no new infections in America.

The President has now proposed to direct more than $90 million to the purchase and distribution of rapid HIV test kits in order to facilitate testing of more than 3 million people. This program would focus on areas with the highest rates of new HIV infections and the highest rates of undetected cases. Examples include the testing of inmates in jails and prisons and intravenous drug users. We believe this is a very positive development, both with regard to the country's fight against HIV/AIDS, and more specifically for our Company.

Intercept®

Lab-based oral fluid drug testing

Increasing demand for oral fluid drug testing.

The continued significant year-over-year growth of Intercept® is indicative of the increasing demand for oral fluid drug testing.

- Total Intercept® revenues were up 61% over 2004, reflecting an 87% increase in workplace testing, a 63% increase in criminal justice, and a 14% increase in international sales.

- During 2005, we added more than 170 new Intercept® customers, including Lowe's Home Improvement, to our already strong list of satisfied users which includes Kroger, Shop Rite, Georgia Pacific, and Fruit of the Loom.

- The State of New Jersey Probation and Parole Department, which includes probation, parole, and drug courts, began deploying the Intercept® oral fluid drug testing system as part of its state-wide testing efforts. This program gives us a model to pursue with other large state agencies. We have also continued to grow our sales to substance abuse/drug treatment clinics.

We are making great progress converting the market from traditional urine drug testing to oral fluid drug testing.

Adopting the emerging standard.

In addition to Lowe's Home Improvement, recent major businesses adopting Intercept® include Capital Returns, a leader in pharmaceutical returns management solutions, and Allied Barton Security Services, a premiere provider of office security services.

Intercept® is also continuing to see growth in the food services industry as evidenced by the addition of Boddie-Noell Enterprises, which owns the Hardee's and Texas Steakhouse & Saloon Restaurants. The Company is successfully deploying Intercept® and is extremely pleased with the performance of the test.

Forging new product development.

Several new assays are in development for use with our Intercept® oral fluid drug screening system. By expanding the menu of drugs that can be detected with the Intercept® system, we expect to grow our business and sell to customers that have expressed an interest in a broader panel of oral fluid drug assays.

Expanding distribution globally.

Sales to our U.K. based lab partner, Altrix Healthcare plc, have grown 41% since 2003, as they continue to make impressive gains, year over year, in the criminal justice market. In addition, we are actively identifying and pursuing new distributors for our drug testing products in other European countries and additional foreign territories.

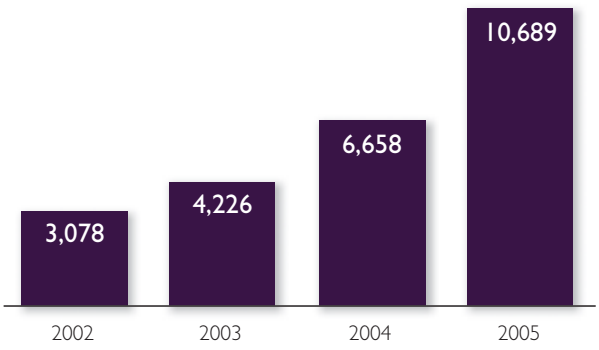
Oral fluid drug screening has become

“ Intercept® lets us offer lab-based oral fluid drug screening to our testing clients as a new option, answering a whole range of needs that drug treatment programs have had for years. ”

Bill Closson, Ph.D.
Director of Toxicology
Bendiner & Schlesinger, Inc.

Intercept® Revenues

(Dollars in thousands)



The future – opening new markets.

Currently, workers employed in federally-regulated industries are not eligible for oral fluid drug testing with Intercept®. However, that may all change. Oral fluid drug testing guidelines are under final review by SAMHSA which could potentially make available our Intercept® test to a market where approximately 11 million drug tests are being conducted annually. In its March 2006 meeting, SAMHSA's Drug Testing Advisory Board indicated that the review process continues to move forward. The revised guidelines are in the final stages of approval.

the emerging industry standard.

Histofreezer®
Compound W® Freeze Off™
Scholl Freeze

Cryosurgical wart removal

So effective, doctors use it. So simple, consumers can too.

“ SSL remains excited about Scholl Freeze as part of our extensive range of personal care products. Our European launch programme will include both TV and written media support. ”

Ian Adamson
Managing Director - Europe
SSL International PLC

Building a global brand.

During 2005, global expansion into new markets served as the primary driver for our overall cryosurgical systems business, which grew 13% over 2004.

~ In late 2005, we successfully launched an OTC cryosurgical product in Europe through our distributor, SSL International, Plc. The product is being sold under SSL's Scholl tradename.

~ Sales of the Compound W® Freeze Off™ product to Prestige Brands Holdings, Inc., also contributed to the increase in cryosurgical systems revenues, as a result of the launch of this product in the Canadian OTC market, during the third quarter of 2005.

Expanding our base business.

Physician offices continue to enjoy the benefits associated with portable cryosurgery.

~ Sales of our professional cryosurgery product, Histofreezer®, grew nicely during 2005 in both the U.S. and international markets, increasing 13% and 28%, respectively, as compared to 2004.

~ Growth in domestic Histofreezer® revenues reflects enhanced sales and marketing efforts and strengthening partnerships with new and existing independent distributors. In 2006, for example, we are pleased to have been included in the Cardinal Health Physician Plus Program as a Preferred Cryosurgical Provider.

Launching into New Markets.

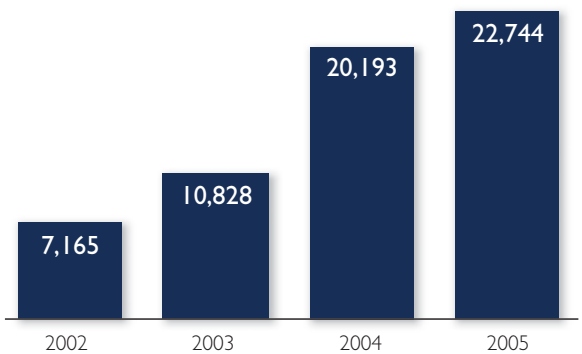
In 2005, we launched the Scholl cryosurgical wart removal product in the OTC footcare market in select European countries with SSL International. In 2006, we will be working with SSL to roll out the product in other countries throughout the year.

- Our partners launched Freeze Off™ into Canada and Freeze in Germany, France and Spain. We are also engaged in active discussions with potential distributors to represent our OTC cryosurgical products in Japan and Asia.

- For the professional market, we recently signed a South Korean distributor for Histofreezer® and we are actively pursuing new Histofreezer® distributors in Mexico.

Cryosurgical Systems Revenues

(Dollars in thousands)



Making a world of difference.

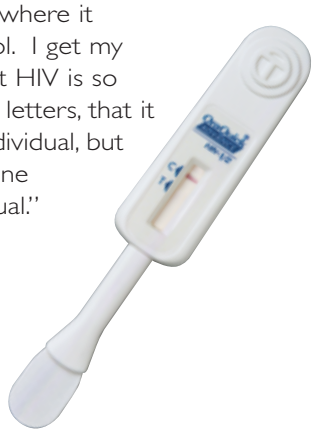
"I applaud the efforts of OraSure and the Mazzoni Center for their commitment to empowering young adults to learn their HIV status and, if they have a positive test result, seek prompt treatment - both steps that will help to stem the spread of this disease."

Tom Donohue
Founder and Executive Director
Who's Positive

Humanizing HIV.

Tom Donohue's national non-profit HIV awareness organization, Who's Positive, is geared toward bringing HIV awareness to youth. He and others in his organization travel the country speaking to high school and college students about the importance of being tested for HIV.

In Tom's words, "I just share my story. I humanize HIV to the point where it becomes a prevention tool. I get my peers to understand that HIV is so much more than three letters, that it not only infects an individual, but it also affects everyone around that individual."



“Histofreezer® is easy to use. I like it, and I use it often. It’s effective, easy to explain, easy to store and kids tolerate it well.”

Dr. Scott Rice
Pediatrician
Allentown, PA

Treating the doctor and the patient better.

Dr. Scott Rice has been using Histofreezer® in his practice for 7 years, ever since he moved to Allentown. Previously, he had used liquid nitrogen to remove warts and had to make room to store the awkward canisters of gas. Now storage isn’t a problem.

To quote Dr. Rice, “Histofreezer® has allowed me to enhance my patient services without referring them to another specialist.”

“The process for oral fluid testing is great, simple and accurate!”

Pat Tolston
Personnel Manager
Boddie-Noell Enterprises, Inc.

Saving money without compromising values.

Boddie-Noell Enterprises, Inc., which owns the Hardee’s and Texas Steakhouse & Saloon Restaurants, is extremely pleased with the performance of our Intercept® test because it provides cost-effective drug testing in a dignified manner.

To quote Pat, “The best part is the participation of the donor in this entire process. The process is giving employees a feeling of ownership. From the administrative end of coordinating the drug program, life is better too.”

Board of Directors and Executive Officers

Board of Directors

Douglas G. Watson (1, 3)
Chairman of the Board, OraSure Technologies, Inc.
Founder and Chief Executive Officer,
Pittencrieff Glen Associates

Frank G. Hausmann (2)
President, Capricorn Advisors

Ronny B. Lancaster (2, 3)
Senior Vice President for Federal Government Relations,
Assurant, Inc.

Douglas A. Michels
President and Chief Executive Officer,
OraSure Technologies, Inc.

Charles W. Patrick (1)
Principal, Patrick Consulting

Roger L. Pringle (1, 2, 3)
President, The Pringle Company

Committees of the Board
1. *Compensation*
2. *Audit*
3. *Nominating and Corporate Governance*

Executive Officers

Douglas A. Michels
President and Chief Executive Officer

Ronald H. Spair
Executive Vice President and Chief Financial Officer

Stephen R. Lee, 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

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K
ANNUAL REPORT PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(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, 2005

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 if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

State the aggregate market value of the voting and non-voting common equity held by nonaffiliates, 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 30, 2005): $448,190,024

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of March 1, 2006: 45,862,788 shares.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement for the 2006 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

Table of Contents

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. Factors that could affect our results are discussed more fully under Item 1A., entitled "Risk Factors," and elsewhere in this Annual 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 forward-looking statements are made as of the date of this Report and we undertake no duty to update these statements.

PART I

ITEM 1. Business.

Our business principally involves the development, manufacture, marketing and sale of oral fluid specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types, and other medical devices. Our diagnostic products include tests which are processed in a laboratory and tests which are performed on a rapid basis at the point of care. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. One of our products is also sold in the over-the-counter ("OTC") or consumer retail market in the United States, Canada and certain other foreign countries.

In vitro diagnostic testing is the process of analyzing oral fluid, blood, urine and other bodily fluids or tissue for the presence of specific substances or markers for infectious diseases, drugs of abuse or other conditions. *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 is 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.

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.

Additional information about us 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. These 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 Annual Report.

Products

The following is a summary of our principal products and their regulatory and commercial status:

Product	Description	FDA Approval Status	Commercial Status
OraQuick® *ADVANCE*™	A rapid, point-of-care test for antibodies to the Human Immunodeficiency Virus Type 1 and Type 2 ("HIV-1/2") that can be visually read at the point of care in approximately 20 minutes.	Premarket approval ("PMA") approved by the U.S. Food and Drug Administration ("FDA") (March 2004 – June 2004) for use with oral fluid, finger-stick and venous whole blood and plasma. CLIA (Clinical Laboratory Improvement Amendments of 1988) waived for use with oral fluid, finger-stick and venous whole blood (June 2004).	Marketed
		CE mark application filed.	Pending
		Registered in Mexico.	Marketed
OraSure®	Oral fluid collection device for the detection of antibodies to HIV-1 in an oral fluid sample in a laboratory setting.	PMA approved by FDA in December 1994.	Marketed
		Also FDA 510(k) cleared for use of device in detecting cocaine and cotinine (an indicator of nicotine) in oral fluid.	Marketed
		CE marked and registered in the United Kingdom. Also Registered in Mexico, Canada, Columbia, South Africa, Afghanistan, Argentina, Brazil, and Trinidad.	Marketed
Intercept®	Oral fluid collection device, along with nine related immunoassays, for oral fluid drug testing in a laboratory setting. Used to detect the following drugs in an oral fluid sample: marijuana, cocaine, opiates, amphetamines, methamphetamines, PCP, benzodiazepines, barbiturates and methadone.	Collection device—FDA 510(k) cleared in 2000.	Marketed
		Nine drug assays—FDA 510(k) cleared during 2000-2001.	Marketed
		Intercept® device CE marked and registered in the United Kingdom. Various assays are CE marked and registered in the United Kingdom, Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Korea, Canada, Afghanistan and Brazil.	Marketed
Cryosurgical Systems (Wart Removal Products)	Cryosurgical (freezing) system for the removal of warts and other benign skin lesions, marketed under the Histofreezer® tradename primarily to the physicians' office market.	Nine indications—FDA 510(k) cleared during 1991—1999.	Marketed
		CE marked and registered in Europe, Venezuela, Thailand, New Zealand, Hong Kong, Brazil, Mexico, Canada, and Afghanistan.	Marketed

Product	Description	FDA Approval Status	Commercial Status
	Cryosurgical (freezing) system for the removal of common and plantar warts, sold in the over-the-counter markets in the United States and Canada under the Compound W® Freeze Off™ tradenames by Prestige Brands Holdings, Inc., and in Europe, Australia and New Zealand under the Scholl and Dr. Scholl Freeze Spray tradenames by SSL International plc.	FDA 510(k) cleared for two indications in February 2003.	Marketed
		Freeze Off™ registered in Canada.	Marketed
		Scholl Freeze Spray CE marked and registered in several European countries.	Marketed

In addition to the above products, we also sell certain immunoassay tests and reagents for insurance risk assessment, substance abuse testing and forensic toxicology applications; an oral fluid Western blot HIV-1 confirmatory test approved by the FDA for confirming positive HIV-1 test results obtained from the use of our OraSure® collection device; and the FDA 510(k) cleared Q.E.D.® saliva alcohol test.

OraQuick® Rapid Test Platform

OraQuick® is our rapid test platform designed to test an oral fluid, whole blood (i.e., both finger-stick and venous) or plasma sample for the presence of various antibodies or analytes. The device uses a porous flat pad to collect an oral fluid specimen. After collection, the pad is inserted into a vial containing a pre-measured amount of developer solution and allowed to develop. When whole blood or plasma is to be tested, a loop collection device is used to collect a drop of blood or plasma and mix it in the developer solution, after which the collection pad is inserted into the solution. In all cases, the specimen and solution then flow through the testing device where test results are observable in approximately 20 minutes. The OraQuick® device is a screening test and requires a confirmation test where an initial positive result is obtained.

Our first product utilizing this technology was the OraQuick® rapid HIV-1 antibody test, a rapid test for the presence of antibodies against HIV-1. In 2002, we received premarket approval of this test from the FDA for detecting HIV-1 in finger-stick whole blood samples and in 2003 we received FDA approval for use of the OraQuick® test with venous whole blood samples.

As a result of this FDA approval, the OraQuick® test was made available for use by nearly 40,000 locations in the United States certified under the Clinical Laboratory Improvements Amendments of 1988, or CLIA, to perform moderately complex diagnostic tests. Additionally, in January 2003, we received a waiver under CLIA for OraQuick® which permitted the use of this 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 the period March to June 2004, we received FDA approval for use of a new OraQuick® test to detect antibodies to both HIV-1 and a second type of the HIV virus, known as HIV-2, in finger-stick and venous whole blood, oral fluid and plasma. In June 2004, we also received a CLIA waiver of this test for oral fluid, finger-stick whole blood and venous whole blood. We named this new test OraQuick® *ADVANCE*™.

We believe that the OraQuick® *ADVANCE*™ device, because it is approved for detecting antibodies to both HIV-1 and 2 in finger-stick and venous whole blood, oral fluid and plasma samples, provides a significant competitive advantage in the market for rapid HIV testing in the United States. Demand for OraQuick® *ADVANCE*™ has quickly grown since the launch of that product and, as a result, we have stopped manufacturing and selling the OraQuick® HIV-1 test.

In April 2003, the Centers for Disease Control and Prevention ("CDC") announced a new four-part initiative for HIV testing and diagnosis, which is intended to increase the use of rapid HIV testing as part of routine medical care. Under this program, the CDC purchased 250,000 OraQuick® devices during 2003, 250,000 devices during 2004, and 217,000 devices in 2005.

In August 2004, the Substance Abuse and Mental Health Services Administration ("SAMHSA") placed an order to purchase $4.0 million of our OraQuick® *ADVANCE*™ tests and HIV confirmatory test services. The OraQuick® tests have been deployed by SAMHSA to substance abuse treatment and prevention sites throughout the United States. We expect that all tests ordered by SAMHSA will be fully deployed in early 2006.

In late 2005, we received reports that specific clinical sites had experienced increased levels of false positive results using our OraQuick® *ADVANCE*™ test with oral fluid. Immediately after receiving the reports, we commenced a scientific and systematic evaluation of each situation and have worked closely with the affected customers, healthcare officials and government agencies, including the CDC and FDA. The evaluation includes the collection of test data, an assessment of test procedures, specimen collection and other clinical variables that could affect test results at the sites. We have also conducted a thorough review of our manufacturing processes and all related variables that may affect product performance and quality, and have been contacting our customers throughout the country to determine if they are experiencing any unexpected results or issues with regard to the performance and procedures associated with the test. Based on the data and information collected to date, we believe that the OraQuick® *ADVANCE*™ test, when used with oral fluid, continues to perform overall as expected and in a manner consistent with its FDA-approved label claims.

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 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 systems for infectious disease testing, for both health care professionals and the individuals being tested. These advantages include eliminating the risk of needle-stick accidents, providing a non-invasive 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 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 bioMerieux, Inc. ("BMX"). We have completed clinical trials with BMX as part of an application to obtain FDA approval of the use of a new EIA screening test for HIV-1 with an OraSure® device. The FDA submission is expected to be made by BMX during 2006.

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 primarily for insurance risk assessment purposes.

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. Each of these EIA's is also FDA 510(k) cleared for use with the Intercept® device.

We believe that the Intercept® device has several advantages over competing urine and other drugs-of-abuse testing products, including its lower total testing cost, its non-invasive nature, 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, eliminate scheduling costs and inconvenience, and thereby streamline the testing process.

Cryosurgical Systems (Wart Removal Products)

The Histofreezer® cryosurgical removal system is a low-cost alternative to liquid nitrogen and other methods for removal of warts and other benign skin lesions by physicians. The Histofreezer® product mixes two environmentally friendly cryogenic gases in a small aerosol canister. When released, these gases are delivered to a specially designed foam bud, cooling the bud to –50°C. The frozen bud is then applied to the wart or lesion for 15 to 40 seconds (depending on the type of lesion) creating localized destruction of the target area by freezing. We have received 510(k) clearance for use of the Histofreezer® product to remove common warts and eight other types of benign skin lesions, and this product has been CE marked and registered for distribution throughout Europe.

In February 2003, we received FDA 510(k) clearance to market and sell a cryosurgical product similar to the Histofreezer® product in the OTC or retail market for the removal of common and plantar warts only. This product is being distributed in the United States and Canada OTC markets under the name Freeze Off™ by a subsidiary of Prestige Brands Holdings, Inc. ("Prestige"), the owner of the Compound W® line of wart removal products. Prestige is the owner of both the Freeze Off™ and Compound W® tradenames.

In June 2005, we entered into an agreement with SSL International plc ("SSL") to distribute a similar cryosurgical wart removal product into the OTC footcare market in Europe, Australia and New Zealand. This product is CE marked and is being distributed under SSL's Scholl and Dr. Scholl trademarks. SSL is the owner of the Scholl and Dr. Scholl trademarks in countries outside North and South America.

Immunoassay Tests and Reagents

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

In a MICRO-PLATE kit, the sample to be tested is placed into a small plastic receptacle, called a microwell, along with the reagents. The result of the test is determined by the color of the microwell upon completion of the reaction. Controlling the reaction involves the use of a variety of reagents by laboratory personnel. Test results are analyzed by any of a variety of commercially available laboratory instruments, which we may also provide to our laboratory customers. MICRO-PLATE tests can be performed on commonly used instruments and can detect drugs in urine, serum, and sweat specimens. MICRO-PLATE tests are also used as part of the Intercept® product line to detect drugs of abuse in oral fluid specimens.

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

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

Western blot HIV-1 Confirmatory Test

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

Q.E.D.® Saliva Alcohol Test

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

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

OraQuick® Platform

We believe that OraQuick® has significant potential as a point-of-care testing platform for clinics and other public health entities, hospitals, physicians' offices and other markets. We believe that OraQuick® provides a platform technology that can be modified for detection of a variety of infectious diseases in addition to HIV, such as viral hepatitis and certain sexually transmitted diseases. During 2005, we obtained a license from Ortho-Clinical Diagnostics and Chiron Corporation to patents relating to the Hepatitis C virus ("HCV"), and we are currently developing a rapid HCV test using the OraQuick® platform.

OraSure®/Intercept® Applications

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

In 2004, SAMHSA issued proposed regulations for oral fluid drug testing for federal workers. When issued in final form, these regulations may require certain modifications to our Intercept® product in order to permit its

use by federal workers. As a result, we are developing modifications to the Intercept® collection device that we anticipate will be required by these regulations or are otherwise likely to be desired by our customers. We are also currently developing additional drugs of abuse assays for use with our Intercept® collection device.

UPT™ and UPlink®

For several prior years, we devoted significant research and development efforts on our Up-Converting Phosphor Technology ("UPT™") and our first application of UPT™, the UP*link*® rapid, point-of-care system for detecting drugs of abuse in oral fluid.

To date, we have not been able to successfully develop potential UPT™ applications other than the UP*link*® application for rapid detection of drugs of abuse in oral fluid. The UP*link*® product was developed pursuant to agreements with Dräger Safety AG & Co. KGaA ("Dräger"). Dräger had agreed to distribute UP*link*® on an exclusive basis to law enforcement officials for determining if an operator or passenger of a motor vehicle is under the influence of one or more drugs of abuse ("roadside testing market") and to certain military, criminal justice and workplace testing markets.

As part of a strategic review of our business completed in late 2004, we concluded that the roadside testing market was not as attractive an opportunity for the UP*link*® product as we initially believed. We therefore explored other options with respect to UP*link*® during the first half of 2005, including possibly transitioning the manufacturing of the product to Dräger. We were not able to reach any agreement on this matter with Dräger, and Dräger eventually informed us that they would no longer promote the sale of the UP*link*® product. In light of slower than expected sales, difficult channel economics and higher than expected manufacturing costs for this product, both we and Dräger decided to stop further investment in the UP*link*® product, and our agreements with Dräger were terminated.

As a result, during 2005 we recorded a reserve against the carrying value of assets related to the UP*link*® product. We have also been evaluating the technical and commercial viability of UPT™ as a technology platform.

Business Strategy

We have adopted a multi-part growth strategy, pursuant to which we intend to leverage our extensive diagnostic experience in order to maximize the available opportunities from our existing products and technologies, and supplement our existing product pipeline by accessing other technologies and products. We intend to follow a disciplined approach to maximize the value of our business for the benefit of our stockholders.

Our overall vision is to become a recognized global leader focused on providing innovative diagnostic solutions that add substantial value to existing and emerging healthcare needs. In order to achieve this vision, our business strategy includes the following key elements:

- *Extension of Base Businesses*. We intend to maximize the sales potential of our existing product lines and technologies in the markets where they are currently sold, with a focus on expanding, where possible, the number of our oral fluid product offerings. Under this part of the strategy, we intend to fully capitalize on the potential market reach of our OraQuick®, OraSure®, Intercept®, Histofreezer® and Freeze Off™ products by investing in our sales and marketing efforts where appropriate, making product improvements and enhancements, and optimizing our distribution channels. We also intend to expand the reach of our existing products and technology platforms into new markets and will focus specifically on expanding into international markets.
- *Infectious Disease Testing*. We will pursue new products and technology platforms in the infectious disease, point-of-care testing business to supplement our existing product pipeline. This may include either the development of new infectious disease products or the acquisition of new technologies or products. One new product we are pursuing is the development of a rapid HCV test on our OraQuick® platform.

- *OTC Opportunities*. We intend to identify or develop products that can be sold in the OTC or retail marketplace. We made significant progress during 2005 under this part of our strategy when we entered into an agreement with SSL to distribute our cryosurgical wart removal product in the OTC market in Europe and other countries. Another opportunity that we are pursuing under this part of our strategy is to seek FDA approval to sell our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test in the United States OTC market.
- *Operational Improvements*. We intend to create a culture focused on the continuous improvement of our operations. These improvements will include, but not be limited to, expanding the use of automated manufacturing for our product lines as demand increases, expanding the global sourcing of components and assemblies to achieve efficiencies and cost improvements, making infrastructure and information technology investments as needed to improve effectiveness and productivity, and modifying our processes in order to continuously improve quality and the effectiveness of our operations.

Research and Development

In 2005, our research and development activities focused primarily on the development of a rapid HCV test using our OraQuick® technology platform, clinical and regulatory activities related to obtaining a CE mark for the OraQuick® *ADVANCE*™ test, preliminary work to obtain approval for use of OraQuick® *ADVANCE*™ in the United States OTC market, and development of certain improvements to existing products in both the Intercept® and cryosurgical wart removal product lines.

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

Research and development expenses totaled $5.3 million in 2005, $6.1 million in 2004 and $8.0 million in 2003. These expenses include the costs associated with research and development, regulatory affairs and clinical trials.

Sales and Marketing

We attempt to reach our major target markets through a combination of direct sales, strategic partnerships, and independent distributors. Our marketing strategy is to raise awareness through a full array of marketing activities, which include trade shows, print advertising, special programs 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 were $59.9 million, $47.8 million and $35.9 million in 2005, 2004 and 2003, respectively. Revenues attributable to international customers amounted to $9.5 million, $6.2 million and $4.6 million, or 14%, 11% and 11% of our total revenues, in 2005, 2004 and 2003, respectively.

Infectious Disease Testing

We market the OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test directly to customers in the public health market for HIV testing. This market consists of a broad range of clinics and laboratories and includes states, counties, and other governmental agencies, the CDC, SAMHSA, colleges and universities, correctional facilities and the military. There are also a number of organizations in the public health market such as AIDS service organizations and various community-based organizations set up primarily for the purpose of encouraging and enabling HIV testing.

In February 2005, we entered into an agreement with Abbott Laboratories for the distribution of the OraQuick® *ADVANCE*™ test, appointing Abbott as our exclusive distributor in the U.S. hospital market and as a non-exclusive distributor in the U.S. physicians' office marketplace. As our exclusive distributor to hospitals,

Abbott sells OraQuick® *ADVANCE*™ to federal hospitals under the terms of our Federal Supply Schedule on file with the General Services Administration. Under our agreement with Abbott, we have retained exclusive rights for all other markets including sales to the public health and criminal justice markets, the military, the CDC, SAMHSA and other governmental agencies. We have a small sales force that supports Abbott in order to maximize the penetration of OraQuick® *ADVANCE*™ in the hospital market.

We also market the OraSure® oral fluid collection device for HIV-1 testing, separately and as a kit in combination with laboratory testing services. To better serve our public health customers, we have entered into agreements with two commercial laboratories 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.

Substance Abuse Testing

Our substance abuse testing products are marketed to laboratories serving the workplace testing, forensic toxicology, criminal justice, and drug rehabilitation markets.

We have entered into agreements for the distribution of Intercept® collection devices and associated MICRO-PLATE assays 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 and Clinical Reference Laboratory, and internationally for workplace, criminal justice and forensic toxicology testing through Bio-Rad Laboratories, Altrix HealthCare, plc, and other distributors. In some cases, 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. Lab*One* was recently acquired by Quest Diagnostics.

The forensic toxicology market in the United States for our substance abuse testing products 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 also distribute our Q.E.D.® saliva alcohol test primarily through various distributors in the United States and internationally. 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. Typical usage situations include pre-employment, random, post-accident, reasonable-cause, and return-to-duty testing.

Cryosurgical Systems

Most of our Histofreezer® sales occur in the United States to distributors that, in turn, resell the product to 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 established a sales office in Reeuwijk, The Netherlands, and we are selling the Histofreezer® product through a network of distributors in more than 20 countries worldwide.

We sell Freeze Off™, a product similar to Histofreezer®, in the OTC market in the U.S. and Canada pursuant to a distribution agreement with Prestige, the owner of the Compound W® line of wart removal products. Additionally, in June 2005, we entered into an agreement under which SSL distributes a cryosurgical wart removal product in the OTC footcare market in Europe, Australia and New Zealand. SSL sells this product under its Scholl and Dr. Scholl tradenames and began initial sales of this product during the fourth quarter of 2005.

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 Quest Diagnostics, Heritage Labs and Clinical Reference Laboratory. 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 for life insurance risk assessment. 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 collected with our OraSure® device that initially test positive for HIV-1.

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

During 2005, we experienced a decline in sales of OraSure® and related assays for insurance testing, primarily due to a reduction in the number of applications for life insurance policies and changes in underwriting requirements. However, our sales force continues to encourage additional insurance companies to use OraSure® and to extend the use of the product by existing customers. We believe there are several factors which could help expand the use of our device, 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, the ease of use of the OraSure® device, and the development of new oral fluid assays for use with our OraSure® device for detecting substances or conditions that affect life insurance risk assessment.

We also sell our AUTO-LYTE® and MICRO-PLATE assays and reagents in the insurance testing market directly to laboratories, including Quest Diagnostics, Heritage Labs and Clinical Reference Laboratory.

International Markets

We sell most of our products into international markets primarily through distributors with knowledge of their local markets. Principal markets include physicians' offices, insurance risk assessment, substance abuse, 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, cryosurgical systems products, and OraQuick® rapid HIV test accounted for total revenues of $16.1 million, $22.7 million, and $21.6 million in 2005, $14.6 million, $20.2 million, and $10.2 million in 2004, and $14.5 million, $10.8 million and $6.3 million in 2003, respectively. As new products are developed and commercialized, we expect to receive a greater portion of our revenues from these new products.

We currently have two customers, Prestige and Quest Diagnostics (including its wholly-owned subsidiary, Lab*One*, Inc.), which accounted for 17% and 13% of our total revenues, respectively, during 2005.

The loss of Prestige or Quest, or a significant decrease in the volume of products purchased by either customer, could have a material adverse effect on our results.

Supply and Manufacturing

We manufacture our OraQuick® *ADVANCE*™ test in our Bethlehem, Pennsylvania facility. 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 supply agreement had an initial term of one year, and automatically renews 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 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, under a supply agreement with a five-year term ending in 2009. 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. This in turn would require significant time to complete and could disrupt our ability to manufacture and sell the OraQuick® device.

We manufacture both the OraSure® and Intercept® collection devices in our Bethlehem, Pennsylvania facilities. During 2003 and 2004, we successfully transferred the manufacturing of these products from a contract manufacturer in Oregon to Bethlehem, and we believe this transfer will lower our manufacturing costs and help us maintain our quality control for these products in the future.

The oral fluid Western blot HIV-1 confirmatory test is currently manufactured in 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.

Our agreements with BMX provide for the 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 believe we would be able to obtain alternate supplies at a competitive cost. However, a change in the antigen would require FDA approval and some additional development work, which would require significant time to complete and could disrupt our ability to manufacture and sell the Western blot HIV-1 confirmatory test.

Histofreezer® is assembled in The Netherlands by Koninklijke, Utermöhlen, N.V. ("Utermöhlen"), the company from which we acquired the product in 1998. We purchase the product pursuant to an exclusive production agreement. Utermöhlen also supplies Freeze Off™, the OTC cryosurgical product for the U.S. and Canadian markets. Assuming minimum purchase requirements are met, our agreement with Utermöhlen will terminate at the end of 2006 with respect to the Freeze Off™ product and at the end of 2008 with respect to the Histofreezer® product. The cryosurgical wart removal products distributed in international markets by SSL are supplied by vendors located in the United States. We believe that additional suppliers of our cryosurgical products are available on terms no less favorable than the terms of our existing supply agreements in the event that our current suppliers would be unable or unwilling to continue manufacturing these products.

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

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

Employees

As of December 31, 2005, we had 233 full-time employees, including 61 in sales, marketing, and client services; 22 in research and development; 118 in operations, manufacturing, quality control, information systems, purchasing and shipping; 12 in regulatory affairs and quality assurance, and 20 in administration and finance. This compares to 194 employees as of December 31, 2004. Our employees are not currently represented by a collective bargaining agreement.

Competition

The diagnostic industry is a multi-billion dollar international industry and is intensely competitive. Many of our competitors are substantially larger than we are, and they 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;
- The ability to develop and market products and processes;
- The ability to obtain FDA or other regulatory approvals;
- The ability to manufacture products that meet applicable FDA requirements (i.e., good manufacturing practices);
- Access to adequate capital;
- The ability to attract and retain qualified personnel; and
- The availability of patent protection.

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

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

We expect competition to intensify as technological advances are made and become more widely known, and as new products reach the market. Furthermore, new testing methodologies could be developed in the future that render our products impractical, uneconomical or obsolete. There can be no assurance that our competitors

will not succeed in developing or marketing technologies and products that are more effective than those we develop or that would render our technologies and products obsolete or otherwise commercially unattractive. In addition, there can be no assurance that our competitors will not succeed in obtaining regulatory approval for these products, or introduce or commercialize them before we can do so. These developments could have a material adverse effect on our business, financial condition and results of operations.

Several companies market or have announced plans to market oral specimen collection devices and tests both within and 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 rapid blood 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® *ADVANCE*™ rapid test, such as the Ortho Diagnostics division of Johnson & Johnson, Bio-Rad Laboratories, Abbott Laboratories and BMX, sell laboratory-based HIV-1/2 EIAs, and Maximum Biomedical (formerly Calypte, Inc.) sells an HIV-1 screening test for urine, in the United States. In addition, MedMira and Trinity Biotech have each received FDA approval to sell competing rapid HIV-1 blood tests, and Bio-Rad Laboratories has received FDA approval to sell a competing rapid HIV-1/2 blood test in the United States. Under their current FDA approvals, these tests compete with our OraQuick® *ADVANCE*™ test in hospitals or other laboratory settings. In addition, Trinity Biotech has received CLIA waiver for its rapid HIV test, and this test competes with our OraQuick® *ADVANCE*™ test in the markets outside of the traditional hospital and laboratory settings. These companies, or others, may continue to expand the bodily fluids with which a rapid HIV test may be performed, or develop and commercialize new rapid HIV tests, which would provide further competition for our OraQuick® *ADVANCE*™ test. We believe other companies may also seek FDA approval to sell competing rapid HIV tests in the future.

Internationally, our OraQuick® *ADVANCE*™ test competes against rapid HIV tests sold by a number of other entities, including Inverness Medical, and often these competing tests are sold at prices substantially below the prices we charge for our OraQuick® *ADVANCE*™ test. Maximum Biomedical has recently developed a rapid oral fluid HIV test which we believe is now being sold in certain foreign countries.

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

Our MICRO-PLATE oral fluid drug assays, which are sold for use with the Intercept® and OraSure® collection devices, are expected to come under increasing competitive pressure from "home-brew" assays developed internally by our laboratory customers. In fact, on June 30, 2004 Lab*One*, Inc. ceased purchasing our MICRO-PLATE oral fluid assays for use with our OraSure® collection device in the insurance risk assessment testing market and is now, we believe, using internally-developed home-brew assays instead.

Our oral fluid MICRO-PLATE assays also compete with urine-based homogeneous assays that are run on fully-automated, random access analyzers. These tests provide strong competitive pressure because they provide the benefits of automation, including lower costs and short turn-around times. In addition, we believe our competitors are developing oral fluid tests suitable for use on these fully automated homogeneous assay systems and these assays, if and when they are developed and commercialized, will represent a significant competitive threat to our oral fluid MICRO-PLATE business.

Our MICRO-PLATE drugs-of-abuse reagents sold in the forensic toxicology market 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. 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.

Sales of our AUTO-LYTE® urine assays have declined substantially during the past several years, primarily due to competition from assays developed internally by our laboratory customers (i.e., "home brews"), which can be produced at a cost lower than the price typically paid for our products. Many of our customers no longer purchase our AUTO-LYTE® assays, and we eventually expect to stop selling this product line.

The Histofreezer® product's delivery system and operating temperature, which is warmer 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. Wartner may also eventually compete with Histofreezer® in the physician market in the United States.

The Freeze Off™ product, sold by Prestige under its Compound W® tradename, competes with other OTC wart removal products in the United States. Schering-Plough sells a competing cryosurgical wart removal product under its Dr. Scholl's brand and Wartner currently sells a competing cryosurgical wart removal product in the OTC market. Wartner also sells a product that competes with our cryosurgical product in the European OTC footcare market.

Q.E.D.® has two direct competitors, Ansys Technologies, Inc. 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, 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 provide fewer benefits than our Q.E.D.® test.

Patents and Proprietary Information

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

We have 16 United States patents and numerous foreign patents for the OraSure® and Intercept® collection devices and 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 issued patent for our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test in the United States, and we have several related patent applications pending for this product in the United States and

internationally. We have obtained licenses to certain lateral flow patents and to certain HIV-1 and HIV-2 patents held by other parties. We also have obtained a license to certain HCV patents which we intend to use to manufacture and sell a rapid HCV test on the OraQuick® or other technology platform. We obtained these licenses through the payment of certain upfront fees and an agreement to pay ongoing royalties. We believe these fees and royalties are comparable to those generally paid by other companies under similar arrangements.

We may need to obtain licenses or other rights under, or enter into distribution or other business arrangements in connection with, certain other intellectual property patents in order to manufacture and sell the OraQuick® *ADVANCE*™ test. See Section 1A, entitled "Risk Factors," for a further discussion of these issues.

We have five United States patents and numerous foreign patents issued for apparatuses and methods for the topical removal of skin lesions relating to our cryosurgical wart removal products, and we have a pending patent application related to these products. We have also licensed another patent relating to apparatuses and methods for the topical removal of skin lesions relating to our cryosurgical wart removal products.

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

We have or have licensed rights under 16 United States patents and numerous foreign patents for methods, compositions, and apparatuses relating to our UPT™ and UP*link*® technologies. Several additional UPT™ and UP*link*® patent applications remain pending in the United States and abroad.

We 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 OraSure®, Intercept®, OraQuick®, OraQuick® *ADVANCE*™, Histofreezer®, Q.E.D.®, AUTO-LYTE®, UPT™ and UP*link*® trademarks. We also own many of these marks and others in several foreign countries. The Compound W® and Freeze Off™ trademarks are owned by Prestige Brands Holdings, Inc. or its affiliates, in the United States and Canada, and the Scholl and Dr. Scholl tradenames are owned by SSL International in Europe, Australia, New Zealand and other countries outside North and South America.

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.

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 regulated environment 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 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 products are regulated in the United States as medical devices.

There are two mechanisms by which regulated medical devices can be placed on the market in the United States. Some products may qualify for clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act. To obtain this clearance from the FDA, 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 premarket application), the FDA must approve a premarket application, or 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 before approval is granted, if at all.

Some of our 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 assurance 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.

The Clinical Laboratory Improvements Amendments of 1988, or CLIA, prohibit laboratories from performing 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 both our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test and our 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 the 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 a pre-requisite to use of 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. The CE mark is a European Union ("EU") requirement to sell products that fall under the scope of the Medical Devices Directive ("MDD") and the In Vitro Diagnostic Directive ("IVDD"). The CE mark is evidence that the manufacturer meets the requirements of all applicable directives, including the MDD and IVDD.

We received authorization to use the CE mark for the OraSure® and Intercept® collection devices and our Histofreezer® product line, and SSL International has obtained authorization to use the CE mark for our cryosurgical wart removal product in the OTC European footcare market. In addition, we are currently in the process of obtaining authorization to affix a CE mark to our OraQuick® *ADVANCE*™ HIV-1/2 test.

We must also comply with certain registration requirements as dictated by Health Canada, prior to commencing sales in Canada. We have completed this process for several of our current products and may do so with respect to other products in the future. In addition, Canadian law requires manufacturers of medical devices to have a quality management system that meets various ISO requirements in order to obtain a license to sell their devices in Canada.

Anti-Kickback Laws

The Federal Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation, or receipt of any form of remuneration in return for, or to induce:

- The referral of a person;
- The furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other governmental programs; or
- The purchase, lease, or order of, or the arrangement or recommendation of the purchasing, leasing, or ordering of any item or service reimbursable under Medicare, Medicaid, or other governmental programs.

Our products are or may be purchased by customers that will seek or receive reimbursement under Medicare, Medicaid or other governmental programs. Noncompliance with the federal anti-kickback legislation can result in exclusion from Medicare, Medicaid, or other governmental programs, restrictions on our ability to operate in certain jurisdictions, as well as civil and criminal penalties, any of which could have an adverse effect on our business and results of operations.

The Federal Civil Monetary Penalties Law prohibits the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance can result in civil money penalties of up to $10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the Federal healthcare programs.

Many states have also adopted some form of anti-kickback laws. A determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

We believe that we are operating in compliance with these laws.

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.

The foregoing 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 1A. Risk Factors

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

Regulatory Risks

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

Many of our proposed and existing products are subject to regulation by the FDA and other governmental or public health agencies. In particular, we are subject to strict governmental controls on the development,

manufacture, labeling, distribution and marketing of our products. In addition, we are often required to obtain approval or registration with foreign governments or regulatory bodies before we can import and sell our products in foreign countries.

The process of obtaining required approvals or clearances from governmental or public health agencies can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities and other costly, time-consuming procedures. For example, during 2004, we received several FDA approvals for our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test, including approval for use of the test on oral fluid samples. These approvals required the submission of clinical data and required significant time to obtain. The submission of an application to the FDA or other regulatory authority 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 or by another agency.

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

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, during 2004 the Substance Abuse and Mental Health Services Administration ("SAMHSA"), which is part of the U.S. Department of Health and Human Services, issued proposed regulations for the use of oral fluid drug testing for federal workers. The SAMHSA regulations, when issued in final form, could permit us to market and sell our oral fluid drug tests for use with federal workers only if certain modifications are made to our products. If we are unable to make these modifications, or if the modifications require significant time to develop, our ability to sell our oral fluid drug testing products in that market could be limited. In addition, the extent to which the final SAMHSA regulations permit the sale of our oral fluid drug tests for use with federal workers may influence whether customers in the workplace, criminal justice or other unregulated markets use our products.

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, or IVDD. We are not permitted to sell our products in the EU without a CE mark, which could lead to the termination of strategic alliances and agreements for sales of those products in the EU. We have obtained the CE mark for several of our existing products, and we intend to CE mark certain of our future products and are not aware of any material reason why we will be unable to do so. However, there can be no assurance that compliance with all provisions of the IVDD will be demonstrated and the CE mark will be obtained for all products that we desire to sell in the EU.

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

We can manufacture and sell many of our products, both in the United States and internationally, 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.

Although we believe that we have adequate processes in place to ensure compliance with these requirements, the FDA or other regulatory bodies could force us to stop manufacturing or selling our products if

it concludes that we are out of compliance with applicable regulations. The FDA and other regulatory bodies 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" in Item 1 of this Annual Report for a further discussion of applicable regulatory requirements.

Risks Relating to Our Industry, Business and Strategy

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

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

We also face competition from products which may be sold at a lower price. To the extent this competition arises, customers may choose to buy lower cost products from third parties or we may be forced to sell our products at a lower price, both of which could result in a loss of revenues or a lower gross margin contribution from the sale of our products. In addition, the development and commercialization of products outside of the diagnostics industry could adversely affect sales of our product. For example, the development of a safe and effective vaccine to HIV or treatments for other diseases or conditions that our products are designed to detect, could reduce, or eventually eliminate, the demand for our HIV or other diagnostic products and thereby result in a loss of revenues.

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

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

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

During 2005, 2004 and 2003, we incurred $5.3 million, $6.1 million and $8.0 million, respectively, in research and development expenses. We expect to continue to incur significant costs from our research and development activities.

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

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

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

If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively manufacture, sell and market our products, to meet the demands of our strategic partners in a timely fashion, or to support internal research and development programs. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms.

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 2004 we completed the restructuring of our manufacturing operations, which included the transfer of the manufacturing of our Intercept®, OraSure® and oral fluid Western blot products from our Beaverton, Oregon facility and a contract manufacturer in Oregon to Bethlehem, Pennsylvania. We obtained FDA approval to transfer the operations to Pennsylvania, and our Pennsylvania facilities are ISO certified. This type of transfer and the need to obtain FDA approval and ISO certification could interfere with or delay our manufacturing processes and disrupt continued operations. Any delay in or disruption of operations, and in particular manufacturing operations, could result in increased costs or could delay or prevent us from selling certain products and thereby result in a loss of revenue.

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

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

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

The occurrence 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 or otherwise achieve our financial or strategic objectives.

Our Net Sales Could be Affected by Third-Party Reimbursement Policies and Potential Cost Constraints.

The end-users of our products are expected to increasingly include hospitals, physicians and other healthcare providers. Use of our products could be adversely impacted if these end-users do not receive reimbursement for the cost of our products by their patients' healthcare insurers or payors. Our net sales could also be adversely affected by changes in reimbursement policies of governmental or private healthcare payors, including in particular the level of reimbursement for our products. In the United States, healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third-party payors, principally private health insurance plans, Medicare and Medicaid, to reimburse all or part of the cost of the product and procedure. We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the United States in recent years, currently available levels of reimbursement may not continue to be available in the future for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the United States or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, and regulation or reimbursement policies of third-party payors may reduce the demand for our products or our ability to sell our products on a profitable basis.

Increases in Demand for Our Products Could Require Us to Spend Considerable Resources to Meet the Demand or Harm Our Customer Relationships if We are Unable to Meet Demand.

If we experience significant or unexpected increases in the demand for our products, we and our suppliers may not be able to meet that demand without expending additional capital resources. These capital resources could involve the cost of new machinery or even the cost of new manufacturing facilities. This would increase our capital costs, which could adversely affect our earnings. Our suppliers may be unable or unwilling to expend the necessary capital resources or otherwise expand their capacity. If we or our suppliers are unable to develop necessary manufacturing capabilities in a timely manner, our net sales could be adversely affected. Failure to cost-effectively increase production volumes, if required, or lower than anticipated yields or production problems encountered as a result of changes that we or our suppliers make in our manufacturing processes to meet increased demand, could result in shipment delays or interruptions and increased manufacturing costs, which could also have a material adverse effect on our revenues and profitability.

Our inability to meet customer demand for our products could also harm our customer relationships and impair our reputation within the industry. This, in turn, could have a material adverse effect on our business and prospects.

Risks Relating to Collaborators

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

We have marketed many of our products by collaborating with laboratories, diagnostic companies and distributors. For example, our OraSure® oral fluid collection device is distributed to the insurance industry through major insurance testing laboratories, and Abbott Laboratories has exclusive rights to distribute our OraQuick® *ADVANCE*™ HIV-1/2 test in the U.S. hospital market and non-exclusive rights to the U.S. physicians' office market. 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 consolidated in recent years, and such consolidation has had, and may continue to have, an adverse impact on the level of orders for our products. One of these laboratories, Lab*One*, Inc., acquired another large insurance laboratory customer, Osborne Group, Inc., in 2001 and our revenues decreased because of efficiencies resulting from that acquisition. More recently, Lab*One* was acquired by another of our laboratory distributors, Quest Diagnostics, and this acquisition could also affect the level of our revenues.

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, several of our insurance testing laboratories are facing this pressure and are using lower cost "home brew" insurance testing assays that they have developed internally or purchased from our competitors. This has reduced our assay sales and is expected to lower sales of these products in 2006 and beyond.

Finally, some of our distributors may not fulfill their contractual obligations. Although we will try to maintain and expand our business with our distributors and require that they fulfill their contractual obligations, there can be no assurance that such companies will continue to purchase or distribute our products, maintain historic order volumes or otherwise meet their purchase or other obligations, 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 antigen and nitrocellulose required to make our OraQuick® rapid HIV-1 antibody test is purchased from sole source suppliers. If these suppliers are unable or unwilling to supply the required component, we would need to find another source, and perform additional development work and obtain FDA or other regulatory approvals for the use of the alternative component for our products. Completing that development and obtaining such approvals could require significant time to complete and may not occur at all. The availability of critical components from sole supply sources could also reduce our control over pricing, quality and timely delivery. These events could either disrupt our ability to manufacture and sell certain of our products, or completely prevent us from doing so or increase our costs. Any such event could have a material adverse effect on our results of operations, cash flows and business.

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

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

BMX 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 and expect BMX to file a submission for approval with the FDA during 2006. BMX also supplies the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and is the exclusive world-wide distributor of that product.

If BMX ceases to manufacture or sell an HIV-1 screening test approved by the FDA for use with our OraSure® collection device, or if our oral fluid Western blot HIV-1 confirmatory test is not made available to our

customers (because BMX either fails to supply the HIV-1 antigen required to make this product or fails to distribute this product), we would need to find alternate suppliers for these products, which would require additional development work and FDA approval. These activities would likely require significant time to complete. If our customers cannot obtain an HIV-1 screening test or Western blot HIV-1 confirmatory test that has been approved by the FDA for use in connection with our OraSure® collection device, these customers would likely stop purchasing our OraSure® device. Sales of the OraSure® device were $10.0 million and $11.0 million, or 14% and 20% of our total revenues, in 2005 and 2004, respectively.

We May Need 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. Our strategy for development and commercialization of products may entail entering into 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, there is no assurance that they will do so and the amount and timing of resources to be devoted to these activities will be controlled by others. Consequently, there can be no assurance that any revenues or profits will be derived from such arrangements.

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

We Have a History of Losses Prior to 2005.

We achieved our first full year of profitability in 2005, when we recorded net income of $27.4 million, which includes a $17.7 million net income tax benefit. As of December 31, 2005, the Company had an accumulated deficit of $103.7 million.

Our ability to achieve continued profitability in the future will be dependent upon a number of factors including, without limitation, the following:

- Creating market acceptance for and selling increasing volumes of our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test, Intercept® drug testing product, and OraSure® collection device;
- The degree to which certain of our new products may replace sales of our existing products and the financial impact of that change, including the degree to which our OraQuick® *ADVANCE*™ test will replace our OraSure® collection device for HIV-1 testing or sales of our cryosurgical wart removal products in the OTC market will replace sales of our Histofreezer® product to physicians' offices or other professional markets;
- Achieving growth in sales of our wart removal products in the OTC market and selling other products, such as our OraQuick® *ADVANCE*™ test, in the OTC market;
- Achieving growth in international markets with our OraQuick® *ADVANCE*™ test, cryosurgical wart removal products and other products;
- Changes in the level of competition, such as would occur if larger and financially stronger competitors introduced new or lower priced products to compete with our products;
- Changes in economic conditions in domestic or international markets, such as economic downturns, reduced demand, inflation and currency fluctuations;
- Failure to achieve our targets for growth in revenues;

- Changes in distributor buying patterns or a buildup of significant quantities in our distributors' inventories or distribution channels; and
- Commercially developing, and obtaining regulatory approvals and creating market acceptance for new products in a time frame consistent with our objectives.

Even though we achieved profitability for 2005, there can be no assurance that we will be able to sustain such profitability in the future.

Utilization of Our Deferred Tax Assets May Be Limited and is Dependent on Future Taxable Income.

As of December 31, 2005, we had federal net operating loss ("NOL") carryforwards of $66.6 million for federal income tax purposes. The Tax Reform Act of 1986 contains provisions under Section 382 of the Internal Revenue Code that limit the NOLs that may be used in any given year in the event of specified occurrences, including significant ownership changes. If these specified events occur, we may lose some or all of the tax benefits of these carryforwards.

During 2005, we determined, based on our assessment of both positive and negative evidence, which takes into consideration our forecasted taxable income, that it was more likely than not that we will benefit from the use of a significant portion of our deferred tax assets, and therefore we reduced our valuation allowance on our deferred tax assets related to these NOLs. Upon reducing the valuation allowance, we recognized $26.7 million of deferred tax assets of which $18.2 million was recognized as a non-cash tax benefit and $8.5 million was recorded directly as an increase in stockholders' equity. The favorable impact of the tax benefit distorts the trends in our operating results and impacts the comparability of our current period results of operations with other periods. If in the future we determine, based on our assessment of both positive and negative evidence, that it is more likely than not that we will not realize all or a portion of the deferred tax assets, we will record a valuation allowance on the deferred tax assets which would result in recognition of income tax expense.

We May Require Future Additional Capital.

Our future liquidity and ability to meet our future 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 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 liability associated with patent infringement or other types of litigation;
- 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;
- The scope and results of clinical testing;
- 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.

An Economic Downturn, Terrorist Attacks or National Disasters May Adversely Affect Our Business.

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 or the issuance of fewer life insurance policies. 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 or suppliers adversely affected by economic conditions.

Terrorist attacks such as those occurring on September 11, 2001, or national disasters such as Hurricane Katrina, and subsequent governmental responses to these events could cause economic instability. These actions could adversely affect economic conditions both within and outside the United States and reduce demand for our products. Terrorist attacks and natural disasters could cause governments and regulatory agencies, such as the FDA or agencies that perform similar functions outside the United States, to focus their resources on other matters, such as relief efforts or vaccines or other products intended to address the threat of biological or chemical warfare. This diversion of resources could eliminate or delay the bulk procurement of our products by government agencies or delay our ability to obtain regulatory approvals required to manufacture, market or sell our products in the United States and other countries. These events could also disrupt the operations of our customers and suppliers and eliminate, reduce or delay our customers' ability to purchase and use our products and our suppliers' ability to provide raw materials and finished products.

Our Stock Price Could Continue to be Volatile.

Our stock price has been volatile, has fluctuated substantially in the past and may be volatile in the future and could experience substantial declines. The following factors, among others, could have a significant impact on the market for our Common Stock:

- Future announcements concerning us or our products;
- Future announcements concerning our competitors or industry;
- Developments in patent or other proprietary rights;
- Litigation or threatened litigation;
- Public concern as to the performance or safety of products that we or others have developed or sold;
- Failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by securities analysts or major stockholders;
- Governmental regulation;
- Clinical results with respect to our products in development or those of our competitors;
- Changes in the level of competition;
- Loss of or declines in sales to major distributors or customers;
- The relatively low trading volume for our Common Stock;
- Period to period fluctuations in our operating results;
- General market and economic conditions; and
- Terrorist attacks, civil unrest, war and national disasters.

Future Sales by Existing Stockholders, Executive Officers or Directors Could Depress the Market Price of Our Common Stock and Make It More Difficult For Us to Sell Stock in the Future.

Sales of our Common Stock in the public market, or the perception that such sales could occur, could negatively impact the market price of our Common Stock. We are unable to estimate the number of shares of our

Common Stock that may actually be resold in the public market since this will depend on the market price for our Common Stock, the individual circumstances of the sellers and other factors.

We have a number of institutional stockholders that own significant blocks of our Common Stock. If one or more of these stockholders sell large portions of their holdings in a relatively short time, for liquidity or other reasons, the prevailing market price of our Common Stock could be negatively affected. In addition, it is possible that one or more of our executive officers or members of our Board of Directors could sell shares of our Common Stock during an open trading window under our Insider Trading Policy. These transactions and the perceived reasons for these transactions could have a negative effect on the prevailing market price of our Common Stock.

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 creation or interpretation by the Financial Accounting Standards Board, the Securities and Exchange Commission and various bodies formed to interpret and create appropriate accounting principles. A change in these principles 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.

Risks Relating to Intellectual Property

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

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

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

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 amounts. 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.

We are Involved in Pending, and May Become Involved in Future, Intellectual Property Infringement Disputes, Which are Costly and Could Limit or Eliminate Our Ability to Sell Our Products or Use Certain of Our Technologies in the Future.

From time to time, we may seek to enforce our patents or other intellectual property rights through litigation. In addition, there are a large number of patents and patent applications in our product areas, and additional patents may be issued to third parties relating to our product areas. We may be sued for infringement of patents or misappropriation of other intellectual property rights with respect to one or more of our products. Litigation in our industry regarding patent and other intellectual property rights is prevalent and is expected to continue.

Our involvement in litigation with respect to patents or other intellectual property or to determine rights in proprietary technology, either as a plaintiff or defendant, could adversely affect our revenues, market share, results of operations and business because:

- As is common with major litigation, it could consume a substantial portion of managerial and financial resources;
- Its outcome would be uncertain and a court may find that our patents are invalid or unenforceable in response to claims by another party or that the third-party patent claims are valid and infringed by our products;
- An adverse outcome could subject us to the loss of the protection of our patents or to liability in the form of past royalty payments, penalties, special and punitive damages, or future royalty payments significantly affecting our future earnings;
- Failure to obtain a necessary license upon an adverse outcome could prevent us from selling our current products or other products we may develop; and
- A court could award a preliminary and/or permanent injunction which would prevent us from selling our current or future products.

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

Our OraQuick® test is a lateral flow assay device that tests for specific antibodies or other substances. The term "lateral flow" generally refers to a test strip through which a sample flows and which 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 or sell the OraQuick® test in the United States or other countries where these patents are in force.

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 and it is possible that a third party could seek to enforce one or more lateral flow patents against us. In the event that we are unable to successfully defend against such litigation or it is determined that a license is required and it is not possible to negotiate or otherwise obtain a license agreement on reasonable terms under a necessary patent, our ability to manufacture and sell the OraQuick® device could be limited. In such case, we may be able to modify the OraQuick® test such that a license would not be necessary. However, this alternative could delay or limit our ability to sell the OraQuick® test in the United States and other markets, which would adversely affect our results of operations, cash flows and business.

Risks Relating to Products, Marketing and Sales

A Market for Our Products May Not Develop.

Our future success will depend, in part, on the market acceptance, and the timing of such acceptance, of our products such as the OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test, the Intercept® drug test, and other new products or technologies that may be developed or acquired. 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. There may be 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 obtain market acceptance and fill the market need that is perceived to exist.

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

We have made significant progress in gaining acceptance of oral fluid testing for HIV in the insurance and public health markets. We have also made significant progress in gaining acceptance of oral fluid testing for drugs of abuse in the workplace and criminal justice testing markets. However, the ultimate degree of acceptance in these markets is uncertain, and other markets may resist the adoption of oral fluid 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 or the rapid, point-of-care testing for HIV. As a result, there can be no assurance that we will be able to expand the use of our oral fluid testing products in these or other markets.

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

We may be held liable if any of our products, or any product which is made with the use or incorporation of any of our technologies, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. Although we have obtained product liability insurance, this insurance may not fully cover potential liabilities. As we bring new products to market, we may need to increase our product liability coverage.

We are selling cryosurgical wart removal products in the consumer or OTC market in the United States, Canada, and Europe. We expect to expand the OTC sales of these products to other countries and to eventually distribute other types of products, such as our OraQuick® *ADVANCE*™ HIV-1/2 test. We believe the sale of products in the OTC market increases the risk of potential product liability exposure and the required level of insurance coverage that we will need to maintain. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could affect our decision to commercialize new products and our results of operations.

Performance of Our Products May Affect Our Revenues and Stock Price.

Our products are generally sold with labeling that contains performance claims approved or cleared by the FDA or other regulators. If our products fail to perform in accordance with the applicable label claims or otherwise in accordance with the expectations or needs of our customers, customers may switch to a competing

product or otherwise stop using our products, and our revenues could be adversely affected. In addition, poor performance by one or more of our products and publicity surrounding such performance could have an adverse effect on our reputation, our continuing ability to sell products and the prevailing market price of our Common Stock.

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

We intend to increase revenue derived from international sales of our products. Our international sales accounted for $9.5 million or 14% of total revenues for 2005, $6.2 million or 11% of total revenues for 2004, and $4.6 million or 11% of total revenues for 2003.

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 countries;
- 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;
- The inability to maintain ISO certification for our or our suppliers' manufacturing facilities could preclude, interrupt or delay our ability to manufacture products for sale in Europe or other international territories;
- Our ability to obtain the CE mark on our products in a timely manner may preclude or delay our ability to sell products in the European Union;
- Cultural and political differences may make it difficult to effectively market, sell and gain acceptance of products in foreign countries;
- 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, war and natural disasters may slow or limit our ability to sell our products in foreign countries;
- International markets often have long sales cycles, especially for 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 addition, we have entered into a contract for the manufacture and supply of the OraQuick® test in Thailand, and the Histofreezer® and Freeze Off® cryosurgical products are currently manufactured in The Netherlands. We may enter into agreements to manufacture other products in foreign countries as well. However, 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. In addition, foreign currency fluctuations and economic conditions in foreign countries could increase the costs of manufacturing our products in foreign countries.

ITEM 1B. Unresolved Staff Comments.

Not Applicable.

ITEM 2. Properties.

We lease an approximate 48,000 square foot facility, which is our primary corporate office and manufacturing facility, 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. We currently intend to exercise our option to purchase this facility.

We also lease 21,430 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 this lease, which ends in March 2010, is $271,000. The lease also has a ten-year purchase option. We currently intend to exercise our option to purchase this facility.

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

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.

On July 23, 2004, we filed a lawsuit against Schering-Plough Healthcare Products, Inc. for infringement of several of our patents relating to technology for the cryosurgical removal (i.e., freezing) of warts and other benign skin lesions. The suit was commenced in the United States District Court for the Eastern District of Pennsylvania, and alleges that Schering-Plough's manufacture and sale of its Dr. Scholls® Freeze Away™ cryosurgical wart removal product in the United States OTC market infringes the following United States patents: Nos. 5,738,682; 6,092,527 and 4,865,028. We are requesting permanent injunctive relief and the payment of damages. Schering-Plough has asserted various defenses in this matter, including that its Dr. Scholls® Freeze Away™ product does not infringe our patents and that one or more of our patents are invalid and unenforceable.

In November 2004, a Court held a Markman hearing in order to determine as a matter of law the meaning of certain terms and phrases in the claims in our patents which are relevant to an infringement determination. The Court issued a final decision from the Markman hearing in August 2005. Since that time, the period for fact discovery and discovery from expert witnesses has closed.

On November 2, 2005, an initial pretrial conference was held on this matter, at which the Court heard oral argument on motions for summary judgment and certain evidentiary and other motions filed by the parties. We expect the Court to rule on these motions and to set a final trial schedule in the near future.

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, 2005.

PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

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,			
	2005		2004	
	High	Low	High	Low
First Quarter	$ 7.45	$5.35	$12.00	$7.20
Second Quarter	10.23	6.91	10.63	6.65
Third Quarter	11.83	8.42	9.73	5.19
Fourth Quarter	14.14	7.74	7.52	5.54

On March 1, 2006, there were 589 holders of record and approximately 16,000 holders in street name of the Common Stock, and the closing price of the Common Stock was $9.73 per share. We have never paid any cash dividends, and our 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. 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,				
	2005	2004	2003	2002	2001
Operating Results:					
Revenues	$ 69,366	$54,008	$40,451	$32,010	$32,573
Costs and expenses	61,793	55,365	41,737	35,550	36,906
Operating income (loss)	7,573	(1,357)	(1,286)	(3,540)	(4,333)
Other income (expense), net	2,146	797	177	198	634
Income tax (benefit) provision	(17,729)[1]	—	27	—	29
Net income (loss)	27,448[1]	(560)	(1,136)	(3,342)	(3,728)
Earnings (loss) per share					
Basic	$ 0.61	$ (0.01)	$ (0.03)	$ (0.09)	$ (0.10)
Diluted	$ 0.59	$ (0.01)	$ (0.03)	$ (0.09)	$ (0.10)
Shares used in computing earnings (loss) per share					
Basic	45,110	44,464	39,794	37,583	36,868
Diluted	46,147	44,464	39,794	37,583	36,868
Cash Flow:					
Cash flow from operating activities	$ 10,392	$ 3,438	$ 2,702	$ (518)	$ (5,256)

	December 31,				
	2005	2004	2003	2002	2001
Financial Position:					
Cash, cash equivalents, and short-term investments	$ 77,620	$ 66,723	$ 64,024	$ 14,908	$ 15,191
Working capital	90,670	68,910	67,171	18,931	19,764
Deferred tax asset	26,708	—	—	—	—
Total assets	130,747	88,064	86,151	35,737	37,285
Long-term debt, excluding current portion	884	1,334	2,456	3,409	3,586
Accumulated deficit	(103,682)	(131,130)	(130,570)	(129,435)	(126,092)
Stockholders' equity	118,919	75,577	73,509	26,019	26,541

[1] Includes an income tax benefit of $18.2 million resulting from the elimination of a significant portion of the valuation allowance on our deferred tax assets (see Note 9 to the Notes to Financial Statements).

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 Item 1A, entitled "Risk Factors," and elsewhere in this Annual 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.

Overview

Our Company operates primarily in the worldwide $22 billion *in vitro* diagnostics business. 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. We also manufacture and sell medical devices for the removal of warts and other benign skin lesions by cryosurgery, or freezing.

Our diagnostic product offerings primarily target the infectious disease and substance abuse testing segments of the larger *in vitro* diagnostic market, and are used in both laboratories as well as the emerging, and rapidly growing, point-of-care marketplace. Our OraSure® and Intercept® oral fluid collection devices, and their related assays, are processed in a laboratory, while the OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test is designed for use at the point-of-care. Our cryosurgical products are also used at the point-of-care.

In vitro diagnostics have traditionally used blood or urine as the bodily fluids upon which tests are conducted. However, we have targeted the use of oral fluid in our products as a differentiating factor, and believe that it provides a significant competitive advantage over blood and urine. Our oral fluid tests have sensitivity and specificity comparable to blood and/or urine tests and, when combined with their ease of use, non-invasive and dignified nature, and cost effectiveness, represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

We have made significant progress in increasing our sales and gaining market acceptance for our products. As a result, we reported strong financial results for 2005, our first profitable year. Our total revenues were $69.4 million, or an increase of 28% over 2004, and our net income for the year was $27.4 million. Net income includes $18.2 million associated with a deferred tax benefit recorded in the fourth quarter, partially offset by a $436,000 current tax provision. Our liquidity also improved, as we reported $10.4 million in cash flow from operating activities in 2005 and we had $77.6 million in cash, cash equivalents and short-term investments as of December 31, 2005.

Sales into the infectious disease testing market segment increased significantly in 2005 due to the continued market acceptance of our OraQuick® test. This increase resulted largely from sales directly to various public health organizations, sales to Abbott Laboratories for distribution primarily to hospitals, sales to the Substance Abuse and Mental Health Services Administration ("SAMHSA") and Centers for Disease Control and Prevention ("CDC") for further distribution in the public health market, and sales into the international marketplace.

During the period March—June 2004, we received FDA approval of our OraQuick® *ADVANCE*™ test to detect antibodies to both HIV-1 and HIV-2 in oral fluid, finger-stick whole blood, venous whole blood, and plasma samples. In June 2004, we also obtained a CLIA waiver for the OraQuick® *ADVANCE*™ HIV-1/2 test for all specimen types except plasma. This new product was officially launched commercially in October 2004. Since that time, the demand for OraQuick® *ADVANCE*™ has grown quickly, and in 2005 we converted all OraQuick® customers to this new product and have recently ceased selling our original OraQuick® HIV-1 test.

In June 2004, we received a nonexclusive, worldwide sublicense to certain HIV-2 patents held by Bio-Rad Laboratories. We believe that the OraQuick® *ADVANCE*™ test, provides a significant competitive advantage by allowing us to sell a versatile rapid HIV test that is capable of detecting antibodies to both the HIV-1 and HIV-2 strains of the virus in oral fluids, finger-stick whole blood, venous whole blood and plasma.

In 2004, the CDC and SAMHSA ordered a total of $6.3 million of OraQuick® *ADVANCE*™ devices and related testing materials. We expect that these agencies, and perhaps other federal governmental agencies, may make future bulk purchases of OraQuick® *ADVANCE*™ for further distribution to the public health and other markets throughout the United States. Failure to receive, or any delays in receiving, additional bulk orders for OraQuick® *ADVANCE*™ from these government agencies could adversely affect our financial performance.

In February 2005, we entered into an agreement for the distribution of OraQuick® *ADVANCE*™ with Abbott Laboratories. Under this agreement, Abbott was appointed as our exclusive distributor in the U.S. hospital market and as a non-exclusive distributor in the U.S. physicians' office marketplace. As our exclusive distributor to hospitals, Abbott sells OraQuick® *ADVANCE*™ to federal hospitals under the terms and conditions of our Federal Supply Schedule that is filed with the U.S. General Services Administration. We have retained exclusive rights to all other markets, including the public health and criminal justice markets, the military, the CDC, SAMHSA and other government agencies. We utilize a small internal sales force to support Abbott and work together with them to maximize the penetration of OraQuick® *ADVANCE*™ in the hospital market.

The markets for rapid HIV testing are very competitive and the level of competition is expected to increase, which could affect sales of our OraQuick® tests. For example, the Ortho Diagnostics division of Johnson & Johnson, Bio-Rad Laboratories, Abbott and bioMerieux, Inc. each sell competing laboratory-based HIV-1 enzyme immunoassays ("EIAs"), and Maximum Biomedical (formerly Calypte, Inc.) sells an HIV-1 screening test for urine, in the United States. In addition, MedMira and Trinity Biotech have each received FDA approval to sell competing rapid HIV-1 blood tests, and Bio-Rad Laboratories received FDA approval for a rapid HIV-1/2 blood test. Under their current FDA approvals, these tests compete with our OraQuick® *ADVANCE*™ test in the hospital or other laboratory settings. In addition, Trinity Biotech has received CLIA waiver for its rapid finger-stick HIV-1 blood test, and this test competes with our OraQuick® *ADVANCE*™ test in markets outside of the traditional hospital and laboratory settings. These companies, or others, may continue to expand the bodily fluids with which a rapid HIV test may be performed or develop and commercialize new rapid tests, either of which would provide further competition for our OraQuick® *ADVANCE*™ test.

Sales to the substance abuse testing market also increased during 2005, reflecting the growing acceptance of our Intercept® collection device and related oral fluid drug assays, as corporate and criminal justice customers continued to shift to oral fluid and away from traditional urine-based drug testing. This increase was partially offset by lower sales of our drug assays to the forensic toxicology market and lower sales of our UP*link*® product. We expect continuing growth in the utilization of our Intercept® product line, primarily in the United States and United Kingdom.

In April 2004, SAMHSA published proposed guidelines that would, if adopted, include oral fluid testing as an accepted drug testing method for federal employees. We have responded to SAMHSA's proposed guidelines with a comment letter and await the final guidelines that will apply to our Intercept® drugs of abuse testing product. We are unable to predict at this time whether additional modifications may be required to bring our Intercept® product into compliance with the guidelines when finally adopted or what affect, if any, non-compliance with the final guidelines will have on our product offerings. Compliance with the guidelines will be required in order for us to sell our drug testing products to federal employees and possibly other industries that are influenced by the federal guidelines in structuring their drug testing programs.

As part of the strategic business review we completed in late 2004, we concluded that the roadside drugs-of-abuse testing market for UP*link*® may not be as attractive as a number of other opportunities we are pursuing. During the first six months of 2005, we explored our options with respect to the UP*link*® product,

including transitioning the manufacturing of the product to our distribution partner, Dräger Safety. Throughout this period, we were not able to reach an agreement with Dräger Safety or determine an alternative outlet for this product. In addition, we were advised that Dräger would no longer promote the sale of the UP*link*® product. As a result, we recorded a $1.5 million charge in June 2005 to reflect a provision on inventory and fixed assets related to our UP*link*® product. We subsequently terminated our existing research, development and distribution agreements with Dräger for the UP*link*® product.

Sales to the cryosurgical systems market during 2005 have also grown, primarily as a result of our launch into the international over-the-counter ("OTC") market. The cryosurgical systems market represents sales of Histofreezer® into both the domestic and international physicians' office markets and sales of the OTC formulation of this product to both our domestic distributor, a subsidiary of Prestige Brands Holdings, Inc. ("Prestige"), and our international distributor, SSL International plc ("SSL"). Prestige distributes Freeze Off™ to consumers under its Compound W® trademark in the OTC market in the United States and Canada, and is the owner of both tradenames. In June 2005, we entered into an agreement with SSL under which we manufacture and supply, and SSL distributes on an exclusive basis, the Company's cryosurgical wart removal product in the OTC market in Europe, Australia and New Zealand. The product is manufactured and sold under SSL's Scholl and Dr. Scholl trademarks, and was initially available for retail purchase in pharmacies and retail outlets in several European countries in the fourth quarter of 2005. The product is also expected to be made available for retail purchase in other countries during 2006.

In July 2004, we filed a lawsuit against Schering-Plough Healthcare Products, Inc. ("Schering-Plough") for infringement of several of our patents relating to the technology for the cryosurgical removal (i.e., freezing) of warts and other benign skin lesions. The suit was commenced in the United States District Court for the Eastern District of Pennsylvania, and alleges that Schering-Plough's manufacture and sale of its Dr. Scholl's® Freeze Away™ cryosurgical wart removal product in the over-the-counter market infringes three of our patents. We are seeking injunctive relief and the payment of damages, and Schering-Plough has raised several defenses, including that their Freeze Away™ device does not infringe our patents and that one or more of our patents are either invalid or unenforceable. On November 2, 2005, a pretrial conference was held in this matter, at which the Court heard oral argument on motions for summary judgment filed by the parties. We expect the Court to rule on these and other motions and to set a new trial schedule in the near future.

Sales to the insurance risk assessment market continued to decline in 2005, primarily because of a reduction in the number of applications for life insurance and changes in underwriting requirements. In addition, our insurance testing assays have experienced substantial competitive pressure from "home-brew" assays internally developed by our customers. Revenues to this market are expected to continue to decline or at best remain at approximately the levels attained in 2005 unless we are successful in developing and commercializing new oral fluid based diagnostic tests for additional predictive health markers desired by the insurance industry.

During 2004, we received all necessary FDA approvals to transfer the manufacture of our Intercept® and OraSure® collection devices and our oral fluid Western blot HIV-1 confirmatory test from Oregon to our facilities in Bethlehem, Pennsylvania. This transfer was completed and has reduced our annual operating expenses and improved our ability to control the quality of the transferred products. In January 2005, the lease on our Oregon facility expired and all operations at that location ceased. The absence of this lease also reduced our operating expenses in 2005.

Because of the regulatory approvals needed for most of our products, we often are required to rely on sole source providers for critical components and materials and on related products supplied by third parties. This is particularly true for our OraQuick® *ADVANCE*™ test, our OraSure® oral fluid collection device and our oral fluid Western blot HIV-1 confirmatory product. If we are unable to obtain necessary components or materials from these sole sources, the time required to develop replacements and obtain the required FDA approvals could disrupt our ability to sell the affected products. Any delay or interruption in our ability to manufacture the oral fluid Western blot HIV-1 confirmatory test would adversely affect sales of our OraSure® oral fluid collection device, as our customers are not expected to purchase OraSure® devices if an oral fluid Western blot HIV-1

confirmatory test is not readily available. In addition, if the HIV-1 EIA approved by the FDA for use with our OraSure® collection device, which is manufactured by a third party, is either unavailable or experiences quality or performance problems, sales of our OraSure® device could be adversely affected.

We generated 86% of our 2005 revenues in the U.S. marketplace. Consequently, we are evaluating strategies to increase our sales penetration in markets outside the U.S. As our business in foreign countries increases, we will be exposed to additional risks, including economic, political, exchange rate, regulatory and cultural risks.

Results of Operations

Twelve Months Ended December 31, 2005 Compared to December 31, 2004

Total revenues increased 28% to $69.4 million in 2005 from $54.0 million in 2004, primarily as a result of increased sales of our OraQuick® *ADVANCE*™ rapid HIV-1/2 antibody test, our Intercept® oral fluid collection device and related drug assays, and our international OTC cryosurgical product, partially offset by declines in domestic OTC cryosurgical product revenues and assay revenues in the insurance risk assessment market. Revenues derived from products sold in countries outside the U.S. were $9.5 million and $6.2 million, or 14% and 11% of total revenues for the years ended December 31, 2005 and 2004, respectively.

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.

	Years ended December 31,				
	Dollars		%	Percentage of Total Revenues	
Market	2005	2004	Change	2005	2004
Infectious disease testing	$25,988	$15,526	67%	37%	29%
Substance abuse testing	13,519	10,108	34	19	19
Cryosurgical systems	22,744	20,193	13	33	37
Insurance risk assessment	6,815	7,777	(12)	10	14
Product revenues	69,066	53,604	29	99	99
Licensing and product development	300	404	(26)	1	1
Total revenues	$69,366	$54,008	28%	100%	100%

Sales to the infectious disease testing market increased 67% to $26.0 million in 2005, primarily as a result of higher sales of our OraQuick® rapid HIV-1/2 antibody test. OraQuick® and OraSure® sales during 2005 totaled $21.6 million and $4.4 million, respectively, as compared to $10.2 million and $5.3 million, respectively, for 2004.

The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during 2005 and 2004.

	Years ended December 31,		%
Customers	2005	2004	Change
Direct to U.S. Public Health	$ 8,292	$ 4,093	103%
Abbott	4,928	1,983	149
SAMHSA	3,742	—	N/A
CDC	2,322	2,327	—
International	1,528	1,178	30
Direct to Hospitals	741	649	14
Total OraQuick® revenues	$21,553	$10,230	111%

During 2004, we received a total of $6.3 million in purchase orders from the CDC and SAMHSA for OraQuick® *ADVANCE* rapid HIV-1/2 antibody tests, of which $6.1 million and $72,000 were shipped in 2005 and 2004, respectively. As of December 31, 2005, all shipments have been completed under the CDC purchase order and $242,000 remains to be shipped under the SAMHSA purchase order. We expect to complete shipment of the remaining devices pursuant to the SAMHSA purchase order in early 2006.

We believe that our OraQuick® *ADVANCE*™ device, which is FDA-approved for detecting antibodies to both HIV-1 and 2 in oral fluid, finger-stick and venous whole blood, and plasma samples, and is CLIA-waived for use with all sample types except plasma, provides a significant competitive advantage and will allow us to more fully implement a strategy to sell OraQuick® internationally. We are currently pursuing CE marking for our OraQuick® *ADVANCE*™ product which would allow us to sell our product in Europe. Our goal is to obtain a CE mark for OraQuick® *ADVANCE*™ in the next several months, and then obtain several country-specific registrations in order to permit the launch of this product in Europe in the second half of 2006.

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

Sales to the substance abuse testing market increased 34% to $13.5 million in 2005, as a result of higher sales of our Intercept® oral fluid collection device and related drug assays in all marketplaces.

The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market during 2005 and 2004.

	Years ended December 31,		%
Market	**2005**	**2004**	**Change**
Workplace testing	$ 5,664	$3,030	87%
Criminal Justice	2,545	1,566	63
International	1,918	1,684	14
Direct	562	378	49
Total Intercept® revenues	$10,689	$6,658	61%

We expect continued growth in Intercept® sales in 2006 as customers continue to shift from urine-based to oral-fluid based testing methods.

Revenues from our UP*link*® rapid point-of-care oral fluid drug detection system were $286,000 and $564,000 in 2005 and 2004, respectively. As part of a strategic business review we completed in late 2004, we concluded that the roadside drugs-of-abuse testing market for UP*link*® may not be as attractive as a number of other opportunities we are pursuing. During the first half of 2005, we explored our options with respect to the UP*link*® product, including transitioning the manufacturing of the product to our distribution partner, Dräger Safety. Throughout this period, we were not able to reach an agreement with Dräger Safety or determine an alternative outlet for this product. In addition, we were advised that Dräger will no longer promote the sale of the UP*link*® product. As a result, we recorded a $1.5 million charge in June 2005 to reflect a provision on inventory and fixed assets related to our UP*link*® product. We subsequently terminated our existing research, development and distribution agreements with Dräger for the UP*link*® product.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 13% to $22.7 million in 2005. This increase was primarily due to the international

launch of our OTC cryosurgical product pursuant to our agreement with SSL, the launch of the Freeze Off™ product by Prestige in Canada, and an increase in sales of Histofreezer® to United States physicians' offices. This increase was partially offset by a reduction in sales of the Freeze Off™ product to Prestige for distribution in the United States, to $10.6 million in 2005, compared to $13.3 million during 2004.

The Freeze Off™ product is being sold under Prestige's Compound W® trademark. The five-year distribution agreement with Prestige, which was initiated in 2003, requires minimum purchases of at least $2.0 million each year over the life of the contract in order for Prestige to maintain its exclusive distribution rights to the OTC market in the United States. During the second half of 2005, Prestige also launched our OTC cryosurgical product in Canada. Sales of our cryosurgical product to Prestige for distribution in Canada were $1.0 million in 2005.

In June 2005, we entered into an agreement with SSL under which we manufacture and supply, and SSL distributes on an exclusive basis, the Company's cryosurgical wart removal product in the OTC footcare market in Europe, Australia and New Zealand. The product is manufactured and sold under SSL's Scholl and Dr. Scholl trademarks, and was made initially available for retail purchase in pharmacies and retail outlets in several European countries during the fourth quarter of 2005. Sales to SSL under the distribution agreement were $3.2 million in 2005. SSL continues to build distribution networks in pharmacies and mass merchandisers throughout Europe and expects to launch the OTC product in several other countries during 2006. We expect revenues from SSL to increase significantly in 2006. We expect domestic and international sales of OTC cryosurgical products to our distributors to approximate $3.3 million in the first quarter of 2006.

Sales of our Histofreezer® product to physicians' offices in the U.S. and international markets increased 13% and 28% to $5.9 million and $2.1 million, respectively, in 2005, when compared to 2004, primarily as a result of higher distributor purchases. We anticipate that U.S. sales of Histofreezer® in the professional market will continue to increase in 2006. Revenues in the international market are expected to increase above 2005 levels as we increase prices in certain countries and secure additional distributors in countries where the product is currently not sold.

We are beginning to see some evidence that sales of our OTC cryosurgical products may reduce the number of individuals that will seek to obtain treatment of their warts by a physician, which in turn could negatively affect sales of our Histofreezer® product in the professional market. However, it is not possible at this time to estimate the magnitude of the financial impact of this change.

Sales to the insurance risk assessment market declined by 12% to $6.8 million in 2005 from $7.8 million in 2004, primarily as a result of decreased OraSure® device purchases by our insurance lab testing partners. We believe this decrease is a result of an overall reduction in life insurance application activity in the United States and changes in underwriting requirements. As a result, we currently expect that our 2006 revenues in this market segment will decline or at best remain at approximately the levels attained in 2005.

We currently have two customers, Prestige and Quest Diagnostics (including its wholly-owned subsidiary, Lab*One*, Inc.), which accounted for 17% and 13% of total revenues for 2005, respectively.

Licensing and product development revenues decreased 26% to $300,000 in 2005, from $404,000 in the comparable period in 2004. Licensing and product development revenues in both years were primarily related to our collaborative UPT™ and oral fluid research project with the University of Pennsylvania and New York University, under a grant awarded by the National Institutes of Health. The current annual phase of this grant expires in June 2006. Our share of funding under the current annual phase is expected to be $250,000, of which $35,000 was recorded in 2005. Further revenues beyond June 2006 will depend on progress achieved in the research, the level of future funding awarded by the National Institutes of Health, and the Company's decisions regarding the future of UPT™.

The Company's gross margin was 60% in 2005, compared to 59% in 2004. Our 2005 gross margin was positively impacted by more efficient utilization of the Company's manufacturing capacity and renegotiated terms for the assembly and supply of the U.S. OTC cryosurgical product, offset by a less favorable product sales mix and the $1.5 million charge related to the Company's UP*link*® assets. Gross margin is expected to increase in 2006 as a result of increased manufacturing efficiencies, increased prices on certain products, and continued efforts to reduce costs, partially offset by stock option and other non-cash stock compensation expense.

Research and development expenses decreased 13% to $5.3 million in 2005, from $6.1 million in 2004, primarily as a result of lower overall staffing costs and lower expenses for clinical trials, partially offset by fees paid and restricted stock granted to recruit and relocate the Company's new Chief Science Officer and Senior Vice President, Regulatory Affairs/Quality Assurance. Research and development costs are expected to increase in 2006 primarily as a result of costs associated with the development of new product offerings and product enhancements for the infectious disease and substance abuse markets and the expensing of stock options.

Sales and marketing expenses increased 6% to $16.1 million in 2005 from $15.2 million in 2004. This increase was primarily the result of increased levels of staffing, market research, travel and commissions, partially offset by lower advertising expenses. Included in advertising expenses was $1.8 million and $2.9 million for 2005 and 2004, respectively, paid to Prestige as reimbursement for marketing expenses incurred for the Compound W® Freeze Off™ product. We expect that sales and marketing expense will increase in 2006 as we attempt to increase our presence in the international marketplace and expand market awareness and acceptance for our OraQuick®, Intercept® and Histofreezer® products. Pursuant to our agreement with Prestige, we will continue to co-invest in Prestige's marketing activities for the Compound W® Freeze Off™ product, and we will reimburse Prestige, through 2006, for a portion of Prestige's out-of-pocket costs of advertising and promoting this product in the OTC market.

General and administrative expenses increased 4% to $12.5 million in 2005 from $12.0 million in 2004. This increase was primarily attributable to legal fees associated with the Schering-Plough litigation, increased amortization of restricted stock grants to management, and increased staffing related expenses. This increase was partially offset by a reduction in consulting expenses, a reduction in transition expenses related to the Company's former Chief Executive Officer, and a reduction in rent expense due to the expiration of the lease for our Oregon facilities in January 2005. Legal fees associated with the Schering-Plough patent infringement litigation were $2.4 million and $1.2 million in 2005 and 2004, respectively. General and administrative expenses are expected to increase further in 2006 compared to 2005 as a result of the adoption of stock option expensing, increased non-cash stock compensation expense, and expenses related to the implementation of a new enterprise resource planning system.

Interest expense decreased to $97,000 in 2005 from $134,000 in 2004, as a result of lower outstanding debt balances. Interest income increased to $2.2 million in 2005 from $984,000 in 2004, as a result of higher yields on our investment portfolio and larger balances available for investment.

A gain on foreign currency transactions of $57,000 was recorded for the year ended December 31, 2005, versus a loss on foreign currency transactions of $53,000 recorded for the year ended December 31, 2004.

During the year ended December 31, 2005, a net income tax benefit of $17.7 million was recorded, while no provision or benefit was recorded in 2004. The tax benefit recorded during 2005 reflects the release of a significant portion of the valuation allowance on our deferred tax asset. At December 31, 2005, the Company had federal net operating loss ("NOL") carryforwards of $66.6 million. Our ability to use the NOLs and tax credit carryforwards to offset future income tax obligations could be limited by changes in the ownership of the Company's capital stock. Internal Revenue Code Section 382 ("Section 382") contains provisions that limit the amount of NOLs and tax credit carryforwards that can be used in any given year, in the event of a significant ownership change. In the fourth quarter of 2005, the Company engaged in an analysis, with the assistance of independent tax specialists, to determine if any Section 382 ownership changes have occurred that would limit

the amount of NOLs that could be utilized to offset future taxable income. As a result of this analysis, the Company concluded that prior period ownership changes may impose a limitation on the amount of NOLs that can be utilized in a given year. The Company does not believe, however, that this limitation will impair our future ability to utilize NOLs to offset our forecasted taxable income or to realize the related deferred tax asset.

Prior to December 31, 2005, a valuation allowance had been established for the full amount of the deferred tax asset created by these carryforwards and other items. Based on current year and forecasted taxable earnings, a significant portion of the valuation allowance was released in the fourth quarter of 2005, resulting in the recognition of $26.7 million of the deferred tax asset of which $18.2 million was recorded as an income tax benefit in the statement of operations and $8.5 million was recorded directly as an increase in stockholders' equity. Partially offsetting this benefit was an income tax provision of $436,000 that was recorded for the year ended December 31, 2005 related to certain state income taxes and federal alternative minimum tax. We expect our effective tax rate will be 39% for the year ending December 31, 2006.

Twelve Months Ended December 31, 2004 Compared to December 31, 2003

Total revenues increased 34% to $54.0 million in 2004 from $40.5 million in 2003, primarily as a result of increased sales of our Freeze Off™ cryosurgical wart removal product, OraQuick® rapid HIV-1 antibody test and Intercept® oral fluid collection device and related drug assays, partially offset by a decline in assay revenues in the insurance risk assessment market. Revenues derived from products sold in countries outside the U.S. were $6.2 million and $4.6 million, or 11% and 11% of total revenues for the years ended December 31, 2004 and 2003, respectively.

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.

	Years ended December 31,				
	Dollars		%	Percentage of Total Revenues	
Market	2004	2003	Change	2004	2003
Infectious disease testing	$15,526	$11,909	30%	29%	29%
Substance abuse testing	10,108	7,295	39	19	18
Cryosurgical systems	20,193	10,828	86	37	27
Insurance risk assessment	7,777	9,708	(20)	14	24
Product revenues	53,604	39,740	35	99	98
Licensing and product development	404	711	(43)	1	2
Total revenues	$54,008	$40,451	34%	100%	100%

Sales to the infectious disease testing market increased 30% to $15.5 million in 2004, primarily as a result of higher sales of our OraQuick® rapid HIV-1 antibody test. OraQuick® and OraSure® sales during 2004 totaled $10.2 million and $5.3 million, respectively, as compared to $6.3 million and $5.6 million, respectively, for 2003.

The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during 2004 and 2003.

Customers	Years ended December 31, 2004	2003	% Change
Direct to U.S. Public Health	$ 4,093	$3,965	3%
CDC	2,327	—	N/A
Abbott	1,983	1,653	20
International Marketplace	1,178	680	73
Direct to Hospitals	649	—	N/A
Total OraQuick® revenues	$10,230	$6,298	62%

Sales to the substance abuse testing market increased 39% to $10.1 million in 2004 as a result of higher sales of our Intercept® oral fluid collection device and related drug assays.

The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market during 2004 and 2003.

Market	Years ended December 31, 2004	2003	% Change
Workplace testing	$3,030	$1,783	70%
Criminal Justice	1,566	1,133	38
International	1,684	1,246	35
Direct	378	333	14
Total Intercept® revenues	$6,658	$4,495	48%

In April 2004, we launched our UP*link*® rapid oral fluid drug detection system, including assays for the detection of drugs of abuse commonly identified by the National Institute for Drug Abuse ("NIDA") as the NIDA-5 (i.e., cocaine, opiates, amphetamines/methamphetamines, PCP and marijuana) with our partner, Dräger Safety. This product was initially sold to the roadside testing market in Europe. Revenues from this product were $564,000 in 2004.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 86% to $20.2 million in 2004. This increase was primarily the result of an increase of $8.3 million in sales of our domestic OTC cryosurgical product, called Freeze Off™, to Prestige, the owner of the Compound W® line of wart removal products. In 2003, we entered into a distribution agreement with Prestige following receipt of FDA 510(k) clearance for the sale of our cryosurgical system in the OTC market in the U.S. and Canada. Prestige launched the Freeze Off™ product in the third quarter of 2003, and there were $5.0 million of sales to Prestige during 2003.

Freeze Off™ is being sold under Prestige's Compound W® trademark. Our five-year distribution agreement requires minimum purchases by Prestige of at least $2.0 million each year over the life of the contract in order for Prestige to maintain its exclusive distribution rights to the OTC market in the U.S.

Sales of our Histofreezer® product to physicians' offices in the U.S. and international markets increased 21% and 7% to $5.2 million and $1.7 million, respectively, in 2004, when compared to 2003, primarily as a result of higher distributor purchases.

Sales to the insurance risk assessment market declined by 20% to $7.8 million in 2004 from $9.7 million in 2003, primarily as a result of lower insurance testing assay sales. Sales of our urine assays have come under competitive pressure because of sluggish sales and competitive conditions in the life insurance testing market. As a result of these conditions, our laboratory customers eliminated or reduced their purchases of these products and instead use lower cost, internally-developed (i.e., "home-brew") assays or testing products purchased from our competitors.

Prestige accounted for approximately 25% and 12% of total revenues for 2004 and 2003, respectively. Lab*One*, Inc. accounted for approximately 12% and 17% of total revenues for 2004 and 2003, respectively.

Licensing and product development revenues decreased 43% to $404,000 in 2004, from $711,000 in the comparable period in 2003. Licensing and product development revenues in 2004 were primarily related to our collaborative UPT™ and oral fluid research project with the University of Pennsylvania, under a grant awarded by the National Institutes of Health.

The Company's gross margin was 59% in 2004, compared to 60% in 2003. Our 2004 gross margin was positively impacted by more efficient utilization of the Company's manufacturing capacity, offset by higher production costs associated with the Company's UP*link*® rapid oral fluid drug detection system, a less favorable product sales mix, and higher scrap as a result of the transfer of manufacturing operations from Oregon to Pennsylvania.

Research and development expenses decreased 24% to $6.1 million in 2004, from $8.0 million in 2003, primarily as a result of lower staffing costs and costs associated with transferring our manufacturing operations from Oregon to Pennsylvania.

Sales and marketing expenses increased 41% to $15.2 million in 2004 from $10.8 million in 2003. This increase was primarily the result of higher product advertising expenditures, costs associated with our hospital sales force and increased staffing related expenses. Included in advertising expenses was $2.9 million and $1.1 million for 2004 and 2003, respectively, paid to Prestige as reimbursement for marketing expenses incurred for the Compound W® Freeze Off™ product.

General and administrative expenses increased 74% to $12.0 million in 2004 from $6.9 million in 2003. This increase was primarily attributable to legal fees associated with the Schering-Plough litigation, transition costs related to the retirement of our former Chief Executive Officer and the additional costs of hiring our new Chief Executive Officer, consulting fees for strategic planning, increased staffing related expenses and increased professional fees related to compliance with the requirements of the Sarbanes-Oxley Act of 2002.

Interest expense decreased to $134,000 in 2004 from $190,000 in 2003, as a result of lower outstanding debt balances. Interest income increased to $984,000 in 2004 from $425,000 in 2003, as a result of substantially larger balances available for investment.

Losses on foreign currency transactions of $53,000 and $59,000 were recorded for the years ended December 31, 2004 and 2003, respectively.

During the year ended December 31, 2004, no provision for income taxes was recorded, while we had a provision of $27,000 in 2003 related to foreign income taxes.

Liquidity and Capital Resources

	December 31, 2005	December 31, 2004
	(In thousands)	
Cash and cash equivalents	$32,827	$10,121
Short-term investments	44,793	56,602
Working capital	90,670	68,910

Our cash, cash equivalents and short-term investments increased $10.9 million during 2005 to $77.6 million at December 31, 2005, primarily as a result of positive cash flow from operating activities of $10.4 million and proceeds from the exercise of stock options of $6.1 million, partially offset by debt repayments of $1.1 million, purchases of $2.0 million of property and equipment, $601,000 of payments related to the purchase and retirement of common stock, and our expenditure of $1.8 million for patent license rights. At December 31, 2005, our working capital was $90.7 million.

Net cash provided by operating activities was $10.4 million in 2005. This resulted from net income of $27.4 million for the year, depreciation and amortization of $2.3 million, non-cash charges of $1.6 million related to stock-based compensation expense, provisions for excess and obsolete inventories and property of $2.3 million, and an increase of $1.0 million in accounts payable and accrued expenses, offset by a non-cash deferred income tax benefit of $18.2 million, an increase in accounts receivable of $4.6 million, an increase in inventory of $1.2 million, and an increase in prepaid expenses of $361,000.

Net cash used in investing activities during 2005 was $8.0 million. We redeemed a net amount of $11.9 million of short-term investments, expended $1.8 million for patent license rights and purchased $2.0 million of property and equipment.

We expect to incur $8.2 million of capital expenditures in 2006. We expect to incur these expenditures to purchase additional information systems equipment and to upgrade certain older equipment in 2006. In addition to these expenditures, we intend to exercise our options to purchase two currently leased facilities which will require $9.2 million of added expenditures.

Net cash provided by financing activities was $4.4 million, reflecting the proceeds of $6.1 million received from the issuance of common stock pursuant to stock options exercises, partially offset by $1.1 million of loan principal repayments and $601,000 of payments related to the purchase and retirement of common stock.

We have in place an $11.9 million credit facility (the "Credit Facility") with Comerica Bank, which is comprised of an $887,000 mortgage loan, a $3.0 million term loan, a $4.0 million non-revolving line of credit for the purchase of both capital equipment and software, and a $4.0 million revolving working capital line of credit. Interest on outstanding borrowings under the non-revolving line of credit 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 initial borrowing. Interest on outstanding borrowings under the revolving working capital line of credit accrues 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 initial borrowing.

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica's prime rate (7.25% at December 31, 2005), 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, 2005 was $722,233.

The $3.0 million term loan matures in March 2006, bears interest at a fixed rate of 4.97% 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, 2005 was $214,286.

As of December 31, 2005, we had no outstanding borrowings under the $4.0 million non-revolving line of credit or the $4.0 million revolving working capital line of credit.

As of December 31, 2005, we also had an outstanding balance of $169,477 under a non-revolving line of credit with Comerica Bank. This line of credit expired in 2003, however, outstanding borrowings under this line remained payable upon expiration in accordance with their original terms. The outstanding balance at December 31, 2005 consisted of four individual loans of (i) $35,957 with a fixed annual interest rate of 5.07%, (ii) $60,967 with a floating annual interest rate equal to Comerica's prime rate of 7.25% at December 31, 2005, (iii) $38,590 with a floating annual interest rate equal to Comerica's prime rate of 7.25% at December 31, 2005, and (iv) $33,963 with a floating annual interest rate equal to Comerica's prime rate of 7.25% at December 31, 2005.

All borrowings under the Credit Facility are collateralized by a first priority security interest in all of our assets, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventories, and a mortgage on our manufacturing facility in Bethlehem, Pennsylvania. Borrowings under the equipment and software non-revolving line and the revolving working capital line are limited to commercially standard percentages of equipment and software purchases and accounts receivable, respectively. The Credit Facility contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth. We were in full compliance with all covenants at December 31, 2005 and expect to remain in compliance with all covenants during 2006. The Credit Facility also restricts our ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

As of December 31, 2005, we also had a $234,566 note payable to the Pennsylvania Industrial Development Authority related to the purchase of one of our facilities in Bethlehem, Pennsylvania in 1998. This note is secured by a second lien on our building, bears interest at 2%, and requires monthly installments of principal and interest of $4,893 through March 2010.

In 2002, we entered into a ten-year facility lease with Tech III Partners, LLC ("Tech Partners"), an entity owned and controlled by two of our former 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 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. We intend to exercise our option under the lease to purchase the facility.

At December 31, 2005, we had net operating loss carryforwards of $66.6 million for federal income tax purposes. The Tax Reform Act of 1986 contains provisions that limit the amount of federal net operating loss carryforwards that can be used in any given year in the event of specified occurrences, including significant ownership changes. We retained independent tax specialists to perform an analysis to determine the applicable annual limitation applied to the utilization of the net operating loss carryforwards due to ownership changes as defined in Section 382 that may have occurred. The Section 382 study and analysis was completed in the fourth quarter 2005, and as a result of this study, we do not believe that the ownership change limitations would impair our ability to use our net operating losses against our current forecasted taxable income. Prior to December 31, 2005, a valuation allowance had been established for the full amount of the deferred tax asset created by these carryforwards and other items. Based on current year and forecasted taxable earnings, a significant portion of the valuation allowance was released in the fourth quarter of 2005, resulting in the recognition of $26.7 million of the deferred tax asset.

The combination of our current cash position, cash flow from operations and available borrowings under our Credit Facility is expected to be sufficient to fund our operating and capital needs for at least the next twelve months. However, our cash requirements may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of strategic acquisitions, 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, the costs of defending against patent infringement or other types of litigation, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, the timing of market launch of new products, market acceptance of new products, competing technological and market developments, the potential exercise of our options to purchase one, or both, of our leased facilities in Bethlehem, Pennsylvania, and other factors.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 151, "Inventory Costs" ("SFAS No. 151"), which amends the guidance in Accounting Research Bulletin No. 43. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material and requires such costs to be recognized as current-period charges. Additionally, SFAS No. 151 requires that allocation of fixed production overhead costs be based on normal capacity. SFAS No. 151 is effective for years beginning after June 15, 2005, with early adoption permitted. We adopted SFAS No. 151 on January 1, 2006, and the implementation did not have a material effect on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123 Revised, "Share-Based Payment" ("SFAS No. 123R"). SFAS No. 123R requires employee stock options to be accounted for in the statement of operations based on their fair values on the date of the grant, and eliminates the ability to account for these instruments under the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25. SFAS No. 123R requires the use of an option pricing model for estimating fair value, which is amortized to expense over the service period. The requirements of SFAS No. 123R are effective for annual periods beginning after June 15, 2005. The Company adopted SFAS No. 123R on January 1, 2006, using the modified prospective method and will calculate fair value of stock options using the Black-Scholes option pricing model. The adoption of SFAS No. 123R is expected to result in a material reduction of our operating income for 2006 by an amount that is not expected to exceed the pro forma amount shown in the notes to the financial statements included in Item 15. This estimate assumes that the number of employee stock options granted in 2006 will not exceed the number granted in 2005 and is subject to change based on the actual number of stock options granted in 2006, the dates on which the grants are made, and the share price on the date of each grant.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections-a replacement of APB Opinion No. 20 and FASB Statement No. 3" ("SFAS No. 154"). SFAS No. 154 requires retrospective application of a voluntary change in accounting principle such that all prior period financial statements are presented in accordance with the new accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS No. 154 also requires that (1) correction of errors in previously issued financial statements should be termed a "restatement"; and (2) a change in method of depreciating or amortizing a long-lived nonfinancial asset be accounted for as a change in estimate (prospectively) that was effected by a change in accounting principle. SFAS No. 154 is effective for accounting changes and correction of errors made in fiscal years beginning after December 15, 2005. We do not expect the adoption of SFAS No. 154 to have a material effect on our financial position, results of operations or cash flows.

Contractual Obligations and Commercial Commitments. The following sets forth our approximate aggregate obligations at December 31, 2005 for future payments under contracts and other contingent commitments, for the years 2006 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2006**	**2007**	**2008**	**2009**	**2010**	**Thereafter**
Long-term debt[1]	$ 1,340,562	$ 456,541	$ 116,123	$ 100,650	$ 105,086	$ 60,567	$ 501,595
Operating leases[2]	7,221,334	1,256,673	1,158,156	1,165,764	1,181,217	921,748	1,537,776
Employment contracts[3]	1,881,850	1,471,400	410,450	—	—	—	—
Purchase obligations[4]	2,424,672	2,424,672	—	—	—	—	—
Minimum commitments under contracts[5]	11,216,667	3,625,000	725,000	725,000	650,000	650,000	4,841,667
Total contractual obligations	$24,085,085	$9,234,286	$2,409,729	$1,991,414	$1,936,303	$1,632,315	$6,881,038

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. We currently intend to exercise our options to purchase two of the leased facilities. Upon purchase of either facility, we would no longer be required to pay the contractual lease payments related to the given facility. The future lease payments included above that are related to these two facilities are $1,146,954 in 2006, $1,150,017 in 2007, $1,165,764 in 2008, $1,181,217 in 2009, $921,748 in 2010, and $1,537,776 thereafter. See Note 11 to the financial statements included herein.

3 Represents salary or retention bonus 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, capital expenditures and other goods or services. 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. These agreements are cancellable within a specified number of days of communication by the Company to terminate the agreement. See Note 11 to the financial statements included herein. Additional payments of up to $5,500,000 may be required for the achievement of specific development and/or commercial milestones, pursuant to one of the licensing agreements.

Off-Balance Sheet Arrangements. We do not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934, as amended.

Critical Accounting Policies and Estimates

This 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 Annual 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. 104, "Revenue Recognition" ("SAB No. 104"). This bulletin draws on existing accounting rules and provides specific guidance on revenue recognition for 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 No. 104, 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 there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are net of allowances for any discounts or rebates. 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 $278,066 at December 31, 2005. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period (($4,771), $3,541, and $88,659 in 2005, 2004, and 2003, 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, 2005, $4.1 million, or 35% of our accounts receivable, was due from two major customers. Any significant changes in the liquidity or financial position of these customers, 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 2005, 2004, and 2003, we wrote-off inventory which had a cost of $2.1 million, $839,000, and $540,000, respectively, as a result of a provision for loss on our UP*link*® product in 2005, scrap levels and product expiration issues. During the first half of 2005, we explored options with respect to the UP*link*® product, however, we were not able to determine an outlet for this product. As a result, we recorded a $1.3 million charge in June 2005 to reflect a provision on the UP*link*® inventory. 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 $9.0 million or 7% of our total assets at December 31, 2005. 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 depreciated or 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. In August 2005, we recorded a $1.5 million intangible asset related to a payment under a license agreement to certain patents related to the Hepatitis C Virus. Management's intent in executing this license is to provide for various alternatives for use, including uses in the international market that would not require additional research and development expense or regulatory approvals. This $1.5 million asset was capitalized based on management's estimate of the cash flows to be received from future product sales in these international markets. A similar analysis of estimated future cash flows will be prepared upon payment of additional license fees under this agreement, or upon changes in circumstances, to determine the appropriate accounting treatment for payments under this license agreement. 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 overall business strategy, significant negative industry or economic trends, shortening of product life-cycles or changes in technology, and negative financial performance of the 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. In June 2005, we recorded a $196,000 provision for loss on our UP*link*® fixed assets as a result of our inability to reach an agreement to transfer these assets to our distribution partner or determine an alternative outlet for these assets. We currently believe the future cash flows to be received from all other long-lived and intangible assets will exceed their book value and, as such, we have not recognized any additional impairment losses through December 31, 2005. 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. At December 31, 2005, we had federal net operating losses ("NOL") of $66.6 million. The net deferred tax asset associated with these NOLs and other temporary differences was $26.7 million at December 31, 2005. In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible or the NOLs and credit carryforwards can be utilized. We consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment.

Our ability to use our net operating loss carryforwards to offset future federal income tax obligations, could be limited by changes in the ownership of our stock. Internal Revenue Code ("IRC") Section 382 contains provisions that limit the amount of federal net operating loss carryforwards that can be used in any given year in the event of specified occurrences, including significant ownership changes. In the fourth quarter of 2005, the Company completed an analysis, with the assistance of independent tax specialists, to determine if any IRC Section 382 ownership changes have occurred that would limit the amount of NOLs that could be utilized to offset future taxable income. As a result of this analysis, the Company concluded that prior period ownership changes may impose a limitation on the amount of NOLs that can be utilized in a given year. The Company does not believe, however, that this limitation will impair our future ability to utilize NOLs to offset our forecasted taxable income or to realize the related deferred tax asset.

Prior to December 31, 2005, a valuation allowance had been established for the full amount of the deferred tax asset created by these carryforwards and other items. Based on our 2005 results and our projections for future taxable income over the periods in which the deferred tax assets are deductible or the NOLs and credit carryforwards can be utilized, we believe a significant portion of the deferred tax asset was realizable at December 31, 2005. As such, we recorded the estimated net realizable value of the deferred tax asset at December 31, 2005 and have begun providing for income taxes at a rate equal to our combined federal and state effective rates. 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 ("SFAS") No. 5, "Accounting for Contingencies." SFAS No. 5 requires us to record an estimated loss contingency when information available prior to issuance of our financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and the amount of the loss can be reasonably estimated. Accounting for contingencies arising from contractual or legal proceedings requires that we use our best judgment when estimating an accrual related to such contingencies. As additional information becomes known, our accrual for a loss contingency could fluctuate, thereby creating variability in our results of operations from period to period. Likewise, an actual loss arising from a loss contingency which significantly exceeds the amount accrued for in our financial statements could have a material adverse impact on our operating results for the period in which such actual loss becomes known.

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

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

Our holdings of financial instruments are comprised of certificates of deposit, commercial paper, U.S. government and agency obligations, state and local government agency obligations, asset-backed obligations, and U.S. corporate bonds. All such instruments are classified as available-for-sale securities. 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.

As of December 31, 2005, we did not 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 revenues and expenses for these operations from euros to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency represented $2.3 million or 3% of our total revenues for the year ended December 31, 2005. We do not expect the risk of foreign currency fluctuations to be material in the near future.

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.

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

Not applicable.

ITEM 9A. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures.

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of December 31, 2005. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures are adequate and effective to ensure that information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Management's Report on Internal Control Over Financial Reporting.

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a(f) and 15d-15(f) under the Securities Exchange Act of 1934. Under the supervision and with the participation of the Company's management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework, our management concluded that our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles as of December 31, 2005.

Our management's assessment on the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report, which is included below.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

(c) Changes in Internal Control Over Financial Reporting.

There was no change in the Company's internal control over financial reporting identified in connection with the evaluation referred to in paragraph (a) above that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(d) Report of Independent Registered Public Accounting Firm

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

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that OraSure Technologies, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). OraSure Technologies, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that OraSure Technologies, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, OraSure Technologies, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of OraSure Technologies, Inc. as of December 31, 2005 and 2004, and the related statements of operations, stockholders' equity and comprehensive income (loss) and cash flows for each of the years in the three-year period ended December 31, 2005, and our report dated March 13, 2006 expressed an unqualified opinion on those financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 13, 2006

ITEM 9B. Other Information.

Not applicable.

PART III

We have omitted from Part III the information that will appear in our Definitive Proxy Statement for our 2006 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.

Certain 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.

Our Board of Directors has adopted a Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer and principal accounting officer, as well as to the members of our Board of Directors and our other officers and employees. This Code of Business Conduct and Ethics is available on our website at www.orasure.com. We intend to satisfy the amendment and waiver disclosure requirements under applicable securities regulations by posting any amendments of, or waivers to, the Code of Business Conduct and Ethics on our website.

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 and Related Stockholder Matters.

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 caption, "Certain Relationships and Related Transactions," in the Proxy Statement.

ITEM 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated by reference to the information under the caption, "Audit Fees; Audit-Related Fees; Tax Fees; All Other Fees," in the Proxy Statement.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules.

(a)(1) and (a)(2). *Financial Statements and Schedules*. For a list of the Financial Statements filed herewith, see the Index to Financial Statements following the signature page to this Annual 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 Annual Report.

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 15, 2006.

ORASURE TECHNOLOGIES, INC.

By: /s/ DOUGLAS A. MICHELS
Douglas A. Michels
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on March 15, 2006, by the following persons on behalf of the Registrant and in the capacities indicated.

SIGNATURE	TITLE
/s/ DOUGLAS A. MICHELS **Douglas A. Michels**	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)
*FRANK G. HAUSMANN **Frank G. Hausmann**	Director
*RONNY B. LANCASTER **Ronny B. Lancaster**	Director
*CHARLES W. PATRICK **Charles W. Patrick**	Director
*ROGER L. PRINGLE **Roger L. Pringle**	Director
*DOUGLAS G. WATSON **Douglas G. Watson**	Director

*By: /s/ RONALD H. SPAIR
Ronald H. Spair
(Attorney-in-Fact)

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of OraSure Technologies, Inc. as of December 31, 2005 and 2004, and the related statements of operations, stockholders' equity and comprehensive income (loss) and cash flows for each of the years in the three-year period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (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 provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of OraSure Technologies, Inc. as of December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of OraSure Technologies, Inc.'s internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 13, 2006 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 13, 2006

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31, 2005	December 31, 2004
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 32,826,740	$ 10,121,208
Short-term investments	44,793,046	56,602,248
Accounts receivable, net of allowance for doubtful accounts of $278,066 and $345,257	11,602,127	7,073,988
Inventories	4,128,029	4,951,979
Deferred income taxes	6,503,946	—
Prepaid expenses and other	1,553,545	1,195,085
Total current assets	101,407,433	79,944,508
PROPERTY AND EQUIPMENT, net	5,815,233	5,551,261
PATENTS AND PRODUCT RIGHTS, net	2,879,958	2,080,363
DEFERRED INCOME TAXES	20,204,352	—
OTHER ASSETS	440,227	488,192
	$ 130,747,203	$ 88,064,324
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 456,541	$ 1,122,455
Accounts payable	2,546,621	2,360,214
Accrued expenses and other	7,733,941	7,552,279
Total current liabilities	10,737,103	11,034,948
LONG-TERM DEBT	884,021	1,334,236
OTHER LIABILITIES	207,037	118,135
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, 45,775,625 and 44,631,731 shares issued and outstanding	46	45
Additional paid-in capital	226,218,469	209,948,075
Deferred compensation	(3,334,792)	(2,916,503)
Accumulated other comprehensive loss	(282,825)	(324,669)
Accumulated deficit	(103,681,856)	(131,129,943)
Total stockholders' equity	118,919,042	75,577,005
	$ 130,747,203	$ 88,064,324

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

	For the year ended December 31,		
	2005	**2004**	**2003**
REVENUES:			
Product	$ 69,066,152	$53,604,124	$39,740,406
Licensing and product development	300,040	404,140	710,879
	69,366,192	54,008,264	40,451,285
COST OF PRODUCTS SOLD	27,973,907	22,143,190	16,061,457
Gross profit	41,392,285	31,865,074	24,389,828
OPERATING EXPENSES:			
Research and development	5,269,083	6,062,275	7,999,687
Sales and marketing	16,060,413	15,154,174	10,764,642
General and administrative	12,490,074	12,005,309	6,911,242
	33,819,570	33,221,758	25,675,571
Operating income (loss)	7,572,715	(1,356,684)	(1,285,743)
INTEREST EXPENSE	(96,632)	(133,652)	(189,511)
INTEREST INCOME	2,185,486	983,841	425,344
FOREIGN CURRENCY GAIN (LOSS)	57,329	(53,147)	(59,037)
Income (loss) before income taxes	9,718,898	(559,642)	(1,108,947)
INCOME TAX (BENEFIT) PROVISION	(17,729,189)	—	26,590
NET INCOME (LOSS)	$ 27,448,087	$ (559,642)	$ (1,135,537)
EARNINGS (LOSS) PER SHARE			
BASIC	$ 0.61	$ (0.01)	$ (0.03)
DILUTED	$ 0.59	$ (0.01)	$ (0.03)
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE			
BASIC	45,109,580	44,463,861	39,793,919
DILUTED	46,146,612	44,463,861	39,793,919

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME (LOSS)

For the years ended December 31, 2005, 2004 and 2003

	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount					
Balance at January 1, 2003	38,100,557	$ 38	$155,638,314	$ —	$(184,676)	$(129,434,764)	$ 26,018,912
Common stock issued upon exercise of options	849,374	1	3,716,890	—	—	—	3,716,891
Common stock issued via public offering, net of expenses	5,311,000	5	44,827,998	—	—	—	44,828,003
Compensation expense for stock option grants	—	—	33,900	—	—	—	33,900
Restricted stock grants to employees	—	—	650,663	(650,663)	—	—	—
Amortization of deferred compensation expense	—	—	—	36,148	—	—	36,148
Comprehensive loss:							
Net loss	—	—	—	—	—	(1,135,537)	(1,135,537)
Currency translation adjustment	—	—	—	—	16,560	—	16,560
Net unrealized loss on marketable securities	—	—	—	—	(5,588)	—	(5,588)
Total comprehensive loss							(1,124,565)
Balance at December 31, 2003	44,260,931	44	204,867,765	(614,515)	(173,704)	(130,570,301)	73,509,289
Common stock issued upon exercise of options	370,800	1	1,904,160	—	—	—	1,904,161
Restricted stock grants to employees	—	—	3,176,150	(3,176,150)	—	—	—
Amortization of deferred compensation expense	—	—	—	874,162	—	—	874,162
Comprehensive loss:							
Net loss	—	—	—	—	—	(559,642)	(559,642)
Currency translation adjustment	—	—	—	—	(12,983)	—	(12,983)
Net unrealized loss on marketable securities	—	—	—	—	(137,982)	—	(137,982)
Total comprehensive loss							(710,607)
Balance at December 31, 2004	44,631,731	45	209,948,075	(2,916,503)	(324,669)	(131,129,943)	75,577,005
Common stock issued upon exercise of options	1,009,794	1	6,067,868	—	—	—	6,067,869
Compensation expense for stock option grants	—	—	123,916	—	—	—	123,916
Vesting of restricted stock	197,180	—	—	—	—	—	—
Restricted stock grants to employees	—	—	1,918,343	(1,918,343)	—	—	—
Purchase and retirement of treasury shares	(63,080)	—	(601,347)	—	—	—	(601,347)
Amortization of deferred compensation expense	—	—	—	1,500,054	—	—	1,500,054
Deferred taxes related to stock options	—	—	8,761,614	—	—	—	8,761,614
Comprehensive income:							
Net income	—	—	—	—	—	27,448,087	27,448,087
Currency translation adjustment	—	—	—	—	(39,095)	—	(39,095)
Net unrealized gain on marketable securities, net of tax benefit of $26,268	—	—	—	—	80,939	—	80,939
Total comprehensive income							27,489,931
Balance at December 31, 2005	45,775,625	$ 46	$226,218,469	$(3,334,792)	$(282,825)	$(103,681,856)	$118,919,042

The accompanying notes are an integral part of these statements

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

	For the year ended December 31,		
	2005	**2004**	**2003**
OPERATING ACTIVITIES:			
Net income (loss)	$ 27,448,087	$ (559,642)	$ (1,135,537)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Deferred income tax benefit	(18,165,068)	—	—
Stock-based compensation expense	1,623,970	874,162	70,048
Depreciation and amortization	2,346,861	2,487,121	2,576,797
Provision for loss on property and equipment, net	196,011	4,339	43,500
Provision for excess and obsolete inventories	2,062,855	839,130	539,647
Changes in assets and liabilities:			
Accounts receivable	(4,553,469)	1,159,881	(3,036,082)
Inventories	(1,240,049)	(1,787,590)	(454,692)
Prepaid expenses and other	(360,945)	(272,265)	2,996
Accounts payable	457,543	(1,066,064)	1,738,171
Accrued expenses and other liabilities	576,540	1,759,144	2,356,948
Net cash provided by operating activities	10,392,336	3,438,216	2,701,796
INVESTING ACTIVITIES:			
Purchases of property and equipment	(2,048,167)	(912,144)	(993,722)
Proceeds from the sale of property and equipment	—	66,427	—
Purchase of patents and product rights	(1,800,000)	(600,000)	(250,000)
Purchases of short-term investments	(54,071,801)	(65,638,600)	(37,280,182)
Proceeds from maturities and redemptions of short-term investments	65,935,674	42,226,980	14,489,860
(Increase) decrease in other assets	(24,801)	80,160	(5,886)
Net cash provided by (used in) investing activities	7,990,905	(24,777,177)	(24,039,930)
FINANCING ACTIVITIES:			
Borrowings of long-term debt	—	—	211,590
Repayments of long-term debt	(1,116,129)	(1,126,186)	(1,104,041)
Proceeds from issuance of common stock	6,067,869	1,904,161	3,716,891
Purchase and retirement of common stock	(601,347)	—	—
Proceeds from common stock offering, net of expenses	—	—	44,828,003
Net cash provided by financing activities	4,350,393	777,975	47,652,443
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(28,102)	(12,983)	16,560
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	22,705,532	(20,573,969)	26,330,869
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	10,121,208	30,695,177	4,364,308
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 32,826,740	$ 10,121,208	$ 30,695,177

The accompanying notes are an integral part of these statements.

1. 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 internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. One of our products is also sold in the over-the-counter or consumer retail markets in the United States, Canada, and Europe .

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 with a purchased maturity of ninety days or less to be cash equivalents. As of December 31, 2005 and 2004, cash equivalents consisted of commercial paper, U.S. government agency obligations, state and local government agency obligations, and corporate bonds.

Short-term Investments

We consider all short-term investments to be 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, state and local government agency obligations, asset-backed obligations, and corporate bonds, all with purchased maturities greater than ninety days. 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. There were no securities as of December 31, 2005 in a continuous unrealized loss position for twelve or more months.

The following is a summary of our available-for-sale securities at December 31, 2005 and 2004:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2005				
Certificates of deposit	$10,385,000	$ —	$ (464)	$10,384,536
Commercial paper	1,984,999	—	(1,059)	1,983,940
Government and agency bonds	18,544,871	—	(43,851)	18,501,020
State and local government agency obligations	75,000	—	—	75,000
Corporate bonds	13,874,242	1,261	(26,953)	13,848,550
Total available-for-sale securities	$44,864,112	$1,261	$ (72,327)	$44,793,046
December 31, 2004				
Certificates of deposit	$18,702,211	$ 56	$ (29,411)	$18,672,856
Commercial paper	4,281,910	185	—	4,282,095
Government and agency bonds	21,112,676	113	(61,631)	21,051,158
State and local government agency obligations	629,322	162	(1,059)	628,425
Asset-backed obligations	1,002,116	—	(866)	1,001,250
Corporate bonds	10,999,750	431	(33,717)	10,966,464
Total available-for-sale securities	$56,727,985	$ 947	$(126,684)	$56,602,248
At December 31, 2005, maturities of investments were as follows:				
Less than one year	$38,635,227	$ 424	$ (64,480)	$38,571,171
1 – 2 years	6,228,885	837	(7,847)	6,221,875
Total available-for-sale securities	$44,864,112	$1,261	$ (72,327)	$44,793,046

Supplemental Cash Flow Information

In 2005, 2004, and 2003, we paid interest of $99,728, $137,112, and $184,906, respectively.

In 2005, we paid income taxes of $170,000. No income tax payments were made in 2004 or 2003.

For 2005, 2004, and 2003, we recorded a provision (reduction) for bad debts of $(71,962), $(10,360), and $155,671, respectively. We had (credits)/deductions of $(4,771), $3,541, and $88,659 against the allowance for doubtful accounts in 2005, 2004, and 2003, respectively.

For 2005, 2004, and 2003, we recorded accruals for purchases of property and equipment of $57,923, $72,394, and $93,987, respectively.

In 2004, we recorded a $300,000 accrual related to a new license agreement.

Accounts Receivable

Accounts receivable have been reduced by an allowance for amounts that may become uncollectible in the future. This estimated allowance is based primarily on management's evaluation of specific balances as the balances become past due, the financial condition of our customers and our historical experience related to write-offs. If not reserved through these specific examination procedures, our policy is to reserve for uncollectible accounts by applying fixed percentages to the aging categories of accounts receivable.

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. In addition to reserving for these items identified through specific identification procedures, we also reserve for unidentified scrap or spoilage under a fixed-formula methodology. We currently buy a portion of our cryosurgical product line from a foreign vendor, with such purchases payable in euros. Changes in the exchange rate of the euro will 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 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, licenses and product distribution rights. Patents and product rights are amortized using the straight-line method over estimated useful lives of three to ten years. Accumulated amortization was $3,568,671 and $2,868,294 at December 31, 2005 and 2004, respectively. Amortization expense for 2005, 2004, and 2003 was $700,377, $705,808, and $657,348, respectively. Amortization expense for each of the five succeeding fiscal years is estimated at $537,051 for 2006, $517,052 for 2007, $347,105 for 2008, $240,000 for 2009, and $240,000 for 2010.

Other Assets

Included in other assets is a $337,253 investment, representing a 7.7% 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 and patents and product rights, by determining whether the carrying value of such assets can be recovered through the sum of the undiscounted future operating cash flows and eventual disposition of the asset. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the assets to the fair value of these assets, which is generally determined based on the present value of the expected future cash flows associated with the use of the asset. During 2005, we recorded a $196,011 impairment on certain property and equipment because the assets' carrying value exceeds the future cash flows to be received from these assets. We believe the future cash flows to be received from all other long-lived assets will exceed the assets' carrying value, and accordingly we have not recognized any additional impairment losses through December 31, 2005.

Revenue Recognition

We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are net of allowances for any discounts or rebates. 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.

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. 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

During 2005, two of our customers each accounted for more than 10 percent of our total revenues. Prestige Brands Holdings, Inc. and Quest Diagnostics (including its wholly-owned subsidiary, Lab*One*, Inc.) accounted for 17 percent and 13 percent, respectively, of our total revenues in 2005.

Additionally, two customers each accounted for more than 10 percent of our accounts receivable at December 31, 2005. SSL International plc and Prestige Brands Holdings, Inc. accounted for 20 percent and 15 percent, respectively, of our accounts receivable at December 31, 2005.

During 2004 and 2003, two of our customers accounted for more than 10 percent of our total revenues. Prestige Brands Holdings, Inc. accounted for 25% and 12% of total revenues for 2004 and 2003, respectively. Lab*One*, Inc. accounted for 12% and 17% of total revenues for 2004 and 2003, respectively.

At December 31, 2004, Prestige Brands Holdings, Inc. accounted for 23% of our accounts receivable.

Research and Development

Research and development costs are charged to expense as incurred.

Advertising Expenses

Advertising costs are charged to expense as incurred. During 2005, 2004, and 2003, we incurred $2,232,945, $3,512,037, and $1,774,093, respectively, in advertising expenses. Included in advertising expenses for 2005, 2004 and 2003 were $1,820,022, $2,883,145 and $1,130,045, respectively, paid as reimbursement for marketing expenses incurred for the Compound W® Freeze Off™ product.

Stock-Based Compensation

We account for stock-based compensation to employees and directors using the intrinsic value method in accordance with Accounting Principles Board ("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" and Emerging Issues Task Force ("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 No. 123, as amended by SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure." Under SFAS No. 123, compensation

expense related to stock awards granted to employees and directors is computed based on the fair value of the award at the date of grant using a valuation methodology, typically the Black-Scholes option pricing model. Pursuant to the disclosure requirements of SFAS No. 123, had compensation expense for our common stock awards been determined based upon the fair value of the awards at the date of grant, our net income (loss) for 2005, 2004, and 2003 would have changed as follows:

	Year ended December 31,		
	2005	2004	2003
Net income (loss):			
As reported	$27,448,087	$ (559,642)	$(1,135,537)
Add: stock-based employee compensation expense included in net income (loss)—net of tax	945,634	874,162	70,048
Deduct: total stock-based employee compensation expense determined under the fair value-based method for all awards—net of tax	(3,004,813)	(5,921,957)	(4,306,587)
Pro forma	$25,388,908	$(5,607,437)	$(5,372,076)
Earnings (loss) per share:			
Basic			
As reported	$ 0.61	$ (0.01)	$ (0.03)
Pro forma	$ 0.56	$ (0.13)	$ (0.13)
Diluted			
As reported	$ 0.59	$ (0.01)	$ (0.03)
Pro forma	$ 0.55	$ (0.13)	$ (0.13)

The weighted average fair value of the options granted during 2005, 2004, and 2003 is estimated at $3.17, $4.60, and $4.15 per share, respectively, using the Black-Scholes option pricing model, with the following assumptions: dividend yield of zero; volatility of 58 percent, 65 percent, and 70 percent, respectively; weighted average risk-free interest rate of 3.72 percent, 3.21 percent, and 2.93 percent, respectively; and an expected life of 4.0, 5.0 and 5.0 years, respectively, for each year's grants.

In May 2005, we modified the term of two individual stock option grants. As a result, compensation expense of $123,916 was recorded in 2005.

Income Taxes

We follow the asset and liability method for accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax basis of assets and liabilities, and operating loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates that are expected to apply to taxable income in the years in which those temporary differences and operating loss and credit carryforwards are expected to be recovered, settled or utilized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

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 in accumulated other comprehensive loss, which is a separate component of stockholders' equity.

Earnings (Loss) Per Share

We have presented basic and diluted earnings (loss) per share pursuant to SFAS No. 128, "Earnings per Share." In accordance with SFAS No. 128, basic earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per share is computed in manner similar to basic earnings per share except that the weighted average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of dilutive securities, such as common stock options, warrants and unvested restricted stock. The number of incremental shares is calculated by assuming that outstanding stock options and warrants were exercised and unvested restricted shares were vested, and the proceeds from such exercises or vesting were used to acquire shares of common stock at the average market prices during the reporting period.

The computations of basic and diluted earnings (loss) per share are as follows:

	Year ended December 31,		
	2005	2004	2003
Net income (loss)	$27,448,087	$ (559,642)	$ (1,135,537)
Weighted average shares of common stock outstanding:			
Basic	45,109,580	44,463,861	39,793,919
Dilutive effect of stock options, warrants and restricted shares	1,037,032	—	—
Diluted	46,146,612	44,463,861	39,793,919
Earnings (loss) per share:			
Basic	$ 0.61	$ (0.01)	$ (0.03)
Diluted	$ 0.59	$ (0.01)	$ (0.03)

For the years ended December 31, 2005, 2004, and 2003, outstanding common stock options, warrants and unvested restricted stock representing 1,069,181, 5,479,504, and 4,130,463 shares, respectively, were excluded from the computation of diluted earnings (loss) per share as their inclusion would have been anti-dilutive.

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 stockholders' equity section of our balance sheet.

Fair Value of Financial Instruments

As of December 31, 2005, 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 values, approximate their fair values, given that the interest rates on outstanding borrowings approximate market rates.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 151, "Inventory Costs." SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material and requires such costs to be recognized as current-period charges. Additionally, SFAS No. 151 requires that allocation of fixed production overhead costs be based on normal capacity. SFAS No. 151 is

effective for years beginning after June 15, 2005, with early adoption permitted. We adopted SFAS No. 151 on January 1, 2006 and the implementation did not have a material effect on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123 Revised, "Share-Based Payment" ("SFAS No. 123R"). SFAS No. 123R requires employee stock options to be accounted for in the statement of operations based on their fair values on the date of grant, and eliminates the ability to account for these instruments under the intrinsic value method prescribed by APB Opinion No. 25. SFAS No. 123R requires the use of an option pricing model for estimating fair value, which is amortized to expense over the service period. The requirements of SFAS No. 123R are effective for fiscal years beginning after June 15, 2005. We adopted SFAS No. 123R on January 1, 2006 using the modified prospective method and will estimate the fair value of stock options using the Black-Scholes option pricing model. The adoption of SFAS No. 123R is expected to result in a material reduction of our operating income for 2006 by an amount that is not expected to exceed the pro forma amount shown in the table above. This estimate assumes that the number of employee stock options granted in 2006 will not exceed the number granted in 2005 and is subject to change based on the actual number of stock options granted in 2006, the dates on which the grants are made, and the share price on the date of each grant.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections-a replacement of APB Opinion No. 20 and FASB Statement No. 3", ("SFAS No. 154"). SFAS No. 154 requires retrospective application of a voluntary change in accounting principle such that all prior period financial statements are presented in accordance with the new accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS No. 154 also requires that (1) correction of errors in previously issued financial statements should be termed a "restatement"; and (2) a change in method of depreciating or amortizing a long-lived nonfinancial asset be accounted for as a change in estimate (prospectively) that was effected by a change in accounting principle. SFAS No. 154 is effective for accounting changes and correction of errors made in fiscal years beginning after December 15, 2005. We do not expect the adoption of SFAS No. 154 to have a material effect on our financial position, results of operations or cash flows.

3. INVENTORIES:

	December 31,	
	2005	2004
Raw materials	$2,625,889	$3,405,578
Work in process	718,804	659,304
Finished goods	783,336	887,097
	$4,128,029	$4,951,979

In 2005, we recorded a $1,288,655 provision on our UP*link*® inventory as a result of the inability to determine an alternative use for this product and termination of the agreement with our distribution partner.

4. PROPERTY AND EQUIPMENT:

	December 31,	
	2005	2004
Building and leasehold improvements	$ 4,895,253	$ 4,780,874
Machinery and equipment	7,855,947	7,859,207
Computer equipment	2,052,741	1,809,582
Furniture and fixtures	847,512	804,061
Construction in progress	1,966,125	526,030
	17,617,578	15,779,754
Less—Accumulated depreciation	(11,802,345)	(10,228,493)
	$ 5,815,233	$ 5,551,261

Depreciation expense was $1,573,852, $1,739,733, and $1,879,092 for 2005, 2004, and 2003, respectively. In addition, in connection with the transfer of all operations to our Bethlehem facilities in 2004, we retired or disposed of $6,298,345 in fully depreciated assets that were previously utilized in our Oregon facility. No gain or loss was recognized on these disposals.

5. PATENTS AND PRODUCT RIGHTS:

In June 1998, we acquired the patents and exclusive worldwide distribution rights to our cryosurgical product line. 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 cryosurgical product line, with a current term extending through 2008.

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 had an initial term ending December 31, 2005, and renew annually for one-year periods. As consideration for BMX entering into the new agreements, we paid BMX $750,000, which we recorded as patent and product rights on our balance sheet. This amount is fully amortized as of December 31, 2005.

In June 2004, we entered into a sublicense agreement with a third party, pursuant to which we have been granted a limited, worldwide, non-exclusive sublicense to certain HIV-2 patents held by such party. The agreement requires us to pay the third party a one-time non-refundable license fee of $900,000, $600,000 of which was paid in August 2004 and $300,000 of which was paid in June 2005. The $900,000 was recorded as patent and product rights on our balance sheet and is being amortized through June 30, 2014.

In August 2005, we entered into a license agreement with third parties, pursuant to which we have been granted a limited, personal, non-transferrable, non-exclusive license to certain patents related to the Hepatitis C Virus ("HCV") held by such parties. The agreement required us to pay the third parties a one-time non-refundable license fee of $1,500,000, which was paid in August 2005. We may also be required to pay additional license fees up to $8,500,000, upon the achievement of specific development and/or commercial milestones.

Management's intent in executing the HCV license agreement is to provide for various alternatives for use of the licensed patents. Some of these uses require additional research and development expense and regulatory approvals, while others, specifically in the international market, do not require additional research and development expense or regulatory approvals. Based on management's estimate of the cash flows to be received from future product sales in these international markets, we capitalized the $1,500,000 license fee in the accompanying balance sheet. We are amortizing this amount to cost of products sold on a straight-line basis over a ten-year period, which represents management's estimate of the useful life of the licensed patents.

Under the terms of the HCV license agreement, we are also obligated to pay royalties based on our net sales of certain products, which incorporate the technology covered by the licensed patents. Royalties under the license agreement vary based upon the geographical territory where the product is sold. No sales have been made under the terms of this license agreement through December 31, 2005.

6. ACCRUED EXPENSES AND OTHER:

	December 31, 2005	December 31, 2004
Payroll and related benefits	$2,510,240	$2,069,309
Deferred revenue	1,302,791	1,353,711
Professional fees	487,712	1,227,087
Royalties	1,925,679	1,069,932
Advertising	757,906	603,009
License fees	—	300,000
Laboratory testing fees	210,604	249,041
Other	539,009	680,190
	$7,733,941	$7,552,279

At December 31, 2005, accrued payroll and related benefits increased primarily as a result of an increase in annual bonuses. Deferred revenue includes customer prepayments of $1,012,891 and $1,041,711 at December 31, 2005 and 2004, respectively. Professional fees at December 31, 2005 decreased primarily as a result of the payment of legal fees related to current litigation. Accrued royalties and advertising expenses at December 31, 2005 and 2004 are primarily related to our OraQuick® and Freeze Off™ products, respectively. License fees at December 31, 2004 are related to the sublicense agreement, which we entered into in June 2004, as discussed in Note 5.

7. CREDIT FACILITIES:

As of December 31, 2005, we had an $11,887,000 credit facility ("Credit Facility") with Comerica Bank, comprised of an $887,000 mortgage loan, a $3,000,000 term loan, a $4,000,000 non-revolving equipment line of credit, and a $4,000,000 revolving working capital line of credit. Interest on outstanding borrowings under the non-revolving line of credit 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 initial borrowing. Interest on outstanding borrowings under the revolving working capital line of credit accrues 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 initial borrowing. We also had outstanding payments under a non-revolving line with Comerica Bank that was initially borrowed under the Credit Facility, but expired (see Note 8). The Credit Facility was initially entered into in September 2002, and was most recently amended in April 2005 to extend the maturity date of the revolving line until April 29, 2006. We had no outstanding borrowings under the revolving line at December 31, 2005.

All borrowings under the Credit Facility, as amended, 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 revolving line are limited to commercially standard percentages of accounts receivable. The Credit Facility, as amended, contains certain covenants that set forth minimum requirements for our quick ratio, liquidity, and tangible net worth and 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, 2005	December 31, 2004
Term loan payable to bank, interest at 4.97%, monthly principal installments of $71,429, plus interest, through March 2006, secured by a first priority security interest in all of our assets.	$ 214,286	$ 1,071,429
Mortgage loan payable to bank, interest at an annual floating rate equal to the bank's prime rate (7.25% at December 31, 2005), 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.	722,233	765,953
Note payable to bank, interest at an annual floating rate equal to the bank's prime rate (7.25% at December 31, 2005), monthly principal installments of $5,081, plus interest, through December 2006, secured by certain equipment.	60,967	121,935
Note payable to bank, interest at 5.07%, monthly principal installments of $3,995, plus interest, through September 2006, secured by certain equipment.	35,957	83,900
Note payable to bank, interest at an annual floating rate equal to the bank's prime rate (7.25% at December 31, 2005), monthly principal installments of $2,144, plus interest, through June 2007, secured by certain equipment	38,590	64,317
Note payable to bank, interest at an annual floating rate equal to the bank's prime rate (7.25% at December 31, 2005), monthly principal installments of $2,264, plus interest, through March 2007, secured by certain equipment.	33,963	61,134
Note payable to Pennsylvania Industrial Development Authority, interest at 2%, monthly installments of principal and interest of $4,893 through March 2010, secured by a second lien on our building.	234,566	288,023
	1,340,562	2,456,691
Less—Current portion	(456,541)	(1,122,455)
	$ 884,021	$ 1,334,236

Long-term debt maturities as of December 31, 2005 are as follows:

2006	$ 456,541
2007	116,123
2008	100,650
2009	105,086
2010	60,567
Thereafter	501,595
	$1,340,562

Certain of these notes payable require, among other items, the maintenance of certain financial covenants. We were in compliance with these covenants as of December 31, 2005.

9. INCOME TAXES:

The components of the (benefit) provision for income taxes for the years ended December 31, are as follows:

	2005	2004	2003
Current			
Federal	$ 224,153	$ —	$ —
State	211,726	—	—
Foreign	—	—	26,590
	435,879	—	26,590
Deferred			
Federal	3,285,740	(123,009)	(316,156)
State	495,298	(18,823)	(48,924)
Foreign	—	—	—
	3,781,038	(141,832)	(365,080)
Change in valuation allowance	(21,946,106)	141,832	365,080
	(18,165,068)	—	—
Total (benefit) provision	$(17,729,189)	$ —	$ 26,590

A reconciliation of the statutory United States federal tax rate to our effective tax rate for the year ended December 31, is as follows:

	2005	2004	2003
Statutory U.S. federal tax rate-expense (benefit)	34.0%	(34.0)%	(34.0)%
State income taxes, net of federal	4.8	(2.2)	(2.9)
Tax rate differential on foreign income	—	—	2.4
Nondeductible expenses and other	4.6	10.9	4.0
Net change in valuation allowance, federal and state	(225.8)	25.3	32.9
Effective tax rate	(182.4)%	— %	2.4%

Deferred income taxes reflect the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting purposes and tax purposes, and net operating loss and tax credit carryforwards. Significant components of our total deferred tax asset, net of valuation allowance, as of December 31, are as follows:

	2005	2004
Net operating loss carryforwards	$22,827,988	$ 25,307,329
Research and development credit carryforwards	1,641,012	1,770,898
Inventory	1,165,890	605,743
Capitalized research and development costs	665,353	782,557
Accruals and reserves currently not deductible	579,584	787,029
Patent costs	579,347	551,480
Depreciation and amortization	391,677	622,752
Deferred compensation	359,573	339,224
Alternative minimum tax credit carryforwards	138,886	—
Total deferred tax asset before valuation allowance	28,349,310	30,767,012
Valuation allowance on deferred tax asset	(1,641,012)	(30,767,012)
Total deferred tax asset, net of valuation allowance	$26,708,298	$ —

In assessing the realizability of our deferred tax asset, we follow the guidance contained within SFAS No. 109, "Accounting for Income Taxes," which requires that deferred income tax assets be reduced by a valuation allowance, if after considering all relevant positive and negative evidence, it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the loss carry forwards. In order to realize the benefit associated with our federal net operating loss (NOL) carryforwards, the Company must earn cumulative taxable income of $66,573,636 prior to the expiration of those NOLs. Our federal NOL carryforwards expire as follows:

Year of Expiration	NOLs
2006	$ 5,533,711
2007	5,370,000
2008	3,459,000
2009	7,053,000
2010	795,394
2011	7,731,587
2017-2021	30,396,051
2022-2024	6,234,893
Total	$66,573,636

The Tax Reform Act of 1986 contains provisions that limit the annual amount of NOLs available to be used in any given year in the event of a significant change in ownership. On September 29, 2000, two separate companies, STC Technologies, Inc. and Epitope, Inc. merged to form our company. A significant change in ownership, as defined by Section 382 of the Internal Revenue Code, occurred in connection with this merger. As such, the utilization of NOLs generated prior to September 29, 2000 is limited to approximately $13,700,000 per year. We do not believe that this limitation will have a material adverse impact on the utilization of our NOL carryforwards.

At the end of 2005, we concluded that it was more likely than not that the majority of our deferred tax asset would be recovered. Accordingly, we reduced our valuation allowance by approximately $26,700,000. The remaining valuation allowance of approximately $1,600,000 at December 31, 2005 relates to certain federal research and development tax credits that we believe are not likely to be recovered.

Included in the 2005 reduction of the valuation allowance is approximately $8,500,000 related to prior years' tax benefits associated with the exercise of employee stock options. This amount was recognized as an increase to additional paid-in capital in the current period. A current tax benefit of approximately $245,000 associated with employee exercises of non-qualified stock options and disqualifying dispositions of stock acquired with incentive stock options during the year ended December 31, 2005 was also recorded as additional paid-in capital during 2005.

10. STOCKHOLDERS' EQUITY:

Common stock

On October 7, 2003, we successfully completed a public offering in which we sold 5,000,000 shares of our common stock. Upon the exercise of the underwriters' over-allotment option on November 5, 2003, we sold an additional 311,000 shares of common stock. The price to the public of the 5,311,000 shares of common stock was $9.00 per share. We received proceeds of $44,828,003, net of expenses, from this offering.

Stock-based Awards

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 related interpretations in accounting for stock awards granted to employees and directors. Accordingly, compensation cost, 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 cost, if any, is deferred and charged to expense over the respective vesting period.

We account for stock-based compensation to non-employees using the fair value method, in accordance with SFAS No. 123 and EITF Issue No. 96-18. In May 2005, we modified the term of two individual non-employee stock option grants. As a result, compensation expense of $123,916 was recorded during 2005, based on the estimated fair value of such awards using the Black-Scholes option pricing model. No such expense was recorded in 2004 or 2003.

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, January 1, 2003	3,879,608	$0.80–15.03	$5.83
Granted	1,129,885	5.51–10.47	6.97
Exercised	(849,374)	0.80– 7.88	4.38
Canceled	(224,656)	0.80–13.66	6.61
Balance, December 31, 2003	3,935,463	0.80–15.03	6.42
Granted	1,629,891	6.63–10.29	8.07
Exercised	(370,800)	0.80– 9.92	5.14
Canceled	(320,050)	3.83–13.19	7.89
Balance, December 31, 2004	4,874,504	0.80–15.03	6.98
Granted	778,572	5.60–10.99	6.60
Exercised	(1,009,794)	0.80–11.98	6.01
Canceled	(426,497)	4.40–15.03	7.55
Balance, December 31, 2005	4,216,785	$0.80–12.69	$7.08

The following table summarizes information about stock options outstanding at December 31, 2005:

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–$5.04	411,489	16.65	$ 3.64	387,218	$ 3.62
$5.60	512,462	9.07	5.60	104,165	5.60
$5.76	1,459	7.04	5.76	104	5.76
$5.87	439,728	6.08	5.87	430,899	5.87
$6.10–$6.87	139,279	6.60	6.68	127,653	6.69
$6.96	526,313	7.08	6.96	404,481	6.96
$6.98–$7.64	442,135	5.18	7.21	417,135	7.21
$7.77–$8.03	429,000	8.27	7.78	176,500	7.80
$8.09–$8.20	766,377	8.04	8.20	406,285	8.20
$8.36–$12.69	548,543	7.12	10.00	331,288	10.44
	4,216,785	8.24	$ 7.08	2,785,728	$ 6.95

The 2000 Plan also permits us to grant restricted shares of our common stock to eligible employees, including officers. Generally, these shares are nontransferable and are subject to vesting requirements or forfeiture, as determined by the Compensation Committee of our Board of Directors. Upon granting of these restricted shares, deferred compensation cost equivalent to the market value of such shares at the date of grant is recorded in stockholders' equity and subsequently amortized to compensation expense over the periods during which the restrictions lapse, which is generally three years. During 2005, 2004, and 2003, we recorded $1,918,343, $3,176,150, and $650,663 of deferred compensation, respectively, related to restricted stock grants to certain members of management. Amortization of deferred compensation related to these grants was $1,500,054, $874,162, and $36,148 in 2005, 2004, and 2003, respectively.

The following table summarizes restricted stock award activity for the years ended December 31:

	2005	2004	2003
Issued and unvested, January 1,	485,000	75,000	—
Granted	332,188	410,000	75,000
Vested	(197,180)	—	—
Cancelled	(13,563)	—	—
Issued and unvested, December 31,	606,445	485,000	75,000

In connection with the vesting of restricted shares during the year ended December 31, 2005, we repurchased and immediately retired 63,080 shares with an aggregate value of $601,347 to satisfy minimum statutory tax withholding requirements.

As of December 31, 2005, 1,838,435 shares were available for future grants under the 2000 Plan.

Common Stock Warrants

As of December 31, 2005, 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 and royalty payments. Under the terms of the Phosphor Agreements, these payments are cancellable within 90 days of communication by either party to terminate the agreements. These sponsored research funds were $50,000 in 2005 and will continue to be $50,000 per year through 2008. Related royalty payments are $25,000 per year until 2008. All of these amounts are expensed as incurred. Future minimum payments under these agreements are as follows:

2006	$ 225,000
2007	225,000
2008	225,000
2009	150,000
2010	150,000
Thereafter	1,050,000
	$2,025,000

Sublicense Agreement

In June 2004, we entered into a sublicense agreement with a third party, pursuant to which we have been granted a limited, worldwide, non-exclusive sublicense to certain HIV-2 patents held by such party. Under the terms of this sublicense agreement, we are obligated to pay royalties based on a percentage of our net sales of certain products, which incorporate the technology covered by the licensed patents. Future minimum payments under this agreement are as follows:

2006	$ 400,000
2007	500,000
2008	500,000
2009	500,000
2010	500,000
Thereafter	3,791,667
	$6,191,667

Royalties from our commercial sale of products covered by the sublicense can be credited against these minimum royalty obligations.

License Agreement

In August 2005, we entered into a license agreement with third parties, pursuant to which we have been granted a limited, personal, non-transferrable, non-exclusive license to certain patents related to HCV held by such parties. Under the terms of the HCV license agreement, we are also obligated to pay royalties based on our

net sales of certain products which incorporate the technology covered by the licensed patents. Royalties under the license agreement vary based upon the geographical territory where the product is sold. Future minimum payments under this agreement are $3,000,000 in 2006. No minimum payments are required in 2007 or thereafter. We may, however, be required to pay additional license fees, up to an additional $5,500,000, upon the achievement of specific development and/or commercial milestones.

Leases

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

2006	$1,256,673
2007	1,158,156
2008	1,165,764
2009	1,181,217
2010	921,748
Thereafter	1,537,776
	$7,221,334

We currently intend to exercise our option to purchase two of the leased facilities. Upon purchase of either facility, we would no longer be required to pay the contractual lease payments related to the given facility. The future lease payments included in the table above related to these two facilities are $1,146,954 in 2006, $1,150,017 in 2007, $1,165,764 in 2008, $1,181,217 in 2009, $921,748 in 2010, and $1,537,776 thereafter.

Rent expense for 2005, 2004 and 2003 was $1,146,697, $1,690,858, and $1,594,240, respectively.

Purchase Commitments

As of December 31, 2005, we had outstanding noncancelable purchase commitments in the amount of $2,424,672, of which $1,412,707, $171,811 and $840,154 are related to inventory, capital expenditures, and other goods or services, respectively.

Employment Agreements

Under terms of employment agreements with certain executive officers and other employees, extending through 2007, we are required to pay each individual a base salary for continuing employment with our Company. The agreements require payments of $1,471,400 and $410,450 in 2006 and 2007, respectively.

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. RETIREMENT PLANS:

Substantially all employees of the Company are eligible to participate in the OraSure Technologies, Inc. 401(k) Plan (the "401(k) Plan"). The 401(k) 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 401(k) Plan also provides for us to match employee contributions up to $4,000 per year. Contributions to the 401(k) Plan, net of forfeitures, were $361,629, $330,552, and $330,275 in 2005, 2004, and 2003, respectively.

13. GEOGRAPHIC INFORMATION:

Based on guidance in SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information," we believe we operate within one reportable segment. Our products are sold principally in the United States and Europe. Segmentation of operating income and identifiable assets is not applicable since our revenues outside the United States are export sales, and we do not have significant operating assets outside the United States.

The following table represents total revenues by geographic area, based on the location of the customer (amounts in thousands):

	For the year ended December 31,		
	2005	2004	2003
United States	$59,859	$47,843	$35,896
Europe	7,868	4,318	3,062
Other regions	1,639	1,847	1,493
	$69,366	$54,008	$40,451

14. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2005 and 2004. 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).

	2005 Results				
	Three months ended				Year ended
	March 31, 2005	June 30, 2005	September 30, 2005	December 31, 2005	December 31, 2005
Revenues	$15,828	$17,430	$18,077	$ 18,031	$ 69,366
Costs and expenses	14,613	16,468	14,863	15,849	61,793
Operating income	1,215	962	3,214	2,182	7,573
Other income (expense), net	346	481	594	725	2,146
Income before income taxes	1,561	1,443	3,808	2,907	9,719
Income tax benefit	—	—	—	(17,729)	(17,729)
Net income	$ 1,561	$ 1,443	$ 3,808	$ 20,636	$ 27,448
Earnings per share(1)					
Basic	$ 0.03	$ 0.03	$ 0.08	$ 0.45	$ 0.61
Diluted	$ 0.03	$ 0.03	$ 0.08	$ 0.44	$ 0.59
Shares used in computing earnings (loss) per share:					
Basic	44,645	44,784	45,372	45,624	45,110
Diluted	45,046	45,872	46,676	47,030	46,147

	2004 Results				
	Three months ended				Year ended December 31, 2004
	March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004	
Revenues	$12,409	$13,214	$14,176	$14,209	$54,008
Costs and expenses	12,734	13,265	14,657	14,709	55,365
Operating loss	(325)	(51)	(481)	(500)	(1,357)
Other income (expense), net	168	198	192	239	797
Income (loss) before income taxes	(157)	147	(289)	(261)	(560)
Income taxes (benefit)	5	5	5	(15)	—
Net income (loss)	$ (162)	$ 142	$ (294)	$ (246)	$ (560)
Earnings (loss) per share—basic and diluted(1)	$ (0.00)	$ 0.00	$ (0.01)	$ (0.01)	$ (0.01)
Shares used in computing earnings (loss) per share:					
Basic	44,271	44,465	44,539	44,578	44,464
Diluted	44,271	45,334	44,539	44,578	44,464

(1) The summation of the quarterly amounts does not equal the year-end basic and diluted earnings (loss) per share due to rounding.

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Stock Information

OraSure'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 Corporate Secretary at OraSure Technologies, Inc.



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