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

FORM 10-K
ANNUAL REPORT PURSUANT TO SECTION 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, 2008

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:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock $0.000001 par value per share	**The NASDAQ Stock Market LLC**

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

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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐

(Do not check if a smaller reporting company)

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, 2008): $173,253,510

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of March 4, 2009: 45,861,222 shares.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement for the 2009 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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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, expected manufacturing performance, 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 words, such as "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 Annual 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 diagnostic products and 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 performed on a rapid basis at the point of care and tests which are processed in a laboratory. 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 has been sold in the over-the-counter ("OTC") or consumer retail markets in the United States, Canada, Europe, Mexico and Australia.

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. 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, our Current Reports on Form 8-K and our other filings with the Securities and Exchange Commission ("SEC"), as well as any amendments to those Reports and filings. These Reports and filings are made available as soon as reasonably practicable after they are filed or furnished to the SEC. 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	Regulatory Status	Commercial Status
OraQuick *ADVANCE*® HIV-1/2	A rapid, point-of-care test for antibodies to the Human Immunodeficiency Virus Type 1 ("HIV-1") and Type 2 ("HIV-2" and together with HIV-1, "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") 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. Twelve month shelf life approved in December 2008.	Marketed
		CE mark (European Union) approved.	Marketed
		Registered in the United Kingdom, Ireland, Spain, Mexico, Brazil, and Peru.	Marketed
		Registrations filed in Colombia, Argentina, Romania, Croatia, Bosnia and Herzegovina.	Pending
OraQuick® HIV-1/2 OTC	A rapid, point-of-care oral fluid HIV-1/2 test intended to be sold in various OTC markets.	Clinical trials initiated. Data from observed user study submitted to FDA.	Pending
OraQuick® HCV	A rapid, point-of-care test for antibodies to the hepatitis C virus ("HCV").	PMA submitted to FDA in October 2008. Clinical studies for CE mark are in process.	Pending
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.	Marketed
		FDA 510(k) cleared for use 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 drugs of abuse ("DOA") testing in a laboratory setting.	Collection device—FDA 510(k) cleared.	Marketed

Product	Description	Regulatory Status	Commercial Status
MICRO-PLATE DOA Assays	Used to detect the following drugs in an oral fluid sample: marijuana, cocaine, opiates, amphetamines, methamphetamines, PCP, benzodiazepines, barbiturates and methadone.	Nine drug assays—FDA 510(k) cleared.	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, Mexico, Netherlands, Portugal, Spain, Sweden, Korea, Canada, Afghanistan and Brazil.	Marketed
Homogeneous DOA Assays	Homogeneous fully-automated oral fluid DOA assays.	Collaboration with Roche Diagnostics.	In Development
Cryosurgical Systems—Professional	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.	Marketed
		CE marked and registered in Europe, Canada, Venezuela, Thailand, New Zealand, Hong Kong, Brazil, Mexico, Canada and Afghanistan.	Marketed
Cryosurgical Systems—OTC	Cryosurgical system for the removal of common and plantar warts, sold in various OTC markets.	FDA 510(k) cleared. Sold under new national brand, Freeze 'n Clear Skin Clinic™.	Marketed
		Registered in Canada.	Marketed
		CE marked and registered in several European countries under Scholl Freeze Spray name.	Marketed
		Registered in Mexico, Argentina, Guatemala, Costa Rica, El Salvador and Chile under POINTTS name.	Marketed
		Registrations filed in Ecuador, Peru, Brazil, Honduras, and Colombia.	Pending
Cryosurgical Systems—OTC Product Line Extension	Cryosurgical system for an indication other than common warts or plantar warts.	Registrations applied for under POINTTS name in certain South and Central American countries and South Africa.	Pending
		FDA 510(k) filed.	Pending

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.® point-of-care saliva alcohol test.

OraQuick® Rapid Test Platform

OraQuick® is our rapid test platform designed to test oral fluid, whole blood (i.e., both finger-stick and venous), plasma and serum samples 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 and allowed to develop. In all cases, the specimen and

developer 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.

We have commercialized this technology in the form of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test. This is a rapid, point-of-care test which has received FDA approval for the detection of antibodies to both HIV-1 and HIV-2 in oral fluid, finger-stick and venous whole blood and plasma. This test is available for use by the nearly 40,000 locations in the United States certified under the Clinical Laboratory Improvements Amendment of 1988 ("CLIA") to perform moderately complex tests. We have also received a CLIA waiver for use of the OraQuick *ADVANCE*® test with oral fluid and finger-stick and venous whole blood. As a result, the test can be used by approximately 140,000 additional sites in the United States not certified under CLIA to perform moderately complex tests, such as outreach clinics, community-based organizations and physicians' offices.

On the international front, we have obtained a CE mark for our OraQuick *ADVANCE*® test so that we can sell this product in Europe and other countries accepting the CE mark for commercialization. We have distributors in place for the United Kingdom, Ireland, Spain, Russia and France and are pursuing distribution arrangements in several additional European countries. We are selling the OraQuick® HIV-1/2 test in Mexico and Africa and are completing registrations in several countries in Latin America, Asia and the Middle East. We are seeking to expand our distribution network for this product throughout the world.

In late 2008, the FDA approved our request to increase the shelf life for OraQuick *ADVANCE*® to twelve months from the date of manufacture. This approval was based on enhancements we made to the manufacturing process and product packaging for this product and represented a substantial increase in shelf life from the six months approved for the OraQuick *ADVANCE*® test then on the market. OraQuick® product with twelve month dating became available in the U.S. market in February 2009. In June 2008, we began to sell OraQuick® tests with twelve month dating in certain international markets and have submitted the new dating for approval in Europe.

We believe that the OraQuick *ADVANCE*® device, because it is approved for detecting antibodies to both HIV-1 and HIV-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 and elsewhere around the world. We also believe the twelve month shelf life recently approved by the FDA further strengthens the competitiveness of this product.

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.

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 enzyme immunoassay ("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 received premarket approval from the FDA to sell the OraSure® collection device for use with a laboratory-based EIA screening test for HIV-1 antibody detection. In the past, this EIA screening test was manufactured and sold by bioMerieux, Inc. ("BMX"). 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.

In 2007, BMX discontinued manufacturing the HIV-1 EIA screening test. As a result, we are performing clinical studies and plan to seek FDA approval of an alternative HIV-1 EIA screening test for use with oral fluid samples collected with our OraSure® device.

A collection device that is substantially similar to the OraSure® device is sold by us 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 EIAs is also FDA 510(k) cleared for use with the Intercept® device.

We have received a CE mark for the Intercept® and OraSure® devices and our oral fluid assays, all of which are distributed in Canada, the United Kingdom and Mexico. The OraSure® device and our oral fluid drugs of abuse assays are also sold in several other foreign countries.

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 (Skin Lesion 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 three 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 a maximum of –50°C to –55°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 in Canada, throughout Europe and in certain other foreign countries.

We have also 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. Prior to 2008, this product was distributed for us in the United States and Canadian OTC markets under the name Freeze Off® by Prestige Brands Holdings, Inc. ("Prestige"), the owner of the Compound W® line of wart removal products. As a result of a decision in arbitration proceedings with respect to Prestige's acquisition of the

competing Wartner® cryosurgical product line, our agreement with Prestige terminated on December 31, 2007. In early 2009, we launched our OTC cryosurgical wart product in the U.S. under a new national brand called Freeze 'n Clear Skin Clinic™. This launch has started with one major retailer, and we will look to expand to other retailers in the future.

Internationally, we distribute a CE marked cryosurgical wart removal product into the OTC footcare market in Europe, Australia and New Zealand through our distributor, SSL International plc ("SSL"), under the Scholl and Dr. Scholl trademarks. SSL is the owner of the Scholl and Dr. Scholl trademarks in countries outside North and South America. We also distribute an OTC cryosurgical product through our distributor Genomma Labs, under the POINTTS tradename, in Mexico, a number of South and Central American countries, and South Africa.

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 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. In recent years, sales of our AUTO-LYTE® tests have been substantially reduced largely because of competition from cheaper "home-brew" tests used by our laboratory customers. As a result, we expect to eventually stop selling our AUTO-LYTE® tests.

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. Our oral fluid Western blot HIV-1 confirmatory test was previously marketed under an exclusive arrangement with BMX.

At the end of 2007, BMX terminated the agreement under which it supplied the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and the agreement under which it distributed that product on an exclusive, world-wide basis. As a result, we are now supplying this test directly to our laboratory customers. Pursuant to the terms of our antigen supply agreement with BMX, we purchased an additional two-year supply of the antigen from BMX so that we can continue to manufacture and sell our oral fluid Western blot test. When this additional two-year supply is combined with our existing inventory of the HIV-1 antigen, we believe we have a sufficient supply of HIV-1 antigen to meet the demand for our Western blot test for at least the next several years.

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, has been

cleared for sale by the FDA and has received a CLIA waiver. The U.S. Department of Transportation ("DOT") has also approved the test for purchase.

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. Because the OraQuick® platform is simple to use and can operate in a non-invasive manner with oral fluid, we believe it will be suitable for use by consumers without the assistance of a doctor or other medical professional. We also 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.

We are currently devoting significant resources to obtaining FDA approval to sell our OraQuick® HIV-1/2 test in the United States OTC market. We have completed an observed user study and submitted our data to the FDA. We have also developed an information and referral system and product packaging and labeling suitable for the OTC market. We expect to conduct additional clinical work through 2009, and we intend to submit an application for FDA approval after our clinical studies are completed.

We have developed a rapid test on the OraQuick® platform which can detect antibodies to the Hepatitis C virus, or HCV, in oral fluid, blood, serum and plasma samples. A PMA application for this test was submitted to the FDA in October 2008. Additional clinical studies required to obtain a CE mark are underway. In addition, during 2008, we obtained rights to a rapid HCV test manufactured by a third party for distribution into certain developing foreign countries.

We have entered into agreements with Schering-Plough Corporation ("Schering-Plough") to collaborate on the development and promotion of our OraQuick® HCV test for use with oral fluid. Under the terms of these agreements, we have been and may be reimbursed by Schering-Plough for a portion of our costs to develop the test and obtain regulatory approvals, and Schering-Plough will provide detailing and other promotional support for the test in the physicians' office market in the United States and internationally.

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, the Substance Abuse and Mental Health Services Administration ("SAMHSA") issued proposed regulations for oral fluid drug testing for federal workers. These proposed regulations have since been withdrawn. If and when reissued 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. In 2008, we signed a development agreement with Roche Diagnostics for homogeneous fully-automated

oral fluid drugs of abuse assays that can be run on random access chemistry analyzers. The oral fluid assays are being developed for use with our Intercept® collection device and Roche's KIMS (kinetic information of microparticles in solution) technology. The assays will run on various automated analyzers to allow oral fluid samples to be processed with the same efficiency currently achieved with urine-based drug tests. Assays for cocaine, opiates, methamphetamine, amphetamine, PCP and cannabinoids (marijuana) have been developed and are being transferred to manufacturing by Roche. We are currently negotiating a commercialization agreement with Roche pursuant to which a drug testing system comprised of our Intercept® device and the newly developed homogeneous assays will be marketed and sold on a worldwide basis.

OTC Cryosurgical Systems Products

We currently sell our Histofreezer® cryosurgical systems product in the physicians' office or professional market. This product has been approved by the FDA for the treatment of a total of nine different types of benign skin lesions. Our OTC cryosurgical product has been approved by the FDA for two types of skin lesions – common warts and plantar warts.

We believe that one or more of the seven remaining Histofreezer® indications may be attractive to the OTC market. We have submitted an application for FDA 510(k) clearance of an OTC cryosurgical product for one of these indications and that application remains pending before the FDA.

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 OTC cryosurgical 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. An important new product that we recently developed is a rapid HCV test on our OraQuick® platform and we have acquired distribution rights in certain African countries to a rapid HCV test manufactured by a third party.
- *OTC Opportunities*. We intend to identify or develop products that can be sold in the OTC or retail marketplace. A significant opportunity that we are pursuing as part of this strategy is to seek FDA approval to sell our OraQuick® rapid HIV-1/2 antibody test in the United States OTC market. We have also relaunched our OTC cryosurgical product in the United States on a limited basis under our new national brand, Freeze 'n Clear Skin Clinic™, and plan to expand the international sale of our OTC cryosurgical product.

- *Operational Improvements*. We intend to remain 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 2008, 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 PMA approval for our OraQuick® HCV test, clinical work to obtain FDA approval for use of an OraQuick® HIV test in the United States OTC market, and development of certain improvements to existing products in the OraQuick®, Intercept® and cryosurgical wart removal product lines.

From time to time, we may also contract with third parties to conduct research and development activities and we may continue to do so in the future.

Research and development expenses totaled $20.3 million in 2008, $14.1 million in 2007 and $8.6 million in 2006. These expenses include our costs associated with research and development, regulatory affairs, clinical trials and product support.

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 create or raise awareness through a full array of marketing activities, which include trade shows, print advertising, special programs and distributor promotions, in order to stimulate sales in each target market.

We market our products in the United States and internationally. Revenues attributable to customers in the United States were $57.4 million, $64.6 million and $56.8 million in 2008, 2007 and 2006, respectively. Revenues attributable to international customers amounted to $13.7 million, $18.1 million and $11.4 million, or 19%, 22% and 17% of our total revenues, in 2008, 2007 and 2006, 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, the Centers for Disease Control and Prevention ("CDC"), SAMHSA and other governmental agencies, family planning clinics, 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.

Since November 2002, Abbott Laboratories ("Abbott") had been our exclusive distributor of OraQuick® in the U.S. hospital market and non-exclusive distributor in the U.S. physicians' office marketplace. Our agreement with Abbott was terminated at the end of 2008. As a result, we are now selling OraQuick *ADVANCE*® directly to U.S. hospitals and will continue to sell to U.S. physician offices through distributors. In anticipation of the transition of this business, we increased the size of our hospital sales force and added additional inside sales, customer service and sales support resources. In addition to selling OraQuick *ADVANCE*® to hospitals, we expect our hospital sales force to eventually sell new products to this market, including our OraQuick® HCV test, once FDA approval is obtained.

We currently distribute our OraQuick® test in several foreign countries. During 2007, we obtained a CE mark for this product and launched sales in the United Kingdom, Ireland and Spain. We expect to increase the number of countries where this product is sold as we find new distributors and complete registrations in additional countries.

We also market the OraSure® oral fluid collection device for HIV-1 testing, on its own and as a kit in combination with laboratory testing services. To better serve our public health customers, we have contracted with two commercial laboratories to provide prepackaged OraSure® test kits, with prepaid laboratory testing and specimen shipping costs included. We also sell the OraSure® device in the international public health market.

In October 2008, we submitted a PMA application with the FDA for approval of a rapid HCV test using the OraQuick® platform, and plan to apply for CLIA waiver, a CE mark and other international registrations. We intend to sell this product on a worldwide basis. We have entered into agreements with Schering-Plough to collaborate on the development and promotion of our OraQuick® HCV test for use with oral fluid. Under the terms of these agreements, we have been and may be reimbursed by Schering-Plough for a portion of our costs to develop the test and obtain regulatory approvals, and Schering-Plough will provide detailing and other promotional support for the test in the physicians' office market in the United States and internationally.

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 Quest Diagnostics ("Quest") and Clinical Reference Laboratory, and internationally for workplace, criminal justice and forensic toxicology testing through Bio-Rad Laboratories, Concateno (which acquired our prior distributor, 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.

We also market the Intercept® collection device on its own and as a kit in combination with laboratory testing services. To better serve our workplace customers, we have contracted with two commercial laboratories to provide prepackaged OraSure® test kits, with prepaid laboratory testing and specimen shipping costs included.

The criminal justice market in the United States for our substance abuse testing products 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. The forensic toxicology market consists of several hundred laboratories including federal, state and county crime laboratories, medical examiner laboratories and reference laboratories.

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. Our major U.S. distributors include Cardinal Healthcare, McKesson HBOC, Physicians Sales & Service, AmerisourceBergen Corporation, and Henry Schein. Internationally, we sell the Histofreezer® product through a network of distributors in more than 20 countries worldwide.

In past years, we sold a cryosurgical wart removal product similar to Histofreezer® in the OTC market in the United States and Canada pursuant to a distribution agreement with Prestige, the owner of the Compound W® line of wart removal products. That distribution agreement terminated at the end of 2007. In early 2009, we launched our OTC cryosurgical wart product in the U.S. under a new national proprietary brand called Freeze 'n Clear Skin Clinic™. This launch has started with one major retailer, and we intend to expand to other retailers in the future.

Additionally, we distribute cryosurgical wart removal products in the OTC footcare market in Europe, Australia and New Zealand through our distributor, SSL, under its Scholl and Dr. Scholl tradenames, and in the OTC markets in Mexico and several Central and South American countries under the POINTTS tradename through our distributor, Genomma Labs.

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, Heritage Labs and Clinical Reference Laboratory. These laboratories in turn provide the devices to insurance companies, usually in combination with testing services.

We also promote 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 was previously 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 BMX elected not to renew the Western blot agreements after December 31, 2007, we now distribute the Western blot test directly to our laboratory customers.

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.

In recent years, we have 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, as well as some consolidation in the industry leading to a reevaluation of testing methods.

We also sell our AUTO-LYTE® assays and reagents in the insurance testing market directly to laboratories, including 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 foreign governments, 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 10% or more of our total revenues during the past three years. The OraQuick® rapid HIV testing products, the cryosurgical systems products, and the OraSure® and Intercept® oral fluid collection devices accounted for total revenues of $35.3 million, $10.7 million and $13.6 million in 2008, $32.7 million, $23.5 million and $15.5 million in 2007, and $25.6 million, $17.3 million and $15.1 million in 2006, respectively.

We had two customers, Quest and Abbott, which each accounted for 10% of our total revenues during 2008. Our distribution agreement with Abbott terminated at the end of 2008, and we are now selling OraQuick *ADVANCE*® directly to hospitals and other customers previously served by Abbott. The loss of Quest, or a significant decrease in the volume of products purchased by this customer, could have a material adverse effect on our financial results.

Revenue by Segment

We operate our business within one reportable segment and all of our revenues are generated from this one segment. Our net revenue is generated by our product sales and licensing and product development activities. For more information about our revenues from external customers, income and total assets, please see the sections entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Note 13 to the financial statements, included elsewhere in this Annual Report.

Supply and Manufacturing

We manufacture our OraQuick *ADVANCE*® test in our Bethlehem, Pennsylvania facility. In addition, we have contracted with a third party in Thailand for the assembly of the OraQuick® device, 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. We currently purchase the antigen from a single contract supplier under a long-term agreement with an initial term ending in 2010 and one-year automatic renewal terms thereafter. We also purchase the nitrocellulose used in the test from a single vendor, under a supply agreement with a five-year term ending in 2009. We intend to renew this agreement prior to its expiration. If for any reason these suppliers are unwilling or 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 facility, and we expect to continue to do so for the foreseeable 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 currently available from only a limited number of sources. For many years, we purchased the antigen for this product from BMX on an exclusive basis. Our agreement with BMX for the supply of HIV-1 antigen terminated on December 31, 2007. As a result, we purchased an additional two-year supply of the antigen from BMX as permitted under the agreement. When this additional supply is combined with our existing inventory of the HIV-1 antigen, we believe we have a sufficient supply of the HIV-1 antigen to meet the demand for our Western blot test for at least the next several years.

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. The cryosurgical wart removal products distributed in OTC markets are supplied by vendors located in the United States. We believe that additional suppliers of all 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, 2008, we had 287 full-time employees, including 84 in sales, marketing and client services; 16 in research and development; 136 in operations, manufacturing, quality control, information systems, purchasing and shipping; 24 in regulatory affairs; and 27 in administration and finance. This compares to 290 employees as of December 31, 2007. Our employees are not currently represented by a collective bargaining agreement.

In light of the ongoing negative economic conditions, we re-examined our staffing levels and, in December 2008, we eliminated 18 positions in order to reduce our future costs. At the same time, we refocused our resources on parts of our business having the greatest strategic impact. A primary example was the expansion of our sales force and related support functions needed to implement a direct hospital sales model for our OraQuick *ADVANCE*® HIV-1/2 test. We believe these actions were necessary to lower our costs where possible while taking steps to ensure the future success of our business.

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, performance, 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®, OraQuick® and OraSure® devices to increase as the benefits of oral fluid-based testing become more widely accepted.

Competition in the HIV testing market 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 and Abbott, sell laboratory-based HIV-1/2 EIAs, and Maxim Biomedical (formerly Calypte, Inc.) sells an HIV-1 screening test for urine, in the United States. MedMira and Trinity Biotech each sell competing rapid HIV-1 blood tests, and Bio-Rad Laboratories and Inverness Medical/ Chembio sell competing rapid HIV-1/2 blood tests in the United States. These tests compete with our OraQuick *ADVANCE*® test in hospitals and other laboratory settings. In addition, Trinity Biotech and Inverness Medical/ Chembio have received CLIA waivers for their rapid HIV tests, and these tests compete 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, and often these competing tests are sold at prices substantially below the prices we charge for our OraQuick *ADVANCE*® test. Inverness Medical sells a rapid HIV-1/2 blood test outside the United States and Calypte has developed a rapid oral fluid HIV test which is now being sold in certain foreign countries. Lower priced rapid HIV blood tests are also sold internationally by various third parties.

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, continue to come under increasing competitive pressure from "home-brew" assays developed internally by our laboratory customers. 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. In order to meet this competition, we are developing fully-automated homogeneous oral fluid drugs of abuse assays with Roche Diagnostics for use with our Intercept® device.

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. 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 "home-brew" assays developed internally by our laboratory customers, 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. Major competitors for the Histofreezer® product include Cryosurgery, Inc. in the United States and Wartner in Europe.

Competition in the United States and Canadian OTC markets comes primarily from cryosurgical products sold by Schering-Plough under the Dr. Scholl's® brand and by Prestige under the Compound W® and Wartner® tradenames. Salicylic acid wart removal products also compete against our OTC cryosurgical product. Internationally, our OTC products compete against cryosurgical products sold by Wartner and several other firms.

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 patents 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 ten 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. The patents expire from April 2009 to March 2018. We have also applied for additional patents, in both the United States and certain foreign countries, on such products and technology.

We have two United States patents for our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test, and we have several related patent applications pending for this product in the United States and internationally. These patents expire from March to April 2019. 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 platforms. 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 or other tests that use the same or similar technology platform. See Section 1A, entitled "Risk Factors," for a further discussion of these issues.

We have four 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 pending patent applications related to these products in the United States and in certain foreign countries. These patents expire from July 2012 to August 2013. 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 two United States patents and numerous foreign patents and patent applications for the technology used in the Q.E.D.® test. These patents expire from May to August 2009. These patents are related to the analog-to-digital technology color control systems and methods, systems and devices for the test, and detection of biochemical molecules.

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

We own rights to trademarks and service marks that we believe are necessary to conduct our business as currently operated. In the United States, we own the OraSure®, Intercept®, OraQuick®, OraQuick *ADVANCE*®, Histofreezer®, Freeze 'n Clear Skin Clinic™, Q.E.D.® and AUTO-LYTE® trademarks. We also own many of these marks and others in several foreign countries. With respect to our international OTC cryosurgical products, the Scholl and Dr. Scholl tradenames are owned by SSL in Europe, Australia, New Zealand and other countries outside North and South America, and the POINTTS tradename is owned by Genomma Labs.

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 manufacture and 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 only 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, or PMA), the FDA must approve a 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 and facility inspections 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 laboratories 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 the QSRs, manufacturers must continue to expend time, money and effort in the area of production and quality 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 PMA 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 the 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 and the product meet the requirements of all applicable directives, including the MDD and IVDD.

We received authorization to use the CE mark for the OraQuick *ADVANCE*® rapid HIV-1/2 test, the OraSure® and Intercept® collection devices and our Histofreezer® product line, and SSL has obtained authorization to use the CE mark for our cryosurgical wart removal product in the OTC European footcare market.

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, and/or 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.

Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act ("FCPA") prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Our present and future business has and will continue to be subject to the FCPA and various other laws, rules and/or regulations applicable to us as a result of our international sales.

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.

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.

ITEM 1A. Risk Factors

You should carefully consider the risks and uncertainties described below, together with all of the other information included in this Annual Report and our other SEC filings, in considering our business and prospects. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not disclosed or not presently known to us or that we currently deem immaterial also may impair our business operations. The occurrence of any of the following risks could harm our business, financial condition or results of operations.

Regulatory Risks

The Need to Obtain Regulatory Approvals Could Increase Our Costs and Adversely Affect Our Financial Performance.

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. These approvals can require the submission of a large amount of clinical data which can be expensive and may require significant time to obtain. It is also possible that a product will not perform at a level needed to generate the clinical data required to obtain an approval or clearance. The submission of an application to the FDA or other international 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. Our future performance depends on, among other things, our estimates as to when and at what cost we will receive regulatory approvals for new products.

We are conducting clinical studies to support an application for FDA approval of our OraQuick® HIV-1/2 test for sale in the United States OTC market. We have also conducted clinical trials and submitted a PMA application for FDA approval of our OraQuick® HCV test for professional use. There can be no assurance that these clinical trials will support FDA approval of either product or that FDA approval will be obtained. Failure to obtain or any delay in obtaining FDA approval for either product could significantly reduce future revenues, increase our costs and adversely affect our financial performance.

In addition, all *in vitro* diagnostic products that are to be sold in the EU must bear the CE mark indicating conformance with the essential requirements of the 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. We also intend to obtain CE mark for 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 or maintained for all products that we desire to sell in the EU.

Our Ability to Respond to Changes in Regulatory Requirements Could Adversely Affect Our Business.

Newly promulgated or changed regulations could require changes to our products, necessitate additional clinical 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 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. Although the SAMHSA regulations have been withdrawn, if and when they are issued in final form, they 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.

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.

Our businesses are extensively regulated by the FDA and other federal, state and foreign regulatory agencies. Our suppliers and distributors often are subject to similar regulation. These regulations impact many aspects of our operations, and the operations of our suppliers and distributors, including manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. For example, our manufacturing facilities and those of our suppliers and distributors are, or can be, subject to periodic regulatory inspections. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any product approvals that could restrict the commercial applications of those products. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product, including withdrawal of the product from the market. We are also subject to routine inspection by the FDA and certain state agencies for compliance with Quality System Requirement and Medical Device Reporting requirements in the United States and other applicable regulations worldwide, including but not limited to ISO 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, selling or exporting our products if it concludes that we are out of compliance with applicable regulations. The ability of our suppliers to supply critical components or materials and of our distributors to sell our products could be adversely affected if their operations are determined to be out of compliance. 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. Such actions by the FDA and other regulatory bodies could adversely affect our revenues.

In the ordinary course of business, we must frequently make subjective judgments with respect to compliance with applicable laws and regulations. If regulators subsequently disagree with the manner in which we have sought to comply with these regulations, we could be subjected to substantial civil and criminal penalties, as well as product recall, seizure or injunction with respect to the sale of our products. The assessment of any civil and criminal penalties against us could severely impair our reputation within the industry and any limitation on our ability to manufacture and market our products could have a material adverse effect on our business.

We Are Subject to Numerous Government Regulations in Addition to FDA Requirements, Which Could Increase Our Costs or Affect Our Operations.

In addition to FDA and other regulations described previously, 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.

We must also comply with numerous laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, disposal of hazardous substances and

labor or employment practices. Compliance with these laws or any new or changed laws regulating our business could result in substantial costs. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of these requirements. To the extent the costs and procedures associated with complying with these laws and requirements are substantial or it is determined that we do not comply, our business and results of operations could be adversely affected.

Risks Relating to Our Industry, Business and Strategy

Our Ability to Sell Products Could be Adversely Affected by Competition From New and Existing Diagnostic Products and by Treatments 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 prevent HIV or preventative 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 2008, 2007 and 2006, we incurred $20.3 million, $14.1 million and $8.6 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 or gain commercial acceptance for our 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.

Failure to Achieve Our Financial and Strategic Objectives Could Have a Material Adverse Impact on Our Business Prospects.

As a result of any number of risk factors identified in this Annual Report, no assurance can be given that we will be successful in implementing our financial and strategic objectives, including our clinical development programs for a rapid HIV OTC test and/or a rapid HCV test using the OraQuick® technology platform. In addition, the funds for the foregoing projects have in the past come primarily from our business operations. If our business slows and we become less profitable, and as a result have less money available to fund research and development and clinical programs, we will have to decide at that time which programs to cut, and by how much. Similarly, if adequate financial, personnel, equipment or other resources are not available, we may be required to delay or scale back our strategic efforts. Our operations will be adversely affected if our total revenue and gross profits do not correspondingly increase or if our technology, product, clinical and market development efforts are unsuccessful or delayed. Furthermore, our failure to successfully introduce new products and develop new markets could have a material adverse effect on our business and prospects.

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

Our success depends 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.

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 many risk factors, including the following:

- Suitable acquisitions or investments may not be found or consummated on terms or schedules 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, increased competition and our ability to complete the acquisition and integrate the acquired entity's operations and business; and

- An acquisition of a foreign business may involve additional risks, including, but not limited to, foreign currency exposure, liability or restrictions under foreign laws or regulations and our inability 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 Revenues 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 end-users do not receive adequate reimbursement for the cost of our products from 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 Expend Considerable Resources to Meet the Demand or Harm Our Customer Relationships if We are Unable to Meet That 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. In addition, new manufacturing equipment or facilities may require FDA approval before they can be used to manufacture our products. To the extent we are unable to obtain or are delayed in obtaining such approvals, our ability to meet the demand for our products could be adversely affected.

If we or our suppliers are unable to develop necessary manufacturing capabilities in a timely manner, our sales could be adversely affected. If we fail to increase production volumes cost effectively or if we experience lower than anticipated yields or production problems as a result of changes that we or our suppliers make in our manufacturing processes to meet increased demand, we could experience shipment delays or interruptions and increased manufacturing costs, which could also have a material adverse effect on our revenues and profitability.

Unexpected increases in demand for our products could also require us to obtain additional raw materials in order to manufacture products to meet the demand. Some raw materials require significant ordering lead time and some are currently obtained from a sole supplier or a limited group of suppliers. We have long-term supply agreements with many of these suppliers, but these long-term agreements involve risks for us, such as our potential inability to obtain an adequate supply of raw materials and components and our reduced control over

pricing, quality and timely delivery. It is also possible that one or more of these suppliers may become unwilling or unable to deliver materials to us. Any shortfall in our supply of raw materials and components, and our inability to quickly and cost-effectively obtain alternative sources for this supply, could have a material adverse effect on our total revenue or cost of sales and related profits.

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. Our sales depend to a substantial degree on our ability to sell products to these customers and on the marketing abilities of the companies with which we collaborate.

Some of our distributors or other customers may not fulfill their contractual obligations to us or otherwise market and distribute our products in the manner or at the levels we expect. Although we will try to maintain and expand our business with distributors and customers 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 our expectations, or that new distribution channels will be available on satisfactory terms. The failure of these distributors or other customers to purchase our products could adversely affect our revenues.

Some of our distributors have also 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. 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. This may cause customers to stop using our products or to purchase or manufacture lower cost alternatives.

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

We currently purchase certain critical components of our products from sole supply sources or other third party suppliers. For example, all of the HIV antigen and nitrocellulose required to make our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test is purchased from sole source suppliers. In addition, the conjugates used in our MICROPLATE oral fluid drugs of abuse assays are obtained from third party suppliers.

If these suppliers are unable or unwilling to supply the required component or if they make changes in the component or do not supply materials meeting our specifications, we may need to find another source and perform additional development work. We may also need to 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 and may not occur at all. The availability of critical components from sole supply sources or other third parties 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 EIA 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.

Historically, BMX manufactured and sold the only oral fluid HIV-1 EIA 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 also supplied the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and was the exclusive world-wide distributor of that product.

BMX discontinued manufacturing the HIV-1 EIA screening test in 2007. As a result, we will be conducting clinical trials and intend to seek FDA approval of an alternative HIV-1 EIA screening test manufactured by a third party for use with oral fluid samples collected with our OraSure® device.

If at some point in the future our customers cannot obtain either an HIV-1 EIA screening test or a Western blot or other HIV-1 confirmatory test that has been approved by the FDA for use with our OraSure® collection device, sales of our OraSure® device could be negatively affected.

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.

We may need to collaborate with one or more third parties or find new product distribution channels in order to commercialize our OraQuick® HIV-1/2 test in the United States OTC market should we receive approval from the FDA. In order to successfully commercialize our OraQuick® test in the OTC market, we and/or our distributors may need to invest significantly in advertising and promotion in order to sell this product into the OTC market. If we are unable to collaborate with a third party having sufficient resources to assist in these efforts or find alternative distribution channels to access the OTC market, we may need to incur significant costs for advertising and promotion, and our ability to maximize our future revenues for this opportunity could be adversely affected.

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 our 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 May Become Involved in Intellectual Property Infringement Disputes, Which Could Increase our Costs and 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 or our customers 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 industry is characterized by a large number of patents, claims of which appear to overlap in many cases. As a result, there is a significant amount of uncertainty regarding the extent of patent protection and infringement. Companies may have pending patent applications, which are typically confidential for the first eighteen months following filing, that cover technologies we incorporate in our products. Accordingly, we may

be subjected to substantial damages for past infringement or be required to modify our products or stop selling them if it is ultimately determined that our products infringe a third party's proprietary rights.

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 or acquire;
- The pendency of any litigation may in and of itself cause our distributors and customers to reduce purchases of our products; and
- A court could award a preliminary and/or permanent injunction, which would prevent us from selling our current or future products.

In addition to the foregoing, we may also indemnify some customers and strategic partners under our agreements with such parties if our products or activities have actually or allegedly infringed upon, misappropriated or misused another party's proprietary rights. Further, our products may contain technology provided to us by other parties, such as contractors, suppliers or customers, and we may have little or no ability to determine in advance whether such technology infringes the intellectual property rights of a third party.

The Sales Potential for Our OraQuick® Products Could be Affected by Our Ability to Obtain Certain Licenses and by Current or Future Litigation.

Our OraQuick® test platform is a lateral flow assay 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. We are currently involved in patent infringement litigation filed by Inverness Medical and Church & Dwight, which alleges that the manufacture and sale of our OraQuick *ADVANCE*® test infringes a lateral flow patent held by these parties. In the event that we are unable to successfully defend against the current litigation or future similar 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 OraQuick® devices could be limited and we may incur increased costs or damages. In such case, we may be able to modify the OraQuick® test to avoid the claim of infringement or the need for a license. 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 new products such as an OraQuick® rapid HIV-1/2 antibody test for home use, an OraQuick® HCV test for professional use, and other new products or technologies that may be developed or acquired. To achieve market acceptance, we and/or our distributors will likely be required to undertake 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. 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 public health, hospital, insurance and other 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.

If Our Direct Selling Efforts For Our Products Fail, Our Business Expansion Plans Could Suffer, and Our Ability to Generate Revenue Will be Diminished.

We have a relatively small sales force compared to many of our competitors. At the end of 2008, we terminated our agreement with Abbott, and we are now selling the OraQuick *ADVANCE*® HIV-1/2 test directly into the U.S. hospital market. If our direct sales force is not successful or new additions to our sales team fail to gain traction among our customers, we may not be able to increase market awareness and sales of our products in hospitals and elsewhere. In addition, if any hospital customers elect to use a competitor's product as a result of the transition from Abbott or we are otherwise unable to retain Abbott's hospital customers as our own or attract new hospital customers, our sales could be negatively affected.

Our Customers May Resist Adoption of Rapid Point-of-Care Diagnostic Testing.

We expect sales of our rapid point-of-care diagnostic products, such as our OraQuick *ADVANCE*® HIV-1/2 test, to become an increasingly important part of our business. Hospitals, clinical reference laboratories, physicians and other customers may resist the adoption of rapid point-of-care tests and instead may choose to use or continue to use competing laboratory tests. Our failure to achieve initial or additional market acceptance of our rapid point-of-care diagnostic tests with customers would have a negative effect on our future sales growth.

Our Sales Cycles Can be Lengthy and May Depend on Public Funding, Which Can Cause Variability and Unpredictability in Our Operating Results.

The sales cycles for certain of our products can be lengthy and unpredictable, which makes it more difficult to accurately forecast revenues in a given period and may cause revenues and operating results to vary from period to period. Sales of our products often involve purchasing decisions by large public and private institutions, may require many levels of approval and may be dependent on economic or political conditions and the availability of grants or other funding from governmental agencies which can vary from period to period in both

amount and timing. For example, in past years our OraQuick *ADVANCE*® HIV-1/2 test has been purchased through bulk procurement or other funding provided by the CDC, SAMHSA, city or state governments and other governmental agencies. On an international basis, our OraQuick® HIV-1/2 test has been purchased with funds provided by the President's Emergency Plan for AIDS Relief and other international agencies. There can be no assurance that purchases or funding from these agencies will continue at the same or higher levels or at all, especially if current negative economic conditions continue or intensify. As a result, we may expend considerable resources on unsuccessful sales efforts or we may not be able to complete transactions at all or on a schedule and in an amount consistent with our objectives.

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. Product liability claims could result in liabilities, lost revenues and damage to our image and the reputation of our products. 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 various countries. We expect to expand the OTC sales of these products to other countries and to eventually distribute other types of products in the domestic and international OTC markets, such as our OraQuick® HIV-1/2 test. We believe the sale of products in the OTC market increases the risk of potential product liability exposure and possibly 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.

We Could Suffer Monetary Damages, Incur Substantial Costs or be Prevented From Using Technologies Important to Our Products as a Result of Legal Proceedings.

We have been and in the future may become involved in various legal proceedings arising out of our businesses. These may include commercial disputes, negligence claims or various other lawsuits arising in the ordinary course of our business, including employment matters. Such lawsuits can seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. An adverse ruling or rulings in one or more such lawsuits could, individually or in the aggregate, result in the termination or modification of a material contract or otherwise have a material adverse effect on our sales, operations or financial performance.

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

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 Inability to Manufacture Products in Accordance With Applicable Specifications, Performance Standards or Quality Requirements Could Adversely Affect Our Business.

The materials and processes used to manufacture our products must meet detailed specifications, performance standards and quality requirements to ensure our products will perform in accordance with their label claims, our customers' expectations and applicable regulatory requirements. As a result, our products and

the materials used in their manufacture or assembly undergo regular inspections and quality testing. Factors such as defective materials or processes, mechanical failures, human errors, environmental conditions, changes in materials or production methods by our vendors, and other events or conditions could cause our products or the materials used to produce or assemble our products to fail inspections and quality testing. Any failure or delay in our ability to meet the applicable specifications, performance standards or quality requirements could adversely affect our ability to manufacture and sell our products or comply with regulatory requirements. These events could, in turn, adversely affect our business and financial performance.

Our Increasing International Presence May Increase Our Risks and Expose Our Business to Regulatory, Cultural or Other Restraints.

We intend to increase revenue derived from international sales of our products. Our international sales accounted for $13.7 million or 19% of total revenues for 2008, $18.1 million or 22% of total revenues for 2007, and $11.4 million or 17% of total revenues for 2006.

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) and the need for reimbursement approvals 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;
- Reduced protection for, or enforcement of, our patents and other intellectual property rights in foreign countries;
- 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 inability to obtain or maintain the CE mark on our products may preclude or delay our ability to sell products in the European Union;
- Our inability to identify international distributors and negotiate acceptable terms for distribution agreements may delay or reduce our sales;
- Cultural and political differences may favor local competitors or make it difficult to effectively market, sell and gain acceptance of products in foreign countries;
- Inexperience in international markets and difficulties in staffing and managing foreign operations 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 finding and managing international distributors or representatives may affect our revenues even when product shipments occur;
- The creditworthiness of foreign distributors and customers may be less certain and foreign accounts receivable collection may be more difficult;
- It may be more difficult to enforce contractual obligations or recover damages under foreign legal systems;
- 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;
- Our exposure to liability under the Foreign Corrupt Practices Act and various other laws, rules and/or regulations applicable to us as a result of our international sales may affect our ability to sell into international markets;

- 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.

Currently, most of our international sales are negotiated for and paid in U.S. dollars. Nevertheless, these sales are subject to currency risks since the changes in the values of foreign currencies relative to the value of the U.S. dollar can render our products comparatively more expensive. These exchange rate fluctuations could negatively impact international sales of our products, as could changes in the general economic conditions in those markets.

In addition, we have entered into a contract for the manufacture and supply of our OraQuick® HIV-1/2 test in Thailand, and the Histofreezer® cryosurgical product is currently manufactured in The Netherlands. We may enter into agreements to manufacture other products in foreign countries as well. However, economic, cultural 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. Foreign currency fluctuations and economic conditions in foreign countries could also increase the costs of manufacturing our products in foreign countries.

Risks Relating to the Economy, Our Financial Results, Investments, Stock Price, Credit Facilities and Need for Financing

The Economic Downturn, Which May Continue Indefinitely or Intensify, Could Adversely Affect Our Results of Operations, Cash Flows and Financial Condition or Those of Our Customers and Suppliers.

The current economic downturn, including disruptions in the capital and credit markets, may continue indefinitely and intensify, and could adversely affect our results of operations, cash flows and financial condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct acquisitions or make other discretionary investments. These circumstances could adversely affect our ability to draw on existing credit facilities, which depend on the ability of the bank that is a party to that facility to meet its funding commitments to us. A bank may not be able to meet its funding commitments if it experiences shortages of capital and liquidity. These circumstances may also adversely impact the capital needs of our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. A weakening business climate could 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. Our ability to collect accounts receivable may be delayed or precluded if our customers are unable to pay their obligations.

We Have a History of Losses and May Not Be Able to Achieve Sustained Profitability.

Although we achieved profitability in 2005, 2006 and 2007, we experienced a net loss of $31.3 million in 2008. In addition, as of December 31, 2008, the Company had an accumulated deficit of $127.3 million. Even though we achieved profitability in the past, there can be no assurance that we will be able to achieve or sustain profitability in the future.

Our ability to achieve and sustain 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, cryosurgical products and OraSure® collection device;

- Our ability to successfully launch new products after receipt of required regulatory approvals;
- 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;
- The degree to which our major distributors comply with their contractual obligations, including minimum purchase commitments;
- Our ability to successfully resolve claims or litigation, including patent infringement litigation;
- The level of expenditures we are required to make in order to develop and obtain regulatory approvals for our new products, including our OraQuick® HIV-1/2 test for use in the OTC market and an OraQuick® HCV test for professional use;
- Whether we are successful in obtaining and maintaining required regulatory approvals and registrations for our new products;
- Achieving growth in sales of our wart removal and other cryosurgical products in the OTC market and selling other products, such as our OraQuick® HIV-1/2 test, in the OTC market;
- Whether we are able to obtain FDA approval of a replacement for the BMX HIV-1 EIA screening test for use in connection with oral fluid samples collected with our OraSure® device;
- Achieving growth in international markets with our OraQuick *ADVANCE*® HIV-1/2 test, cryosurgical 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;
- Commercially developing, and obtaining regulatory approvals and creating market acceptance for, new products in a time frame consistent with our objectives; and
- The costs and results of patent infringement and other litigation or claims asserted against us.

We May Experience Fluctuations in Our Financial Results or Fail to Meet Our Financial Projections.

Our operating results can fluctuate from quarter to quarter and year to year, which could cause our growth or financial performance to fall below the expectations of investors and securities analysts. Our financial projections for future periods are based on a number of assumptions, including estimated demand for our products. However, sales to our distributors and other customers may fall short of expectations because of less than estimated customer demand or other factors, including those described elsewhere in this Annual Report. Infrequent, unusual or unexpected revenues or costs could also contribute to the variability of our financial results. In addition, our products provide different contributions to our gross margin and our operating results could also fluctuate and be affected depending on the mix of products sold and the relative prices and gross margin contribution of those products. Failure to achieve operating results consistent with the expectations of investors and securities analysts could adversely affect our reputation and the price of our Common Stock.

Our Portfolio Investments May Be Subject to Volatility and Uncertainty in the Financial Markets and Other Risks.

At December 31, 2008, we had $82.5 million in cash, cash equivalents and short-term investments. We invest our cash in a variety of financial instruments, consisting principally of investments in certificates of deposit, commercial paper, U.S. government and agency obligations, and U.S. corporate bonds. These investments are denominated in U.S. dollars.

We account for our investment instruments in accordance with Statement of Financial Accounting Standards No. 115 ("SFAS No. 115"), *Accounting for Certain Investments in Debt and Equity Securities*. All of the cash equivalents and marketable securities are treated as "available-for-sale" under SFAS No. 115. Investments in both fixed rate and floating rate interest earning instruments carry a degree of interest rate risk. Fixed rate debt securities may have their market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates. We may also suffer losses in principal if we are forced to sell securities that decline in market value due to changes in interest rates. However, because any debt securities we hold are classified as "available-for-sale," no gains or losses are recognized due to changes in interest rates unless such securities are sold prior to maturity.

Recent U.S. sub-prime mortgage defaults have had a significant impact across various sectors of the financial markets, causing global credit and liquidity issues. The short-term funding markets have experienced instability during 2007 and 2008, leading to liquidity disruption in asset-backed commercial paper and failed auctions of auction rate securities. Further deterioration of the global credit market could adversely impact certain financial institutions that may have invested in or offered such securities. To the extent that we hold corporate bonds issued by those financial institutions in our portfolio, we could be adversely impacted and we could determine that some of our investments are impaired, which could adversely impact our financial results. As of December 31, 2008, we had not been adversely affected by these credit and liquidity issues.

If Our Estimates or Judgments Relating to Our Critical Accounting Policies Are Based on Assumptions That Change or Prove to be Incorrect, Our Operating Results Could Fall Below Expectations of Securities Analysts and Investors, Resulting in a Decline in Our Stock Price.

Our discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate significant estimates used in preparing our financial statements, including those related to:

- Revenue recognition;
- Allowance for uncollectible accounts receivable;
- Reserve for inventory write-downs;
- Stock-based compensation;
- Potential impairment of long-lived and intangible assets;
- Clinical trial accruals; and
- Contingencies.

We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as provided in our discussion and analysis of financial condition and results of operations, the results of which form the basis for making judgments about the carrying values of assets and

liabilities that are not readily apparent from other sources. Actual results may differ from these and other estimates if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price.

In 2005 and 2006, we made payments totaling $4.5 million under a license agreement to certain HCV patents and we capitalized these payments as intangible assets to be amortized over their estimated useful lives. We determined that these costs should be capitalized rather than expensed for two primary reasons. First, our intent in executing the HCV patent license was to provide for various alternatives for use of the license, including the sale or distribution of third party produced HVC products in the international marketplace that would not require additional research and development efforts or regulatory approvals. Second, we estimated that the present value of the cash flows to be received from future product sales in these international markets will exceed the net book value of the license payments. It is possible, however, that events or circumstances may occur which could cause us to lower the estimated value of these future cash flows. As of December 31, 2008, there had been no sales of HCV product in the international markets. If we are not successful in selling an HCV product in the international marketplace or such sales are significantly less than forecasted, the cash flows actually received from these sales could be significantly less than planned or nonexistent. If this occurs and we conclude that the present value of the future cash flows is less than the net book value of the license payments, we would be required to record an impairment charge equal to such difference, up to the entire remaining book value of this intangible asset ($3,277,288 at December 31, 2008). Any significant impairment charges that we are required to incur in the future could have a material adverse impact on our balance sheet and future operating results.

Our Credit Facilities Contain Certain Financial Covenants Which, if Not Satisfied, Could Result in the Acceleration of the Amounts Due Under These Facilities and Limit Our Ability to Borrow in the Future.

Our credit facility with Comerica Bank contains various financial and other covenants with which we must comply on an ongoing or periodic basis. Although we do not expect to violate these covenants and obligations, if such a violation were to occur, the outstanding debt under our credit facility could become immediately due and payable, our lender could proceed against any collateral securing such indebtedness and our ability to borrow additional funds in the future may be adversely affected.

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 distributors and other business partners;
- The time, cost and degree of success of conducting clinical trials and 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.

Terrorist Attacks or National Disasters May Adversely Affect Our Business.

Terrorist attacks or natural disasters, 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. These events could 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 manufacturing facilities are located in Bethlehem, Pennsylvania. Although we have business interruption insurance, our facilities and some pieces of manufacturing equipment are difficult to replace and could require substantial replacement lead-time. Various types of disasters, including earthquakes, fires, floods and acts of terrorism, may affect our manufacturing facilities. In the event our existing manufacturing facilities or equipment is affected by man-made or natural disasters, we may be unable to manufacture products for sale or meet customer demands or sales projections. If our manufacturing operations were curtailed or ceased, it would seriously harm our business.

Risks Relating to Our Common Stock

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;
- Timing of completion of clinical studies and receipt of required regulatory approvals;
- Changes in the level of competition;
- Loss of or declines in sales to major distributors or customers or changes in the mix of products sold;
- The relatively low trading volume for our Common Stock;
- Period to period fluctuations in our operating results;
- Additions or departures of key personnel;
- General market and economic conditions; and
- Terrorist attacks, civil unrest, war and national disasters.

Future Sales of Our Common Stock 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 non-employee 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.

Investor Confidence and Share Value May be Adversely Impacted if We and/or Our Independent Registered Public Accounting Firm Conclude That Our Internal Control Over Financial Reporting is Not Effective.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring us, as a public company, to include a report of management in our Annual Reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, our independent registered public accounting firm must report on the effectiveness of these internal controls.

We expect that our internal controls will continue to evolve as our business activities change. Although we seek to diligently and vigorously review our internal control over financial reporting in an effort to ensure compliance with the Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. If, during any year, our independent registered public accounting firm is not satisfied with our internal control over financial reporting or the level at which our controls are documented, designed, operated, tested or assessed, or if the independent registered public accounting firm interprets the requirements, rules or regulations differently than we do, then it may issue a report that is qualified. This could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements and effectiveness of our internal controls, which ultimately could negatively impact the market price of our Common Stock.

Anti-Takeover Provisions in Our Certificate of Incorporation, Bylaws and Stockholder Rights Plan and Under Delaware Law Could Make a Third Party Acquisition of Us Difficult.

Our Certificate of Incorporation, Bylaws and Stockholder Rights Plan contain provisions that could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. We are also subject to certain provisions of Delaware law that could delay, deter or prevent a change in control of us. These provisions could limit the price investors might be willing to pay in the future for shares of our Common Stock.

ITEM 1B. Unresolved Staff Comments.

Not Applicable.

ITEM 2. Properties.

We own a 48,000 square foot facility which is our primary corporate office and manufacturing facility, a 31,700 square foot facility that houses our sales and marketing and research and development offices, and a 33,500 square foot facility which is used for manufacturing activities. Each of these facilities is located in Bethlehem, Pennsylvania and is subject to a mortgage in favor of Comerica Bank.

We rent additional warehouse space on an as-needed basis. We also lease space for a small sales office in Reeuwijk, The Netherlands.

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

ITEM 3. Legal Proceedings.

On April 22, 2008, a complaint was filed against us in the United States District Court for the District of New Jersey by Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and Church & Dwight Co., Inc., alleging that we infringed U.S. Patent No. 6,485,982. The complaint specifically refers to our OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The complaint seeks injunctive relief, damages and an award of attorneys' fees. We have filed our Answer responding to the allegations in the Complaint and asserting various defenses and counterclaims.

On October 10, 2008, the plaintiffs filed a motion for summary judgment of infringement in this case, pursuant to a schedule previously established by the Court. We have filed our response to this motion and briefing is now complete.

We believe that none of our products, including the OraQuick *ADVANCE*® HIV test, infringe the patent asserted in this lawsuit or any other party's intellectual property rights. We also believe that the patent asserted in this matter is invalid or unenforceable, and we intend to defend this lawsuit vigorously. We are unable at this time to determine the impact, if any, that this lawsuit may have on our business or prospects.

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, 2008.

PART II

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

Market Information

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

	Year ended December 31,			
	2008		2007	
	High	Low	High	Low
First Quarter	$9.23	$6.37	$ 9.00	$6.50
Second Quarter	7.81	3.74	8.49	6.92
Third Quarter	6.25	3.69	10.20	7.89
Fourth Quarter	4.96	2.18	10.57	8.13

On March 4, 2009, there were 554 holders of record and approximately 12,000 holders in street name of our Common Stock, and the closing price of our Common Stock was $2.43 per share.

Dividends

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.

Share Repurchases and Retirements

The following is a summary of share repurchase activity during the three months ended December 31, 2008.

Pursuant to our 2000 Stock Award Plan and in connection with the vesting of restricted shares, we retired 135,432 shares to satisfy minimum tax withholding obligations.

In addition, on August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25.0 million of outstanding shares.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as part of a publicly Announced Plan or Program[1]	Maximum Dollar Value of Shares that may yet be Purchased Under the Plan or Program[2]
October 1, 2008—October 31, 2008	384,925	$4.13	384,925	$20,357,484
November 1, 2008—November 30, 2008	127,360	3.55	127,360	19,905,880
December 1, 2008—December 31, 2008	11,885	3.11	9,060	19,878,893
Total	524,170	$3.97	521,345	

1 These shares were purchased under our $25.0 million stock repurchase program.

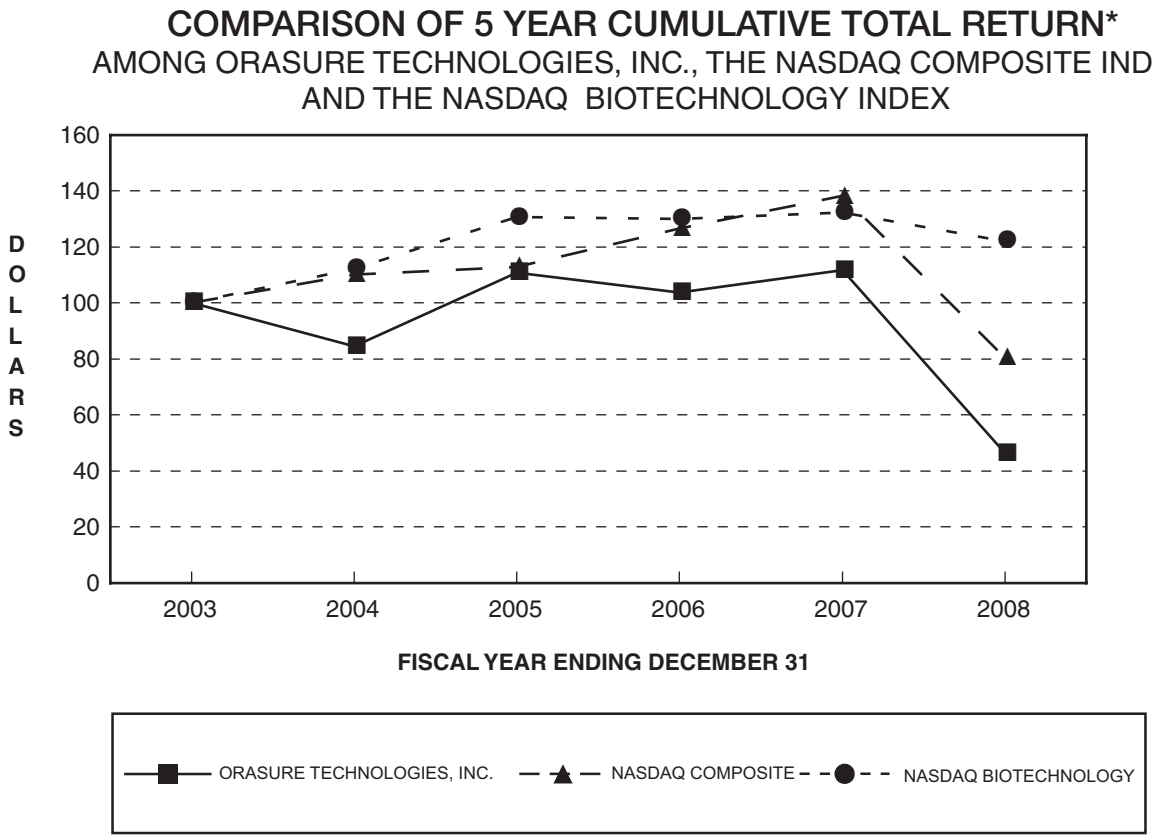
2 Under our stock repurchase program, we are authorized to spend up to an aggregate of $25.0 million for stock repurchases. This column represents the amount that remains available under the $25.0 million stock repurchase program, as of the end of the period indicated. We have made no commitment to purchase any shares, and purchases may be discontinued at any time.

Performance Graph

The performance graph set forth below shall not be deemed "soliciting material" or "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that Section. This graph will not be deemed "incorporated by reference" into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether such filing occurs before or after the date hereof, regardless of any general incorporation language in such filing.

The following graph compares the cumulative total returns to investors in the Company's Common Stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index for the period from December 31, 2003 through December 31, 2008. The graph assumes that $100 was invested on December 31, 2003 in the Company's Common Stock and in each of the above-mentioned indices, and that all dividends, if any, were reinvested.

The NASDAQ Composite Index was chosen because it is a broad index of companies whose equity securities are traded on the NASDAQ Stock Market. The NASDAQ Biotechnology Index was chosen because it includes a number of our competitors. Stockholders are cautioned that the graph shows the returns to investors only as of the dates noted and may not be representative of the returns for any other past or future period.



* $100 invested on 12/31/03 in stock & index-including reinvestment of dividends. Fiscal year ended December 31.

	12/03	12/04	12/05	12/06	12/07	12/08
OraSure Technologies, Inc.	**100.00**	**84.42**	**110.80**	**103.77**	**111.68**	**46.23**
NASDAQ Composite	**100.00**	**110.08**	**112.88**	**126.51**	**138.13**	**80.47**
NASDAQ Biotechnology	**100.00**	**112.17**	**130.53**	**130.05**	**132.24**	**122.10**

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,				
	2008	2007	2006	2005	2004
Operating Results:					
Revenues	$ 71,104	$ 82,686	$ 68,155	$ 69,366	$ 54,008
Costs and expenses	87,435	83,905	62,692	61,793	55,365
Operating income (loss)	(16,331)	(1,219)	5,463	7,573	(1,357)
Other income (expense), net	7,583	5,513	3,599	2,146	797
Income tax provision (benefit)	22,527[1]	1,821	3,794	(17,729)[2]	—
Net income (loss)	(31,275)[1]	2,472	5,268	27,448[2]	(560)
Earnings (loss) per share					
Basic	$ (0.67)	$ 0.05	$ 0.11	$ 0.61	$ (0.01)
Diluted	$ (0.67)	$ 0.05	$ 0.11	$ 0.59	$ (0.01)
Shares used in computing earnings (loss) per share					
Basic	46,550	46,325	45,910	45,110	44,464
Diluted	46,550	46,878	46,580	46,147	44,464
Cash Flow:					
Cash flows provided by (used in) operating activities	$ (2,460)	$ 11,584	$ 16,886	$ 10,392	$ 3,438

	December 31,				
	2008	2007	2006	2005	2004
Financial Position:					
Cash, cash equivalents, and short-term investments	$ 82,523	$ 95,566	$ 91,001	$ 77,620	$ 66,723
Working capital	90,936	105,620	95,979	90,670	68,910
Deferred tax assets	—	22,327	23,522	26,708	—
Total assets	131,918	167,353	156,565	130,747	88,064
Long-term debt, excluding current portion	8,301	8,818	10,031	884	1,334
Accumulated deficit	(127,275)	(96,000)	(98,414)	(103,682)	(131,130)
Stockholders' equity	108,325	140,055	129,504	118,919	75,577

[1] Includes an income tax provision of $25,978 resulting from the establishment of a full valuation allowance on our net deferred tax assets (see Note 8 to the financial statements).

[2] Includes an income tax benefit of $18,165 resulting from the elimination of a significant portion of the valuation allowance on our net deferred tax assets.

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

We operate primarily in the *in vitro* diagnostic business. Our business principally involves the development, manufacture, marketing and sale of oral fluid diagnostic products and 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 used for the removal of warts and other benign skin lesions by cryosurgery, or freezing. Our diagnostic products include tests which are performed on a rapid basis at the point of care and tests which are processed in a laboratory. 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 has been sold in the OTC or consumer retail market in the United States, Canada, Europe, Mexico and Australia.

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. 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. *In vitro* diagnostic tests are performed outside the body, in contrast to *in vivo* tests, which are performed directly on or within the body. When combined with their ease of use, non-invasive and dignified nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

During the year ended December 31, 2008, our total revenues were $71.1 million, which represents a 14% decrease from the $82.7 million we reported in 2007. We recorded a net loss of $31.3 million for the year ended December 31, 2008, which includes a non-cash charge of $26.0 million in our income tax provision for the establishment of a full valuation allowance against our net deferred tax assets. This compares to net income of $2.5 million for the year ended December 31, 2007. During 2008, we continued to invest in our research and development efforts to obtain FDA approval to sell our OraQuick® HIV test over the counter, to develop our rapid HCV test and to develop homogeneous fully automated drugs of abuse assays for use with our Intercept oral fluid collection device in collaboration with Roche Diagnostics. As a result, research and development expenses increased $6.1 million in 2008 compared to the prior year. Our liquidity position remains strong, as we had $82.5 million in cash, cash equivalents and short-term investments at December 31, 2008.

Revenues from the infectious disease testing market continued to grow in 2008 as result of sales of our OraQuick *ADVANCE*® HIV-1/2 test. Sales to public health benefited from the growth in our base business and from the incremental sales driven by the CDC's efforts to increase HIV testing.

We terminated our distribution agreement with Abbott for the sale of OraQuick *ADVANCE*® at the end of 2008 as a result of our decision to sell OraQuick *ADVANCE*® directly to US hospitals and reference laboratories

starting on January 1, 2009. Sales to Abbott decreased in 2008 as a direct result of the reduction of Abbott purchases in the latter months of 2008 in anticipation of the agreement termination at year end and increased competition in the hospital market. Under our former distribution agreement, Abbott was our exclusive distributor in the U.S. hospital market and a non-exclusive distributor in the U.S. physicians' office marketplace.

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.

Revenues from our cryosurgical products decreased significantly in 2008, primarily due to the absence of sales in the U.S. OTC market, reduced sales in certain European and Mexican OTC markets, and a decrease in product sales in the domestic professional market. The cryosurgical systems market is comprised of Histofreezer® sales into both the domestic and international physicians' office markets and sales of our OTC product formulation to our international distributors, SSL and Genomma Labs. SSL distributes our wart removal product under its Scholl's and Dr. Scholl trademarks in the OTC footcare market in several European countries. Genomma Labs has distribution rights to a similar product in the OTC footcare market in Mexico, Argentina, Brazil, and various other Central and South American countries.

Genomma Labs reduced its purchasing levels in 2008, in response to an increase in product returns from retailers due to overstocking during the winter months of 2007. Sales to SSL declined due to lower revenues experienced by SSL in key markets outside of the United Kingdom. The absence of U.S. OTC sales in 2008 resulted from the termination of our domestic distribution relationship with Prestige Brands at the end of 2007. As a result, we have developed our own proprietary nationally branded wart removal product which we started selling in the U.S. OTC market in early 2009. It is not possible to predict at this time how well the new branded product will perform.

Our combined cryosurgical sales to physician offices also experienced a decline in 2008 as the business was negatively impacted by the diversion of some lower-priced Histofreezer® product from international sources back into the U.S. professional market. We addressed this diversion issue by increasing our international pricing, changing product labeling and packaging, and enforcing contractual rights against certain international distributors. We believe this diversion issue was largely confined to 2008, and we do not expect it to have a material impact on 2009 revenues.

Revenues from the substance abuse testing market decreased in 2008 as sales of our Intercept® drug testing system were directly impacted by the decline in pre-employment testing in domestic markets. Pre-employment drug screening represents approximately 50% of our workplace drug testing business. As a result of the decline in the U.S. economy, the related decrease in hiring has had a direct impact on this segment of our business.

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.

In past years, BMX manufactured and sold the only oral fluid HIV-1 screening test that had received FDA approval for use in detecting HIV-1 in an oral fluid specimen collected with our OraSure® collection device. BMX also supplied the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and was the exclusive world-wide distributor of that product. BMX discontinued manufacturing their HIV-1 EIA screening test during 2007. As a result, we intend to seek FDA approval of an alternative HIV-1 EIA screening

test for use with our OraSure® collection device. BMX also elected not to renew our Western blot agreements beyond December 31, 2007, and we are now selling the Western blot oral fluid HIV-1 confirmatory test directly to our laboratory customers.

We also rely heavily on distributors to purchase and resell many of our products. For example, SSL has exclusive rights to our wart removal product in the OTC footcare market in Europe, Australia and New Zealand. We granted Genomma Labs exclusive rights to distribute our wart removal product in the OTC market in Mexico, Argentina, Brazil, and various other Central and South American countries. We have contracted with several distributors to sell our OraQuick *ADVANCE*® HIV-1/2 test to the U.S. physician office market and our Intercept® and OraSure® product lines are sold by several laboratory distributors.

We expect to enter into additional distribution agreements for new and future products, for distribution in the U.S. and internationally. If our distributors are unable or unwilling to meet the minimum purchase commitments set forth in their agreements or otherwise substantially reduce the volume of their purchases, our revenues and results of operations could be adversely affected.

We generated 81% of our 2008 revenues in the U.S. marketplace compared to 78% in 2007. We are continuously evaluating strategies to increase our sales penetration in markets outside the U.S. As our business in foreign countries increases, we could be exposed to other economic, political, exchange rate, regulatory and cultural risks.

The current economic downturn, including disruptions in the capital and credit markets, may continue indefinitely and intensify, and could adversely affect our financial performance and condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct acquisitions or make other discretionary investments. These circumstances may also adversely impact the capital needs of our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components.

Results of Operations

Year Ended December 31, 2008 Compared to December 31, 2007

Total revenues decreased 14% to $71.1 million in 2008 from $82.7 million in 2007. Increased sales in both the infectious disease and insurance risk assessment markets, together with an increase in licensing and product development revenues, were more than offset by declines in sales of our cryosurgical wart removal and substance abuse testing products. Revenues derived from products sold to customers outside the United States were $13.7 million and $18.1 million or 19% and 22% of total revenues for the years ended December 31, 2008 and 2007, respectively. The majority of our international sales are transactions in U.S. dollars. As such, the impact of foreign currencies has not been material to our operating results.

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.

	Year Ended December 31,				
	Dollars		%	Percentage of Total Revenues	
Market	2008	2007	Change	2008	2007
Infectious disease testing	$38,096	$35,791	6%	54%	43%
Substance abuse testing	14,006	15,789	(11)	20	19
Cryosurgical systems	10,655	23,533	(55)	15	28
Insurance risk assessment	6,085	5,464	11	8	7
Product revenues	68,842	80,577	(15)	97	97
Licensing and product development	2,262	2,109	7	3	3
Total revenues	$71,104	$82,686	(14)%	100%	100%

Sales to the infectious disease testing market increased 6% to $38.1 million in 2008, primarily as a result of the continued strong performance of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test in an increasingly competitive environment. OraQuick® and OraSure® sales during 2008 totaled $35.3 million and $2.8 million, respectively, as compared to $32.7 million and $3.1 million in 2007, respectively.

The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during 2008 and 2007.

Customers	Year ended December 31, 2008	2007	% Change
Direct to U.S. Public Health	$25,438	$19,799	28%
Abbott	6,625	8,102	(18)
International	3,234	3,291	(2)
SAMHSA / CDC	12	1,464	(99)
Total OraQuick® revenues	$35,309	$32,656	8%

During 2008, OraQuick® revenue derived from direct sales to the U.S. public health market increased by 28% as compared to 2007. This increase is the result of continued growth in our base business and from incremental sales driven by the CDC's efforts to increase HIV testing. In September 2007, the CDC awarded incremental funding to expand HIV testing and prevention programs in populations disproportionately affected by HIV, primarily African Americans. These funds were allocated to targeted state and public health agencies, for utilization during 2008.

For the year ended December 31, 2008, sales to our former hospital distributor, Abbott, decreased 18% to $6.6 million, as compared to $8.1 million in 2007. This decrease was largely the result of Abbott's ordering patterns, the impact of negotiations to end our distribution agreement at the end of 2008, and increased competition in the hospital market. As previously discussed, commencing in 2009, we began selling our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test directly into the U.S. hospital market.

Revenues derived from the CDC and SAMHSA declined significantly in 2008 when compared to 2007. In 2007, the CDC and SAMHSA placed bulk purchase orders directly with the Company for OraQuick *ADVANCE*® devices and related testing materials, for further distribution to various public health entities. However, both the CDC and SAMHSA did not place new bulk orders in 2008 and are not currently engaging in bulk procurement and distribution activities. As such, it is not expected that comparable-sized bulk purchase orders from these governmental entities or others will be received in the future.

We believe that our OraQuick *ADVANCE*® device, which is FDA-approved for detecting antibodies to both HIV-1 and HIV-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, thereby enabling us to fully implement a strategy for selling OraQuick® in the U.S. and internationally. We received CE mark approval for our OraQuick *ADVANCE*® test and we currently sell small quantities of this product in Europe. We have established distribution channels in several European countries and are pursuing other distributors elsewhere in the European Union and in other countries.

International sales of our OraQuick® test remained relatively flat at $3.2 million in both 2008 and 2007, with sales in Africa contributing $2.4 and $2.5 million of those revenues in 2008 and 2007, respectively.

We have continued to see evidence that sales of OraQuick *ADVANCE*® are negatively impacting sales of our OraSure® oral fluid collection device in the infectious disease testing market in the U.S. During 2008, our sales of OraSure® declined $348,000 from $3.1 million in 2007 to $2.8 million in 2008. Some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are now electing to purchase our

OraQuick *ADVANCE*® test. We believe this is the result of customers recognizing the benefits of rapid HIV testing, especially with oral fluid, and the CDC's efforts to increase rapid HIV testing in healthcare settings. While it is not possible at this time to estimate the extent of such ongoing change in purchasing patterns, we expect the decline in OraSure® sales to continue.

Sales to the substance abuse testing market decreased 11% in 2008 as the use of our Intercept® device for workplace testing was impacted by the continuing adverse economic conditions. The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market during 2008 and 2007.

Market	Year ended December 31, 2008	2007	% Change
Workplace testing	$ 4,750	$ 6,650	(29)%
Criminal justice	2,663	2,570	4
International	2,168	2,188	(1)
Direct	1,204	1,003	20
Total Intercept® revenues	$10,785	$12,411	(13)%

Our workplace testing business decreased 29% from $6.7 million in 2007 to $4.8 million in 2008. Pre-employment drug screening represents approximately 50% of our workplace testing business and the current decline in the domestic economy and rising unemployment has had a direct impact on this segment of our business. Accordingly, we do not expect renewed growth in our Intercept® business until employment conditions in the U.S. improve.

In addition, the microplate oral fluid drug assays, which are sold for use with the Intercept® collection device, are expected to come under increasing competitive pressure in the future from "home-brew" assays developed internally by our laboratory customers. Our oral fluid microplate assays also compete with urine-based homogeneous assays that are run on fully-automated, random access analyzers. 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, could represent a significant competitive threat to our oral fluid microplate business. In order to meet this competition, we are jointly developing and intend to commercialize fully-automated homogeneous oral fluid drugs of abuse assays with Roche Diagnostics for use with our Intercept® device.

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) decreased 55% to $10.7 million in 2008 from $23.5 million in 2007. This decrease was primarily the result of a significant decline in sales of our domestic and international OTC cryosurgical products when compared to 2007.

The table below shows a breakdown of our total cryosurgery revenues (in thousands, except %) generated in each market during 2008 and 2007.

Market	Year ended December 31, 2008	2007	% Change
Professional domestic	$ 3,911	$ 5,247	(25)%
Professional international	2,529	2,349	8
OTC domestic	—	6,237	(100)
OTC international	4,215	9,700	(57)
Total cryosurgical systems revenues	$10,655	$23,533	(55)%

Our domestic OTC cryosurgical product was previously distributed in the United States and Canada by Prestige, owner of the Compound W® line of wart removal products. Our distribution agreement with Prestige terminated on December 31, 2007, and as a result, no sales were made to Prestige in 2008 or will be made in the future to this distributor. Sales to Prestige were $6.2 million in 2007. In 2008, we developed our own proprietary nationally branded wart removal product and began selling this product in the U.S. OTC market in early 2009. It is not possible to predict at this time how successful our new brand will be in the domestic OTC marketplace.

We have an agreement with SSL under which we manufacture and supply, and SSL distributes on an exclusive basis, our 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. Sales to SSL were $3.8 million and $5.3 million in 2008 and 2007, respectively. The $1.5 million sales decline in the current year is due to lower than expected outsales by SSL in key markets outside of the United Kingdom, primarily resulting from intense competition from an already-existing brand and new market entrants.

We have granted Genomma Labs exclusive distribution rights to our cryosurgical wart removal product in the OTC markets in Mexico, Argentina, Brazil, and various other Central and South American countries. Sales to Genomma Labs were approximately $400,000 in 2008 and $4.4 million in 2007. During 2008, Genomma Labs reduced its purchases from us, in response to an increase in product returns from retailers in Mexico who overstocked during the winter months of 2007. Throughout 2008, Genomma worked to reduce its excess inventory position, and accordingly did not purchase additional product from us. We believe these markets represent potential future sales opportunities for our cryosurgical products; however, the full realization of such sales will take time.

Sales of our Histofreezer® product to physicians' offices in the United States decreased 25% to $3.9 million in 2008, as compared to $5.2 million in 2007. Sales of Histofreezer® in the international market increased 8% to $2.5 million from $2.3 million in 2007. On a combined basis, however, cryosurgical sales in the professional market declined in 2008, as this business was affected by the diversion of some lower-priced Histofreezer® product from international sources into the U.S. professional market. The selling prices for our Histofreezer® product are lower in some foreign countries due to differences in the healthcare systems in those countries. During 2008, some distributors in these countries purchased English-labeled Histofreezer® product and resold it into the domestic distribution network to distributors who employ alternate sourcing programs. We aggressively addressed this diversion issue by increasing our international pricing, changing product labeling and packaging, and enforcing contractual rights against certain international distributors. We believe this diversion issue was largely confined to 2008 and we do not expect it to have a material impact on 2009 revenues.

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. It is not possible at this time to estimate the extent of the financial impact of this change.

Sales to the insurance risk assessment market increased 11% from $5.5 million in 2007 to $6.1 million in 2008, primarily as a result of an increase in revenues associated with our oral fluid Western blot HIV-1 confirmatory test. BMX discontinued the distribution of our Western blot HIV-1 confirmatory test and, as a result, we are now selling this product directly to our laboratory customers. Overall, we expect our 2009 revenues in this market will remain at levels comparable to those attained in 2008.

Licensing and product development revenues increased to $2.3 million in 2008, from $2.1 million in 2007. In January 2008, we entered into a license and settlement agreement with Schering-Plough in which they agreed to pay us royalties on sales of their Freeze Away™ product. Pursuant to the terms of that licensing agreement, during 2008, we recorded $2.3 million in royalty payments from Schering-Plough. In December 2006, we entered into a collaboration agreement with Schering-Plough Corporation, for the development and promotion of a rapid oral fluid test for the detection of antibodies to HCV. During 2007, we recognized $2.0 million in revenues associated with funded research and development under this agreement.

The Company's gross margin was 58% in 2008, compared to 61% in 2007. Our 2008 gross margin was negatively impacted by the significant decline in higher-margin cryosurgical sales and by increases in manufacturing scrap and spoilage expense. Scrap expense increased from $1.3 million in 2007 to $2.0 million in 2008. Although scrap and spoilage expense exceeded 2007 levels, OraQuick® scrap and spoilage was down sequentially in each quarter of 2008, as we identified its root cause and made the appropriate adjustments. We expect overall OraQuick® scrap and spoilage expense to be significantly lower in 2009 when compared to 2008, primarily due to the OraQuick® product and manufacturing process enhancements and twelve-month shelf life recently approved by the FDA.

Research and development expenses increased 43% to $20.3 million in 2008, from $14.1 million in 2007, primarily as a result of increased product and clinical development costs for our OraQuick® HCV test, costs associated with our continued efforts to obtain FDA approval to sell our OraQuick® HIV test over the counter, and costs to develop our homogeneous fully-automated drugs of abuse assays for use with our Intercept® oral fluid collection device in collaboration with Roche Diagnostics. Also included in the current year expense is a $1.0 million patent license milestone payment required as a result of our filing of a premarket approval application with the FDA for our OraQuick® HCV device. We believe the majority of the product development and clinical trial costs associated with the OraQuick® HCV device have already been incurred. As such, we expect our research and development costs to decrease in 2009.

Sales and marketing expenses increased 4% to $20.9 million in 2008 from $20.1 million in 2007. This increase was primarily the result of incremental salaries, benefits, and recruiting and relocation expenses related to hiring additional direct sales personnel for the hospital market, as we prepared to assume control of this distribution channel from Abbott in 2009. These increases were partially offset by a decrease in distributor advertising and promotional costs. We expect 2009 sales and marketing expenses to remain at approximately the 2008 level.

General and administrative expenses decreased 6% to $16.3 million in 2008 from $17.3 million in 2007. This decrease was primarily attributable to lower cash and stock compensation costs, bank charges, consulting fees and legal expenses. In 2009, we expect general and administrative costs to increase slightly due to increased staffing costs and legal expenses associated with the patent infringement lawsuit filed against us by Inverness Medical and Church & Dwight.

Interest expense decreased to $346,000 in 2008 from $520,000 in 2007, as a result of lower outstanding debt balances and our election to fix the interest rate on our primary facilities advance at 4.15% until its maturity in June 2011. Interest income decreased to $3.1 million in 2008 from $4.7 million in 2007 primarily as a result of lower yields earned on our investment portfolio, usage of some previously-invested cash to fund inventory purchases, capital expenditures, and the stock repurchase program initiated during 2008, and an overall conservative, shorter-term investment approach.

As a result of the license and settlement agreement we entered into with Schering-Plough to resolve our patent infringement litigation, we received a payment of $4.9 million during the first quarter of 2008, which was recorded as other income. In January 2007, we sold our ownership interest in a privately-held nonaffiliated company and recorded a $1.4 million pre-tax gain on the sale of this investment.

We purchase some of our cryosurgical products from, or utilize the services of, vendors located in The Netherlands. As a result of the weakness of the United States dollar in relation to the Euro, we recorded a net loss on foreign currency transactions in the amount of $36,000 and $105,000 for the years ended December 31, 2008 and 2007, respectively.

During 2008, we recorded a $3.5 million net federal and state tax benefit associated with the pretax loss of $8.7 million for that same period. In the fourth quarter of 2008, however, as global economic conditions worsened, we also re-evaluated whether or not we would realize the benefits associated with our total net deferred tax asset in the future. Given the uncertainty surrounding the magnitude and length of the current economic recession, our loss in 2008, and our projection of a loss in 2009, we determined that it is more likely

than not that we will not realize the benefits associated with our net deferred tax assets in the immediate future. Accordingly, in accordance with Statement of Financial Accounting Standards ("SFAS 109"), "Accounting for Income Taxes, we recorded an income tax charge of $26.0 million in the fourth quarter of 2008 in order to establish a full valuation allowance against our net deferred tax asset.

During 2007, we recorded provisions for federal and state income taxes of $1.8 million, which reflect a 42% effective tax rate. Our effective rate reflects the impact of permanent differences, generated by items which are not deductible on our income tax returns. In addition, during the fourth quarter of 2007, we recorded an income tax benefit of $289,000 related to the inclusion of a federal research and development tax credit.

Year Ended December 31, 2007 Compared to December 31, 2006

Total revenues increased by 21% to $82.7 million in 2007 from $68.2 million in 2006, primarily as a result of increased sales of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test and our OTC cryosurgical products, together with an increase in funded research and development related to our OraQuick® rapid HCV test.

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.

	Year Ended December 31,				
	Dollars		%	Percentage of Total Revenues	
	2007	2006	Change	2007	2006
Infectious disease testing	$35,791	$29,180	23%	43%	43%
Substance abuse testing	15,789	15,752	—	19	23
Cryosurgical systems	23,533	17,333	36	28	25
Insurance risk assessment	5,464	5,565	(2)	7	8
Product revenues	80,577	67,830	19	97	99
Licensing and product development	2,109	325	549	3	1
Total revenues	$82,686	$68,155	21%	100%	100%

Sales to the infectious disease testing market increased 23% to $35.8 million in 2007, primarily as a result of the increasing strength of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test. OraQuick® and OraSure® sales during 2007 totaled $32.7 million and $3.1 million, respectively, as compared to $25.6 million and $3.6 million in 2006, respectively.

The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during 2007 and 2006.

	Year ended December 31,		%
Customers	2007	2006	Change
Direct to U.S. Public Health	$19,799	$15,268	30%
Abbott	8,103	6,897	17
SAMHSA	339	406	(17)
CDC	1,125	1,291	(13)
International	3,291	1,694	94
Total OraQuick® revenues	$32,657	$25,556	28%

During 2007, OraQuick® revenue derived from direct sales to the U.S. public health market increased by 30% as compared to 2006. This increase was the result of continued growth in usage of the OraQuick

ADVANCE® rapid HIV-1/2 antibody test in public health settings, including city-wide testing programs. Revenue in 2007 from HIV testing initiatives in various cities around the country more than doubled from 2006, increasing to over $1.7 million.

For the year ended December 31, 2007, sales to our hospital distributor, Abbott, grew 17% to $8.1 million, as compared to $6.9 million in 2006. This increase was the result of continued penetration of the U.S. hospital market by Abbott in collaboration with our hospital sales team.

In previous periods, the CDC and SAMHSA have placed bulk purchases orders for OraQuick *ADVANCE*® devices and related testing materials directly with the Company. It is not likely that comparable-sized bulk purchase orders from these governmental entities or others will be received in the future.

International sales of our OraQuick® test increased 94% to $3.3 million in 2007 compared to $1.7 million in 2006. The largest contributor of growth was our African business which experienced a 76% increase in sales to almost $2.5 million.

During 2007, our sales of OraSure® declined $500,000 from $3.6 million in 2006 to $3.1 million in 2007.

Sales to the substance abuse testing market remained flat in 2007 at $15.8 million, as sales of our Intercept® device for workplace testing were impacted by a decrease in employment rates domestically and a decrease in funding internationally. The international market experienced a decrease in public sector funding which had slowed the implementation of criminal justice testing.

The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market during 2007 and 2006.

Market	Year ended December 31, 2007	2006	% Change
Workplace testing	$ 6,650	$ 6,616	1%
Criminal justice	2,570	2,398	7
International	2,188	2,314	(5)
Direct	1,003	728	38
Total Intercept® revenues	$12,411	$12,056	3%

Sales of our products in the cryosurgical systems market (which includes both the physicians' office and OTC markets) increased 36% to $23.5 million in 2007 from $17.3 million in 2006. This increase was primarily the result of increased sales of our international and domestic OTC cryosurgical products when compared to 2006.

The table below shows a breakdown of our total cryosurgery revenues (in thousands, except %) generated in each market during 2007 and 2006.

Market	Year ended December 31, 2007	2006	% Change
Professional domestic	$ 5,247	$ 5,360	(2)%
Professional international	2,349	2,284	3
OTC domestic	6,237	5,174	21
OTC international	9,700	4,515	115
Total cryosurgical systems revenues	$23,533	$17,333	36%

Our domestic OTC cryosurgical product, called Freeze Off®, was distributed in the United States and Canada by Prestige, owner of the Compound W® line of wart removal products. In September 2006, Prestige announced that it had acquired the Wartner® cryosurgical wart removal product line, which directly competed with the Freeze Off® product in the OTC market. Our distribution agreement with Prestige contained a covenant not to compete which precluded Prestige from acquiring, manufacturing, distributing or selling a cryosurgical product that directly competed with the Freeze Off® product. We notified Prestige that its acquisition of the Wartner® product constituted a material breach of the distribution agreement and that certain of its other actions constituted additional breaches under the agreement. Efforts to resolve this matter through mediation were not successful and arbitration commenced. Our distribution agreement with Prestige terminated on December 31, 2007 as a result of the arbitration proceeding. Sales to Prestige were $6.2 million and $5.2 million, in 2007 and 2006, respectively

We have 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. Sales to SSL under the distribution agreement were $5.3 million and $4.5 million in 2007 and 2006, respectively.

Early in 2007, we entered into an agreement with Genomma Labs pursuant to which Genomma distributes on an exclusive basis our cryosurgical wart removal product in the OTC market in Mexico. Sales to Genomma under this new distribution agreement were approximately $4.4 million in 2007.

Sales of our Histofreezer® product to physicians' offices in the United States decreased 2% to $5.2 million in 2007, as compared to $5.4 million in 2006. Sales of Histofreezer® in the international market remained relatively flat at $2.3 million.

Sales to the insurance risk assessment market declined by 2% to $5.5 million in 2007 from $5.6 million in 2006, primarily because of a reduction in the number of applications for life insurance and changes in underwriting requirements. For higher face-value policies, it appears insurance companies are more likely to use a blood test for multiple risk factors, rather than an oral fluid test.

Licensing and product development revenues increased to $2.1 million in 2007, from $325,000 in 2006. In December 2006, we entered into a collaboration agreement with Schering-Plough, for the development and promotion of a rapid oral fluid test for the detection of antibodies to HCV. During 2007, we recognized $2.0 million in revenues associated with funded research and development under this agreement. We do not expect to recognize any additional licensing and product development revenues pursuant to this agreement.

The Company's gross margin was 61% in 2007, compared to 64% in 2006. Our 2007 gross margin was negatively impacted primarily from increased scrap expense, higher product support costs and a less favorable product mix. Scrap expense increased from $762,000 in 2006 to $1.3 million in 2007.

Research and development expenses increased 63% to $14.1 million in 2007, from $8.6 million in 2006, primarily as a result of product and clinical development costs for our OraQuick® HCV test, costs associated with OTC clinical trials for our OraQuick® HIV-1/2 test, and a clinical study to gain FDA approval for a product line extension in our OTC cryosurgery business.

Sales and marketing expenses increased 26% to $20.1 million in 2007 from $15.9 million in 2006. This increase was primarily the result of higher salaries and commissions, incremental salaries, benefits, recruiting and relocation expenses associated with additional sales personnel, increases in reimbursable distributor advertising and promotion costs, and increased travel, consulting, and advertising expenses.

General and administrative expenses increased 29% to $17.3 million in 2007 from $13.4 million in 2006. This increase was primarily attributable to higher staffing costs associated with new personnel and increased

charges for stock-based compensation. This increase was also attributable to increased legal expenses associated with the Prestige and Schering-Plough legal proceedings.

Interest expense increased to $520,000 in 2007 from $405,000 in 2006, as a result of higher outstanding debt balances during the current period, resulting from financing the purchase of our Bethlehem facilities in June 2006, partially offset by interest capitalized for construction in progress during 2007. Interest income increased to $4.7 million in 2007 from $4.1 million in 2006, as a result of higher yields on our investment portfolio and larger balances available for investment.

In January 2007, we sold our ownership interest in a privately-held nonaffiliated company and recorded a $1.4 million pre-tax gain on the sale of this investment.

We purchase some of our cryosurgical products from, or utilize the services of, vendors located in The Netherlands. As a result of the decline in the exchange rate between the United States dollar and the Euro, we recorded a $105,000 loss on foreign currency transactions for the year ended December 31, 2007, and a $94,000 loss for the year ended December 31, 2006.

During 2007 and 2006, we recorded provisions for federal and state income taxes of $1.8 million and $3.8 million, respectively, which reflect a 42% effective tax rate in each period. Our effective rate reflects the impact of permanent differences, generated by items which are not deductible on our income tax returns. In addition, during the fourth quarter of 2007, we recorded an income tax benefit of $289,000 related to the inclusion of a federal research and development tax credit.

Liquidity and Capital Resources

	December 31,	
	2008	2007
	(In thousands)	
Cash and cash equivalents	$39,565	$ 32,230
Short-term investments	42,957	63,336
Working capital	90,936	105,620

Our cash, cash equivalents and short-term investments decreased $13.0 million to $82.5 million at December 31, 2008, primarily as a result of using $2.5 million in cash to fund operations, $5.1 million to buy back shares under our stock repurchase plan, $2.6 million for property and equipment purchases, $1.2 million for payments related to patents and product rights, $515,000 for debt repayments, and $995,000 associated with the retirement of common stock to pay minimum tax withholding obligations on the vesting of restricted shares.

Net cash used in operating activities was $2.5 million in 2008, resulting from our net loss of $31.3 million for the year offset by the net non-cash change in our deferred tax asset balance of $22.3 million. Other factors which contributed to the $2.5 million utilization of cash in the current period included non-cash charges for depreciation and amortization of $3.4 million, non-cash stock-based compensation expense of $5.5 million, a provision for scrap and spoilage of $1.6 million and a $1.0 million charge for acquired in-process technology, all offset by a decrease in prepaid expenses and other assets of $1.1 million. At December 31, 2007, we had recorded $930,000 in prepayments to contract research organizations (“CROs”) for clinical work they were to perform in 2008. These services were rendered by the CROs and, accordingly, we expensed these prepayments in 2008. Also contributing to the use of cash was an increase of $2.9 million in inventories, primarily related to raw material purchases for our cryosurgical product line, a $274,000 increase in accounts receivable, and decreases in accounts payable of $1.7 million and accrued expenses of $1.1 million, largely due to payments of our 2007 year-end royalty, legal, and other accruals.

Net cash provided by investing activities during 2008 was $16.3 million. Payments of $1.2 million for certain patent and product rights and $2.6 million for additions to property and equipment, were offset by $20.2 million of net proceeds from maturities and redemptions of short-term investments.

During the year ending December 31, 2009, we expect to invest between $3 and $4 million in capital expenditures, primarily to purchase additional equipment, upgrade certain older equipment and make improvements to our facilities.

Net cash used in financing activities was $6.5 million for the year ended December 31 2008 primarily as a result of the purchase of 1,147,730 shares of common stock, at an aggregate cost of $5.1 million, under our stock repurchase plan which was approved by our Board of Directors on August 5, 2008, partially offset by $93,000 received from the exercise of stock options. Additional uses of cash for financing activities were $515,000 in loan principal repayments and $995,000 used for the purchase and retirement of common stock.

At December 31, 2008, we had in place a $14,000,000 credit facility (the "Credit Facility") with Comerica Bank ("Comerica") which is comprised of a $10,000,000 facilities advance and a $4,000,000 revolving working capital line of credit. At our option, interest on the facilities advance is payable monthly at either a fixed rate equal to the five-year U.S. Treasury Note rate plus 1.03% to 1.73%, or a variable rate equal to the 30, 180, or 360-day LIBOR plus 0.55% to 1.25%. In each case, the interest rate is determined at the date of the advance and is based upon the amount of cash and cash equivalents we invest and retain at Comerica Securities, Inc. We also can choose the fixed rate option, without penalty, at the expiration of a previously elected LIBOR period. Principal is repayable in periodic installments, based upon the rate option that we elect, with the remaining balance of unpaid principal due on June 27, 2011. Interest on any advances under the revolving working capital line of credit is payable at either the U.S. prime rate less 0.25% or 30-day LIBOR pus 2.55%, in each case determined at the time of funding. In January 2008, we elected to fix the interest rate on the facilities advance at 4.15% until its maturity, with principal and interest payable on a monthly basis.

As of December 31, 2008, we had $8,791,679 in outstanding borrowings under the facilities advance and no outstanding borrowings under the $4,000,000 revolving working capital line of credit, which has a maturity date of June 29, 2009.

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 three facilities in Bethlehem, Pennsylvania. Borrowings under the revolving working capital line of credit are limited to commercially standard percentages of accounts receivable. 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, 2008. 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.

At December 31, 2008, we had NOL carryforwards of $49.5 million for federal income tax purposes. During the fourth quarter of 2005, the Company retained independent tax specialists to perform an ownership change study and analysis to determine the annual limitation amount applicable to utilization of the NOL carryforwards due to past ownership changes, as defined in Section 382 of the Internal Revenue Code. We continue to review ownership changes on an annual basis. We do not believe that ownership change limitations would impair our ability to utilize our NOLs against taxable income that we may generate in the future. In the fourth quarter of 2008, we recorded a full valuation allowance against the deferred tax asset generated by these NOLs. Establishment of this valuation allowance does not change our view of the Company's long-term financial outlook or the expected utilization of our NOL carryforwards.

The combination of our current cash, cash equivalents, short-term investments, and available borrowings under our Credit Facility, is expected to be more than sufficient to fund our operating and capital needs through

2009. Our cash requirements, however, 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, 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 and other factors.

Contractual Obligations and Commercial Commitments

The following sets forth our approximate aggregate obligations at December 31, 2008 for future payments under contracts and other contingent commitments, for the year 2009 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2009**	**2010**	**2011**	**2012**	**2013**	**Thereafter**
Long-term debt[1]	$ 8,859,337	$ 557,897	$ 509,761	$7,791,679	$ —	$ —	$ —
Operating leases[2]	71,356	71,356	—	—	—	—	—
Employment contracts[3]	2,781,250	1,901,875	879,375	—	—	—	—
Purchase obligations[4]	3,098,586	1,519,376	1,579,210	—	—	—	—
Minimum commitments under contracts[5]	4,791,667	500,000	500,000	500,000	500,000	500,000	2,291,667
Total contractual obligations	$19,602,196	$4,550,504	$3,468,346	$8,291,679	$500,000	$500,000	$2,291,667

1 Represents principal repayments required under notes payable to our lenders. See Note 7 to the financial statements included herein.

2 Represents payments required under our operating leases.

3 Represents salary payments payable under the terms of employment agreements executed by us with certain executives. See Note 10 to the financial statements included herein.

4 Represents payments required by non-cancellable purchase orders related to inventory, capital expenditures and other goods or services. See Note 10 to the financial statements included herein.

5 Represents payments required pursuant to certain, licensing agreements executed by the Company. These agreements are cancellable within a specified number of days after communication by the Company of its intent to terminate. See Note 10 to the financial statements included herein. Additional payments of up to $4,500,000 may be required pursuant to one of these licensing agreements for the achievement of specific development and/or commercial milestones.

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, clinical trial accruals, 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 SAB No. 104, "Revenue Recognition." 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 milestones are 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.

Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee.

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 $163,100 at December 31, 2008. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period ($101,412, $40,914 and $16,022 in 2008, 2007 and 2006, respectively). Furthermore, there is no assurance that we will experience credit losses at the same rates as we have in the past. The current economic downturn, including disruptions in the capital and credit markets, may continue indefinitely and intensify, and could adversely affect the operations, cash flows and financial condition of our customers. These circumstances may adversely impact the liquidity or financial position of our customers and could have a material impact on the collectability 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 2008, 2007 and 2006, we wrote-off inventory which had a cost of $1.6 million, $922,000 and $751,000, respectively, as a result of scrap and product expiration issues. 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.

Stock-based Compensation. We follow SFAS No. 123 (revised 2004), "Share-Based Payment," which requires us to recognize the fair value of equity-based awards as compensation expense in our statement of operations. The fair value of our stock option awards was estimated using a Black-Scholes option valuation model. This valuation model's computations incorporate highly subjective assumptions, such as the expected stock price volatility and the estimated life of each award. The fair value of awards, after considering the effect of expected forfeitures, is then amortized, generally on a straight-line basis, over the related vesting period of the award.

Long-lived and Intangible Assets. Our long-lived assets are comprised of property and equipment and our intangible assets primarily consist of patents and product rights. Together, these assets had a net book value of $25.6 million, or 19% of our total assets, at December 31, 2008. Property and equipment and patents and product rights are depreciated or amortized on a straight-line basis over their estimated 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 or HCV. We recorded an additional $3.0 million related to this license in 2006. Management's intent in executing this license was to provide for various alternatives for use, including uses in the international market that would not require additional research and development efforts or regulatory approvals. This $4.5 million asset was capitalized based on management's estimate of the cash flows to be received from future product sales in these international markets. No sales of HCV products had been made in the international markets as of December 31, 2008. 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 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, and shortening of product life-cycles or changes in technology. If we believe impairment of an asset has occurred, we measure the amount of such impairment by comparing the net book value of the affected assets to the fair value of these assets, which is generally determined based upon the present value of the expected cash flows associated with the use of these assets. If the net book value exceeds the fair value of the impaired assets, we would incur an impairment expense equal to this difference. We currently believe the future cash flows to be received from all long-lived and intangible assets will exceed their book value and, as such, we have not recognized any impairment losses for the years ended December 31, 2008, 2007 and 2006. 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, 2008, we had federal NOL carryforwards of $49.5 million. The net deferred tax asset associated with these NOLs and other temporary differences was $25.9 million at December 31, 2008. In assessing the realizability of net 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.

During the fourth quarter of 2008, we evaluated our ability to realize our net deferred tax asset, in order to determine if a valuation allowance should be recorded against it. According to SFAS No. 109, a cumulative loss in recent years is significant piece of negative evidence to be considered when evaluating the need for a valuation allowance and this evidence is difficult to overcome. Given the uncertainty surrounding the magnitude and length of the current economic recession, our loss in 2008, and our projection of a loss in 2009, we determined that it is more likely than not that we will not realize the benefits associated with our net deferred tax asset in the immediate future. Accordingly, in accordance with SFAS 109, we recorded an income tax charge of $26.0 million in the fourth quarter of 2008 in order to establish a full valuation allowance against our net deferred tax asset.

Our ability to use our NOL 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 NOL carryforwards that can be used in any given year in the event of specified occurrences, including significant ownership changes. During 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 had 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 future taxable income. The Company continues to review ownership changes on an annual basis.

Clinical Trial Accruals. Some of our research and development is conducted by third parties, including contract research and development service providers. All such costs are charged to research and development expense systematically as incurred, which may be measured by patient enrollment or the passage of time. At the end of each quarter, we compare the payments made to each service provider to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the estimated service provided, we record net prepaid or accrued expense relating to these costs.

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 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.

A significant portion of our assets is comprised of certificates of deposit, commercial paper, U.S. government and agency obligations, and U.S. corporate bonds. All such instruments are classified as

available-for-sale securities. The primary objective of our investment policy is to preserve principal while maximizing the related income without significantly increasing risk. Even so, some of the securities in which we invest may be subject to market risk. Market risk is the risk that a change in prevailing interest rates may cause the fair value of an investment to fluctuate. As interest rates increase, the fair value of a debt instrument would be expected to decrease. Correspondingly, if interest rates decrease the fair value of a debt instrument would be expected to increase. To minimize market risk, we have the ability to hold such debt instruments to maturity, at which time the debt instrument would be redeemed at its stated or face value. To further mitigate market risk, we also typically invest in the shorter end of the maturity spectrum. As such, we do not believe that we have a material exposure to market risk.

In January 2008 we elected to fix the interest rate at 4.15% on our long-term debt until the debt's maturity in June 2011. As a result, we have no exposure to interest rate changes.

As of December 31, 2008, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in Europe and Africa, which are subject to foreign currency fluctuations. As currency rates change, translation of revenues and expenses for these operations from foreign currencies to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency represented approximately $108,000 of our total revenues for the year ended December 31, 2008. 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, 2008. 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-15(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, 2008.

The effectiveness of our internal control over financial reporting as of December 31, 2008 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 during the three months ended December 31, 2008 that was identified in connection with the evaluation referred to in paragraph (b) 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 OraSure Technologies, Inc.'s internal control over financial reporting as of December 31, 2008, 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, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included 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, OraSure Technologies, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, 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, 2008 and 2007, 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, 2008, and our report dated March 10, 2009 expressed an unqualified opinion on those financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 10, 2009

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 2009 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, Executive Officers and Corporate Governance.

Certain information required by this Item is incorporated by reference to the information under the captions, "Corporate Governance—Committees of the Board—Audit Committee," "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, and Director Independence.

The information required by this Item is incorporated by reference to the information under the captions, "Transactions with Related Persons" and "Corporate Governance—Director Independence," 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 10, 2009.

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 10, 2009, 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**	Chief Operating Officer, Chief Financial Officer and Director (Principal Financial Officer)
/s/ MARK L. KUNA **Mark L. Kuna**	Senior Vice President, Finance and Controller (Principal Accounting Officer)
*MICHAEL CELANO **Michael Celano**	Director
*JACK GOLDSTEIN, PH.D. **Jack Goldstein, Ph.D.**	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/ JACK E. JERRETT
Jack E. Jerrett
(Attorney-in-Fact)

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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, 2008 and 2007, 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, 2008. 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, 2008 and 2007, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2008, 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), OraSure Technologies, Inc.'s internal control over financial reporting as of December 31, 2008, 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 10, 2009 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 10, 2009

ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31, 2008	December 31, 2007
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 39,565,218	$ 32,229,697
Short-term investments	42,957,467	63,336,408
Accounts receivable, net of allowance for doubtful accounts of $163,100 and $186,468	11,571,048	11,296,355
Inventories	10,704,088	9,409,743
Deferred income taxes	—	5,060,974
Prepaid expenses and other	1,418,171	2,455,534
Total current assets	106,215,992	123,788,711
PROPERTY AND EQUIPMENT, net	21,235,367	20,911,157
PATENTS AND PRODUCT RIGHTS, net	4,380,540	5,279,471
DEFERRED INCOME TAXES	—	17,265,591
OTHER ASSETS	86,290	107,586
	$ 131,918,189	$167,352,516
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 557,897	$ 556,751
Accounts payable	3,925,662	5,615,998
Accrued expenses and other	10,795,955	11,995,710
Total current liabilities	15,279,514	18,168,459
LONG-TERM DEBT	8,301,440	8,817,669
OTHER LIABILITIES	11,985	311,799
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Preferred stock, par value $.000001, 25,000,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000,000 shares authorized, 45,769,221 and 46,644,046 shares issued and outstanding	46	47
Additional paid-in capital	235,862,999	236,293,489
Accumulated other comprehensive loss	(262,442)	(238,896)
Accumulated deficit	(127,275,353)	(96,000,051)
Total stockholders' equity	108,325,250	140,054,589
	$ 131,918,189	$167,352,516

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

	For the year ended December 31,		
	2008	**2007**	**2006**
REVENUES:			
Product	$ 68,842,755	$80,576,622	$67,830,561
Licensing and product development	2,261,712	2,109,254	324,359
	71,104,467	82,685,876	68,154,920
COST OF PRODUCTS SOLD	29,976,120	32,402,794	24,756,195
Gross profit	41,128,347	50,283,082	43,398,725
OPERATING EXPENSES:			
Research and development	20,255,451	14,136,019	8,647,484
Sales and marketing	20,916,718	20,061,685	15,921,467
General and administrative	16,286,907	17,304,615	13,367,111
	57,459,076	51,502,319	37,936,062
Operating income (loss)	(16,330,729)	(1,219,237)	5,462,663
INTEREST EXPENSE	(345,767)	(520,002)	(404,680)
INTEREST INCOME	3,080,950	4,709,771	4,097,860
OTHER INCOME	4,883,714	1,428,691	—
FOREIGN CURRENCY LOSS	(36,136)	(105,448)	(94,390)
Income (loss) before income taxes	(8,747,968)	4,293,775	9,061,453
INCOME TAX PROVISION	22,527,334	1,821,336	3,793,904
NET INCOME (LOSS)	$(31,275,302)	$ 2,472,439	$ 5,267,549
EARNINGS (LOSS) PER SHARE:			
BASIC	$ (0.67)	$ 0.05	$ 0.11
DILUTED	$ (0.67)	$ 0.05	$ 0.11
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:			
BASIC	46,549,739	46,325,338	45,909,990
DILUTED	46,549,739	46,878,143	46,580,266

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, 2008, 2007 and 2006

	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount					
Balance at January 1, 2006	45,775,625	$ 46	$226,218,469	$(3,334,792)	$(282,825)	$(103,681,856)	$118,919,042
Reclassification of deferred compensation	—	—	(3,334,792)	3,334,792	—	—	—
Reclassification of liability-classified awards	—	—	(230,659)	—	—	—	(230,659)
Common stock issued upon exercise of options	85,013	—	457,334	—	—	—	457,334
Vesting of restricted stock	199,633	—	—	—	—	—	—
Purchase and retirement of common stock	(65,519)	—	(631,509)	—	—	—	(631,509)
Compensation cost for restricted stock	—	—	1,969,178	—	—	—	1,969,178
Compensation cost for stock option grants	—	—	3,621,412	—	—	—	3,621,412
Comprehensive income:							
Net income	—	—	—	—	—	5,267,549	5,267,549
Currency translation adjustment	—	—	—	—	6,787	—	6,787
Unrealized gain on marketable securities, net of tax provision of $72,979	—	—	—	—	124,841	—	124,841
Total comprehensive income							5,399,177
Balance at December 31, 2006	45,994,752	46	228,069,433	—	(151,197)	(98,414,307)	129,503,975
Adoption of FIN 48	—	—	—	—	—	(58,183)	(58,183)
Reclassification of liability-classified awards	—	—	51,550	—	—	—	51,550
Common stock issued upon exercise of options	481,647	1	3,100,036	—	—	—	3,100,037
Vesting of restricted stock	258,093	—	—	—	—	—	—
Purchase and retirement of common stock	(90,446)	—	(785,908)	—	—	—	(785,908)
Compensation cost for restricted stock	—	—	2,877,463	—	—	—	2,877,463
Compensation cost for stock option grants	—	—	2,980,915	—	—	—	2,980,915
Comprehensive income:							
Net income	—	—	—	—	—	2,472,439	2,472,439
Currency translation adjustment	—	—	—	—	1,650	—	1,650
Unrealized loss on marketable securities, net of tax benefit of $52,287	—	—	—	—	(89,349)	—	(89,349)
Total comprehensive income							2,384,740
Balance at December 31, 2007	46,644,046	47	236,293,489	—	(238,896)	(96,000,051)	140,054,589
Common stock issued upon exercise of options	14,786	—	92,517	—	—	—	92,517
Vesting of restricted stock	393,551	—	—	—	—	—	—
Purchase and retirement of common stock	(135,432)	—	(995,367)	—	—	—	(995,367)
Shares purchased and retired pursuant to the stock repurchase plan	(1,147,730)	(1)	(5,121,107)	—	—		(5,121,108)
Compensation cost for restricted stock	—	—	3,352,876	—	—	—	3,352,876
Compensation cost for stock option grants	—	—	2,240,591	—	—	—	2,240,591
Comprehensive loss:							
Net loss	—	—	—	—	—	(31,275,302)	(31,275,302)
Currency translation adjustment	—	—	—	—	(36,201)	—	(36,201)
Unrealized gain on marketable securities	—	—	—	—	12,655	—	12,655
Total comprehensive loss							(31,298,848)
Balance at December 31, 2008	45,769,221	$ 46	$235,862,999	$ —	$(262,442)	$(127,275,353)	$108,325,250

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

	For the year ended December 31,		
	2008	**2007**	**2006**
OPERATING ACTIVITIES:			
Net income (loss)	$(31,275,302)	$ 2,472,439	$ 5,267,549
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Gain on sale of investment in nonaffiliated company	—	(1,428,691)	—
Deferred income taxes	22,305,250	1,313,839	3,113,745
Stock-based compensation	5,456,135	5,830,770	5,590,590
Depreciation and amortization	3,386,670	2,735,999	1,923,275
Acquired in-process technology	1,000,000	—	1,000,000
Provision for excess and obsolete inventories	1,575,910	922,433	750,542
Changes in assets and liabilities:			
Accounts receivable	(274,284)	(937,622)	1,250,552
Inventories	(2,870,255)	(4,797,609)	(2,156,302)
Prepaid expenses and other	1,070,168	(463,674)	(452,502)
Accounts payable	(1,686,143)	2,584,439	465,344
Accrued expenses and other liabilities	(1,148,491)	3,351,556	133,011
Net cash provided by (used in) operating activities	(2,460,342)	11,583,879	16,885,804
INVESTING ACTIVITIES:			
Purchase of property and equipment	(2,643,270)	(5,503,770)	(12,643,266)
Proceeds from sale of investment in nonaffiliated company	—	1,765,943	—
Purchase of patents, product rights, or acquired in-process technology	(1,200,000)	(4,200,000)	(200,000)
Purchase of short-term investments	(67,125,962)	(93,953,103)	(91,494,215)
Proceeds from maturities and redemptions of short-term investments	87,315,645	101,526,541	65,433,600
Net cash provided by (used in) investing activities	16,346,413	(364,389)	(38,903,881)
FINANCING ACTIVITIES:			
Proceeds from long-term debt	—	—	10,000,000
Repayments of long-term debt	(515,083)	(1,264,716)	(701,426)
Proceeds from issuance of common stock	92,517	3,100,037	457,334
Purchase and retirement of common stock	(5,121,108)	—	—
Withholding and retirement of common stock	(995,367)	(785,908)	(631,509)
Net cash provided by (used in) financing activities	(6,539,041)	1,049,413	9,124,399
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(11,509)	10,973	16,759
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	7,335,521	12,279,876	(12,876,919)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	32,229,697	19,949,821	32,826,740
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 39,565,218	$ 32,229,697	$ 19,949,821

The accompanying notes are an integral part of these statements.

1. THE COMPANY:

We develop, manufacture and market oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products, including *in vitro* diagnostic tests that are used on other specimen types, and other medical devices used for the removal of warts and other benign skin lesions by cryosurgery, or freezing. Our diagnostic products include tests which are performed on a rapid basis at the point of care and tests which are processed in a laboratory. 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 has been sold in the over-the-counter or consumer retail markets in the United States, Canada, Europe, Mexico and Australia.

The current economic downturn, including disruptions in the capital and credit markets, may continue indefinitely and intensify, and could adversely affect our results of operations, cash flows and financial condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct acquisitions or make other discretionary investments. These circumstances could adversely affect our ability to draw on existing credit facilities, which depend on the ability of the bank that is a party to that facility to meet its funding commitments to us. A bank may not be able to meet its funding commitments if it experiences shortages of capital and liquidity. These circumstances may also adversely impact the capital needs of our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. This could adversely affect our results of operations, cash flows and financial condition. A weakening business climate could 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. Our ability to collect accounts receivable may be delayed or precluded if our customers are unable to pay their obligations.

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 about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the valuation of accounts receivable, inventories and intangible assets, as well as calculations related to contingencies, accruals and indemnifications, among others. These estimates and assumptions are based on management's best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors which management believes to be reasonable under the circumstances, including the current economic environment. We adjust such estimates and assumptions when facts and circumstances dictate. Illiquid credit markets, volatile equity, foreign currency, and energy markets, and declines in consumer spending have combined to increase the uncertainty inherent in such estimates and assumptions. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in those estimates resulting from continuing changes in the economic environment, will be reflected in the financial statements in those future periods.

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, 2008 and 2007, cash equivalents consisted of money market accounts, commercial paper and U.S. government agency obligations.

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, 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 income (loss). There were no securities held as of December 31, 2008 in a continuous unrealized loss position for twelve or more months.

Recent U.S. sub-prime mortgage defaults have had a significant impact across various sectors of the financial markets, causing global credit and liquidity issues. The short-term funding markets have experienced instability during 2007 and 2008, leading to liquidity disruption in asset-backed commercial paper and failed auctions of auction rate securities. Further deterioration of the global credit market could adversely impact certain financial institutions that may have invested in or offered such securities. To the extent that we hold corporate bonds issued by those financial institutions in our portfolio, we could be adversely impacted and we could determine that some of our investments are impaired, which could adversely impact our financial results. As of December 31, 2008, we had not been adversely affected by these credit and liquidity issues.

The following is a summary of our available-for-sale securities at December 31, 2008 and 2007:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2008				
Certificates of deposit	$ 6,098,000	$ 8,401	$ —	$ 6,106,401
Commercial paper	2,894,609	4,425	—	2,899,034
Government and agency bonds	11,229,287	106,173	—	11,335,460
Corporate bonds	22,730,229	8,639	(122,296)	22,616,572
Total available-for-sale securities	$42,952,125	$127,638	$(122,296)	$42,957,467
December 31, 2007				
Certificates of deposit	$ 2,721,321	$ 3,759	$ (6,925)	$ 2,718,155
Commercial paper	4,383,327	1,158	(92)	4,384,393
Government and agency bonds	5,541,885	15,681	—	5,557,566
Corporate bonds	50,704,757	24,104	(52,567)	50,676,294
Total available-for-sale securities	$63,351,290	$ 44,702	$ (59,584)	$63,336,408
At December 31, 2008, maturities of our available-for-sale securities were as follows:				
Less than one year	$39,446,846	$112,412	$(122,296)	$39,436,962
One to two years	3,505,279	15,226	—	3,520,505
Total available-for-sale securities	$42,952,125	$127,638	$(122,296)	$42,957,467

Supplemental Cash Flow Information

In 2008, 2007 and 2006, we paid interest of $409,902, $663,127, and $350,535, respectively. In 2008 and 2007, we capitalized interest of $47,463 and $131,738, respectively.

In 2008, 2007 and 2006, we paid federal and state income taxes of $381,950, $500,529, and $695,765, respectively.

In 2008 and 2007, we recorded through the statement of operations an increase in our allowance for doubtful accounts of $78,044 and $27,288, respectively. In 2006 we recorded a reduction in our allowance for doubtful accounts of $61,950. We had write-offs of $101,412, $40,914, and $16,022 against the allowance for doubtful accounts in 2008, 2007, and 2006, respectively.

In 2008, 2007, and 2006, we recorded accruals for purchases of property and equipment of $25,250, $66,053, and $346,258, respectively.

In 2006, we recorded a $4,000,000 accrual related to two licensing agreements.

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 or exempted through these specific examination procedures, our policy is to reserve 100% of accounts receivable in aging categories greater than 120 days.

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 and pay for such purchases 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. Buildings are depreciated over 20-40 years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over three to ten years. Building improvements are amortized over their estimated useful lives. 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 their estimated useful lives of three to ten years.

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 cash flows from the use 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. We believe the future cash flows to be received from our long-lived assets will exceed the assets' carrying value, and accordingly we have not recognized any impairment losses for the years ended December 31, 2008, 2007, and 2006.

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 recorded 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.

Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee.

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. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

Significant Customer Concentration

We had the following significant concentrations in revenue and accounts receivable:

	Percentage of Total Revenues		
	For the years ended December 31,		
Customer	**2008**	**2007**	**2006**
Quest Diagnostics, Incorporated	10%	11%	14%
Abbott Laboratories	10	10	10

	Percentage of Accounts Receivable at December 31,	
	2008	**2007**
Quest Diagnostics, Incorporated	8%	11%
SSL International plc	10	13
National Aids Control Program	15	4

Our distribution agreement with Abbott Laboratories terminated at the end of 2008. Effective January 1, 2009, we began selling the OraQuick *ADVANCE*® rapid HIV-1/2 test directly to U.S. hospitals and other customers previously served by Abbott.

Research and Development

Research and development expenses consist of costs incurred in performing research and development activities including salaries and benefits, facilities expenses, overhead expenses, clinical trial and related clinical manufacturing expenses, contract services and other outside expenses. Research and development costs are charged

to expense as incurred. Clinical trial expenses include expenses associated with contract research organizations, or CROs. The invoicing from CROs can precede the services provided or can lag the service period by several months. Invoices paid prior to service being provided are recorded as a prepaid expense and then expensed appropriately as services are provided. We accrue the cost of services rendered but unbilled by CRO's based on purchase order estimates provided by the CRO. Differences between actual and estimated clinical trial expenses recorded are generally not material and would be adjusted for in the period in which they become known.

Advertising Expenses

Advertising costs are charged to expense as incurred. During 2008, 2007, and 2006, we incurred $893,279, $1,261,356, and $805,936, respectively, in advertising expenses. Included in advertising expenses for 2008, 2007 and 2006 were $687,308, $1,164,294 and $539,856, respectively, in reimbursement for marketing expenses incurred for our OTC cryosurgical products.

Stock-Based Compensation

We account for stock-based compensation to employees and directors using the fair value method in accordance with SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"), and stock-based compensation to nonemployees in accordance with SFAS No. 123R 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."

Upon the adoption of SFAS No. 123R on January 1, 2006, our deferred compensation balance of $3,334,792 was reclassified against additional paid-in capital. We have elected to recognize compensation expense for stock option awards issued to employees and directors on a straight-line basis over the requisite service period of the award. To satisfy the exercise of options or to issue new restricted stock, we normally issue new shares rather than purchase shares on the open market.

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.

In assessing the realizability of our net deferred tax assets, we follow the guidance contained within SFAS No. 109, "Accounting for Income Taxes," which requires net deferred tax assets to 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 net deferred tax assets will not be realized. The realization of the net deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. We assess the realizability of our net deferred tax assets on a quarterly basis.

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 a 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,		
	2008	2007	2006
Net income (loss)	$(31,275,302)	$ 2,472,439	$ 5,267,549
Weighted average shares of common stock outstanding:			
Basic	46,549,739	46,325,338	45,909,990
Dilutive effect of stock options, warrants and restricted stock	—	552,805	670,276
Diluted	46,549,739	46,878,143	46,580,266
Earnings (loss) per share:			
Basic	$ (0.67)	$ 0.05	$ 0.11
Diluted	$ (0.67)	$ 0.05	$ 0.11

For the years ended December 31, 2008, 2007, and 2006, outstanding common stock options, warrants and unvested restricted stock representing 4,489,227, 1,827,712, and 1,308,809 shares, respectively, were excluded from the computation of diluted earnings 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, 2008, 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.

We adopted SFAS No. 157, "Fair Value Measurements," effective January 1, 2008, which establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 applies to all financial assets and liabilities that are being measured and

reported on a fair value basis. Upon adoption of SFAS No. 157, there was no impact to our consolidated financial statements. The statement requires that fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

All our available for sale securities were classified and measured as Level 1 instruments.

Recent Accounting Pronouncements

On February 8, 2008, the Financial Accounting Standards Board ("FASB") issued Staff Position 157-2, "Effective Date of FASB 157" ("FSP 157-2"), which deferred the provisions of SFAS No. 157 to annual periods beginning after November 15, 2008 for non-financial assets and liabilities. Non-financial assets include fair value measurements associated with business acquisitions and impairment testing of tangible and intangible assets.

3. INVENTORIES:

	December 31,	
	2008	2007
Raw materials	$ 6,721,102	$4,924,139
Work in process	390,259	386,535
Finished goods	3,592,727	4,099,069
	$10,704,088	$9,409,743

4. PROPERTY AND EQUIPMENT:

	December 31,	
	2008	2007
Land	$ 1,117,788	$ 1,117,788
Buildings and improvements	15,571,279	14,550,060
Machinery and equipment	14,383,479	10,501,812
Computer equipment and software	3,791,012	3,331,647
Furniture and fixtures	1,455,965	1,227,152
Construction in progress	682,955	3,674,054
	37,002,478	34,402,513
Less accumulated depreciation	(15,767,111)	(13,491,356)
	$ 21,235,367	$ 20,911,157

Depreciation expense was $2,278,257, $1,687,126, and $1,371,400 for 2008, 2007, and 2006, respectively.

5. PATENTS, PRODUCT RIGHTS AND ACQUIRED IN-PROCESS TECHNOLOGY:

Patents product rights and licenses were as follows:

	December 31,	
	2008	2007
HIV-related	$ 1,900,000	$ 1,900,000
HCV-related	4,500,000	4,500,000
Lateral flow-related	1,500,000	1,500,000
Cryosurgery-related	2,548,620	2,548,620
	10,448,620	10,448,620
Less accumulated amortization	(6,068,080)	(5,169,149)
	$ 4,380,540	$ 5,279,471

Amortization expense for 2008, 2007, and 2006 was $898,931, $1,048,873, and $551,614, respectively.

Amortization expense for each of the five succeeding fiscal years is estimated as follows:

2009	$791,826
2010	791,826
2011	791,826
2012	719,077
2013	497,826

In June 1998, we acquired the patents and exclusive worldwide distribution rights to our cryosurgical product line. The purchase price of $2,548,620, 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 2009.

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 required us to pay the third party a one-time non-refundable license fee of $900,000, which was recorded as patent and product rights on our balance sheet and is being amortized through June 30, 2014. This agreement also contained an option to expand the application of this sublicense to other immunoassay platforms, in addition to our OraQuick® platform. In June 2006, we exercised this option, which required us to pay the third party a non-refundable license fee of $600,000, in $200,000 increments in July of 2008, 2007, and 2006. We recognized this $600,000 license fee as acquired in-process technology, which was included in research and development expense in our 2006 statement of operations, because other immunoassay platforms for the detection of HIV-2 will require additional research and development efforts and subsequent regulatory approvals.

In August 2005, we entered into a license agreement with third parties, pursuant to which we have been granted a limited, personal, non-transferable, non-exclusive license related to certain Hepatitis C Virus ("HCV") patents 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. In December 2006, the first milestone was achieved and $3,000,000 was paid in 2007. In November 2008, we achieved a second milestone upon filing our OraQuick® HCV pre-market approval application with the FDA and paid a $1,000,000 license fee. This fee was recognized as acquired in-process technology and included in research and development expense in our 2008 statement of operations as additional research and development efforts and regulatory approval is required in order to commercialize this product in the U.S. domestic market. Under the terms of the license agreement, we may also be required to pay additional license fees of up to $4,500,000, 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 efforts and regulatory approvals, while others, specifically in the international market, do not require additional research and development efforts or regulatory approvals. Based on management's estimate of the cash flows to be received from future product sales in international markets, we capitalized both the $1,500,000 and $3,000,000 license fees in the accompanying balance sheet. We are amortizing these amounts to cost of products sold on a straight-line basis over ten years, which represents management's estimate of the remaining 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, 2008.

In December 2006, we amended a license agreement with third parties, pursuant to which we have been granted a limited, non-exclusive license to certain lateral flow technology patents held by such parties. The amendment provided for the renewal of our license to certain lateral flow patents held by these parties, the expansion of these patents to future product applications to be developed by us, and the settlement of prior royalty obligations arising prior to the amendment date. It required us to pay the third parties a one-time non-refundable fee of $1,750,000. We allocated the $1,750,000 fee based upon the relative fair values of the items contained in the agreement. Accordingly, at December 31, 2006, we capitalized $1,000,000 as patent and product rights and are amortizing this amount to cost of products sold through December 2011. Of the remaining $750,000, we recognized $400,000 as acquired in-process technology in our 2006 statement of operations as such amount was allocated to royalties for future product applications that will require additional research and development efforts and regulatory approvals. The remaining $350,000 was recorded as a reduction of the accrued prior royalty obligations, which resulted in the reversal of $738,983 of royalty expense during 2006. The $1,750,000 fee was paid in 2007.

6. ACCRUED EXPENSES AND OTHER:

	December 31,	
	2008	2007
Payroll and related benefits	$ 3,513,124	$ 3,771,489
Royalties	2,481,466	2,485,869
Deferred revenue	1,951,921	2,841,640
Professional fees	472,969	1,371,850
Advertising	365,313	288,020
Clinical research obligations	348,459	191,903
Other	1,662,703	1,044,939
	$10,795,955	$11,995,710

Deferred revenue includes customer prepayments of $1,824,721 and $2,726,440 at December 31, 2008 and 2007, respectively.

7. LONG-TERM DEBT:

	December 31, 2008	December 31, 2007
Note payable to bank, principal and interest payable monthly at 4.15% through June 2011, at which time the remaining unpaid principal balance is payable, secured by a first priority security interest in all of our assets.	$8,791,679	$9,250,012
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 one of our buildings.	67,658	124,408
	8,859,337	9,374,420
Less current portion	(557,897)	(556,751)
	$8,301,440	$8,817,669

At December 31, 2008, we had in place a $14,000,000 credit facility (the "Credit Facility") with Comerica Bank ("Comerica") which is comprised of a $10,000,000 facility advance and a $4,000,000 revolving working capital line of credit. At our option, interest on the facility advance is payable monthly at either a fixed rate equal to the five-year U.S. Treasury Note rate plus 1.03% to 1.73%, or a variable rate equal to the 30, 180, or 360-day London Interbank Offered Rate ("LIBOR"), plus 0.55% to 1.25%. In each case, the interest rate is determined at the date of the advance and is based upon the amount of cash and cash equivalents we invest and retain at Comerica Securities, Inc. We also can choose the fixed rate option, without penalty, at the expiration of a previously elected LIBOR period. Principal is repayable in periodic installments, based upon the rate option that we elect, with the remaining balance of unpaid principal due on June 27, 2011. In January 2008, we elected to fix the interest rate on the facilities advance at 4.15% until its maturity in June 2011, with principal and interest payable on a monthly basis. As of December 31, 2008, we had $8,791,679 in outstanding borrowings under the facility advance and we had no outstanding borrowings under the $4,000,000 revolving working capital line of credit.

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 three facilities in Bethlehem, Pennsylvania. Borrowings under the revolving working capital line of credit are limited to commercially standard percentages of accounts receivable. 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, 2008. 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.

Long-term debt maturities as of December 31, 2008 are as follows:

2009	$ 557,897
2010	509,761
2011	7,791,679
	$8,859,337

8. INCOME TAXES:

The components of the provision for income taxes for the years ended December 31, 2008, 2007 and 2006 are as follows:

	2008	2007	2006
Current			
Federal	$ 9,590	$ 137,520	$ 251,074
State	212,494	369,977	429,085
	222,084	507,497	680,159
Deferred			
Federal	(3,200,853)	1,417,925	2,976,992
State	(472,064)	(104,086)	136,753
	(3,672,917)	1,313,839	3,113,745
Valuation allowance	25,978,167	—	—
	22,305,250	1,313,839	3,113,745
Total provision	$22,527,334	$1,821,336	$3,793,904

A reconciliation of the statutory United States federal income tax rate to our effective tax rate for each of the years ended December 31, 2008, 2007, and 2006 is as follows:

	2008	2007	2006
Statutory U.S. federal income tax rate	34.0%	34.0%	34.0%
State income taxes, net of federal benefit	2.8	4.1	4.1
Nondeductible expenses and other	(3.4)	11.0	3.8
Research and development credits	6.1	(6.7)	—
Change in valuation allowance, federal and state	(297.0)	—	—
Effective tax rate	(257.5)%	42.4%	41.9%

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 net deferred tax asset as of December 31, 2008 and 2007 are as follows:

	2008	2007
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 17,006,767	$15,458,795
Inventory	1,424,523	1,776,780
Capitalized research and development costs	1,445,495	449,572
Accruals and reserves currently not deductible	657,761	411,328
Patent costs	1,193,265	896,212
Depreciation and amortization	(451,061)	37,750
Stock-based compensation	3,240,047	2,451,303
Research and development tax credit carryforward	827,689	289,106
Alternative minimum tax credit carryforwards	633,681	555,719
Net deferred tax asset	25,978,167	22,326,565
Valuation allowance	(25,978,167)	—
Net deferred tax asset	$ —	$22,326,565

In assessing the realizability of our net deferred tax asset, we follow the guidance contained within SFAS No. 109, "Accounting for Income Taxes," which requires deferred income tax assets to 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 net operating loss ("NOL") carryforwards. At December 31, 2007, we concluded that it was more likely than not that we would generate sufficient taxable income in future years to recognize our deferred tax assets.

During the second quarter of 2008, we began to incur quarterly pre-tax losses, which continued through the end of 2008, as global economic conditions worsened and our research and development expenses continued to increase. For the year ended December 31, 2008, we recorded a pre-tax loss of $8,747,968. On a quarterly basis, we evaluate our ability to realize the benefits associated with our net deferred tax asset in order to determine if any valuation allowance is required. Pursuant to SFAS No. 109, a cumulative three-year pre-tax loss is a significant piece of negative evidence in considering whether net deferred tax assets are realizable. Based upon our pre-tax loss in 2008, our expectation of a pre-tax loss in 2009 and the continued volatility and uncertainty in the global economy, we concluded that it is more likely than not that our net deferred tax assets will not be realized in the immediate future. Accordingly, we recorded a charge of $25,978,167 in order to establish a full valuation allowance against our net deferred tax assets as of December 31, 2008.

Our federal NOL carryforwards expire as follows:

Year of Expiration	NOLs
2011	$ 5,765,731
2017-2021	30,428,371
2022-2028	13,330,221
	$49,524,323

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 in future years.

In July 2006, the FASB issued FASB Interpretation ("FIN") No. 48, "Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109," which clarifies what criteria must be met prior to recognition of the financial statement benefit of a position taken in a tax return. FIN No. 48 also provides guidance on derecognition of tax benefits, classification on the balance sheet, interest and penalties, accounting in interim periods, disclosure and transition. We adopted FIN No. 48 effective January 1, 2007, and pursuant to its provisions, decided to classify interest and penalties as a component of tax expense. As a result of the implementation of FIN No. 48, we recognized a $58,183 net increase in our liability for unrecognized tax benefits, which was accounted for as a reduction to the January 1, 2007 balance of retained earnings.

We had gross unrecognized tax benefits of $2,184,370 and $2,370,526 as of December 31, 2008 and 2007, respectively, which if recognized, $2,151,345 and $2,292,624, respectively, would result in a reduction to our effective tax rate. Interest and penalties were immaterial at December 31, 2008 and 2007. As a result of our net operating loss carryforward position, we are subject to audit by the Internal Revenue Service since our inception, as well as by several state jurisdictions for the years ended December 31, 2000 through 2008.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2008	2007
Balance at January 1	$2,370,526	$2,370,300
Additions based on tax positions related to the current period	46,836	40,000
Additions for tax positions of prior periods	28,021	60,226
Reductions for tax positions of prior periods	(105,729)	(100,000)
Settlements	(155,284)	—
Balance at December 31	$2,184,370	$2,370,526

9. STOCKHOLDERS' EQUITY:

Stock-Based Awards

We grant stock-based awards under the OraSure Technologies, Inc. 2000 Stock Award Plan, as amended and restated (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. We recognize compensation expense for stock option awards issued to employees and directors on a straight-line basis over the requisite service period of the award. To satisfy the exercise of options or to issue new restricted stock, we normally issue new shares rather than purchase shares on the open market.

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 be either unlimited or have a specified period in which to vest and be exercised.

In May 2008, the plan was amended to increase the number of authorized shares available for grant by 2,500,000 shares. As of December 31, 2008, 3,732,346 shares were available for future grants under the 2000 Plan.

The fair value of each stock option was estimated on the date of the grant using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	Year Ended December 31,		
Black-Scholes Option Valuation Assumptions	**2008**	**2007**	**2006**
Risk-free interest rate[1]	2.50%	4.79%	4.53%
Expected dividend yield	—	—	—
Expected stock price volatility[2]	46%	49%	56%
Expected life of stock options (in years)[3]	4	4	5

(1) Based on the constant maturity interest rate of U.S. Treasury securities whose term is consistent with the expected life of our stock options.

(2) Expected stock price volatility is based upon historical experience.

(3) Expected life of stock options is based upon historical experience.

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2008, 2007 and 2006 was $2.84, $3.62 and $4.85, respectively.

Amounts recognized in the financial statements related to stock options were as follows:

	Year Ended December 31,	
	2008	2007
Total compensation cost during the year	$2,103,259	$2,953,307
Amounts capitalized into inventory during the year	(142,965)	(303,472)
Amounts recognized in cost of products sold for amounts previously capitalized	229,860	280,283
Amounts charged against income, before income tax benefit	$2,190,154	$2,930,118
Amount of related income tax benefit	$ —	$ 802,300

The aggregate intrinsic value of options (the amount by which the market price of the stock on the date of exercise exceeded the exercise price) exercised during the years ended December 31, 2008, 2007 and 2006 was $31,037, $1,284,319, and $332,261, respectively.

The following table summarizes the stock option activity under the 2000 Plan:

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding on January 1, 2006	4,216,785	$7.08		
Granted	801,900	9.22		
Exercised	(85,013)	5.38		
Forfeited	(145,254)	7.99		
Outstanding on December 31, 2006	4,788,418	7.44		
Granted	519,566	8.37		
Exercised	(481,647)	6.43		
Forfeited	(99,796)	8.22		
Outstanding on December 31, 2007	4,726,541	7.63		
Granted	604,049	7.27		
Exercised	(14,786)	6.26		
Forfeited	(185,097)	7.86		
Outstanding on December 31, 2008	5,130,707	$7.58	6.11	$112,038
Vested or expected to vest as of December 31, 2008	4,973,507	$7.58	6.11	$108,605
Exercisable on December 31, 2008	4,318,302	$7.54	5.65	$112,038

As of December 31, 2008, there was $2,297,037 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted-average period of 1.6 years.

Net cash proceeds from the exercise of stock options were $92,517, $3,100,037 and $457,334 for the years ended December 31, 2008, 2007 and 2006, respectively. As a result of our net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises for these periods.

The following table summarizes information about stock options outstanding at December 31, 2008:

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–$5.60	822,403	9.51	$ 4.76	701,350	$ 4.81
$5.76–$6.96	855,696	3.68	6.51	853,196	6.51
$6.98–$7.77	806,850	4.22	7.53	766,849	7.53
$7.90–$8.18	501,483	8.49	8.05	185,061	8.04
$8.20	590,735	5.04	8.20	590,735	8.20
$8.28–$8.97	619,665	7.27	8.48	442,879	8.51
$9.04–$9.56	583,915	6.88	9.40	436,399	9.43
$9.78–$12.23	344,960	3.47	10.59	336,833	10.59
$12.69	5,000	2.68	12.69	5,000	12.69
	5,130,707	6.11	$ 7.58	4,318,302	$ 7.54

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 three-year vesting requirements or forfeiture, as determined by the Compensation Committee of our Board of Directors. The market value of these shares at the date of grant is recognized on a straight-line basis over the period during which the restrictions lapse. Compensation cost of $3,352,876, $2,877,463 and $1,969,178 related to restricted shares was recognized during the years ended December 31, 2008, 2007 and 2006, respectively.

The following table summarizes restricted stock award activity under the 2000 Plan:

	Shares	Weighted-Average Grant Date Fair Value
Issued and unvested, January 1, 2006	606,445	$6.90
Granted	465,313	9.16
Vested	(199,633)	6.99
Forfeited	(65,071)	7.56
Issued and unvested, December 31, 2006	807,054	8.13
Granted	348,655	8.29
Vested	(258,093)	7.91
Forfeited	(14,655)	8.10
Issued and unvested, December 31, 2007	882,961	8.24
Granted	418,565	7.83
Vested	(393,551)	8.08
Forfeited	(76,487)	8.31
Issued and unvested, December 31, 2008	831,488	$8.11
Issued and expected to vest, December 31, 2008	831,488	$8.11

As of December 31, 2008, there was $4,323,317 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 2.7 years.

In connection with the vesting of restricted shares during the years ended December 31, 2008, 2007 and 2006, we purchased and immediately retired 135,432, 90,446 and 65,519 shares with aggregate values of $995,367, $785,908 and $631,509, respectively, in satisfaction of minimum tax withholding obligations.

SFAS No. 123R addresses accounting for awards issued as part of share-based payment arrangements in exchange for employee services. Certain of our share-based payment arrangements are outside the scope of SFAS No. 123R and are subject to EITF Issue No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock," which requires that vested stock options held by certain nonemployee consultants be accounted for as liability-classified awards. The fair value of these vested and unexercised awards was estimated using the Black-Scholes option pricing model and $109,080 was reclassified from equity to other liabilities as of January 1, 2006 upon the adoption of SFAS No. 123R. An additional $121,579 was reclassified for options that vested during 2006. The fair value of these awards is remeasured at each financial reporting date until the awards are settled or expire. During 2007, $51,500 was reclassified from a liability to equity upon the settlement of 20,000 options. No options held by nonemployees were settled in 2008. As of December 31, 2008 and 2007, $11,985 and $149,317, respectively, was included in other liabilities for stock options to acquire 63,000 shares of common stock which remain unexercised. For the years ended December 31, 2008, 2007 and 2006, the mark-to-market adjustment recorded as a reduction of compensation costs in the statements of operations was $137,332, $27,608 and $2,183, respectively.

Share Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25,000,000 of our outstanding common shares. During the year ended December 31, 2008, we purchased and retired 1,147,730 shares of common stock at an average price of $4.46 per share.

10. COMMITMENTS AND CONTINGENCIES:

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:

2009	$ 500,000
2010	500,000
2011	500,000
2012	500,000
2013	500,000
Thereafter	2,291,667
	$4,791,667

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-transferable, non-exclusive license related to certain HCV patents 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. No minimum payments are required under this agreement in 2009 or thereafter. We may, however, be required to pay additional license fees of up to $4,500,000, upon the achievement of specific development and/or commercial milestones.

Leases

We lease office and warehouse facilities under operating lease agreements. Future payments required under these non-cancelable leases are $71,356 for 2009.

Rent expense for 2008, 2007 and 2006 was $184,128, $186,714, and $624,479, respectively.

Purchase Commitments

As of December 31, 2008, we had outstanding non-cancelable purchase commitments in the amount of $3,098,586 related to inventory, capital expenditures, and other goods or services.

Employment Agreements

Under terms of employment agreements with certain executive officers, extending through 2010, we are required to pay each individual a base salary for continuing employment with us. The agreements require payments of $1,901,875 and $879,375 in 2009 and 2010, 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.

On April 22, 2008, a complaint was filed against us in the United States District Court for the District of New Jersey by Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and Church & Dwight Co., Inc., alleging that we infringed U.S. Patent No. 6,485,982. The complaint specifically refers to our OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The complaint seeks injunctive relief, damages and an award of attorneys' fees. We have filed our Answer responding to the allegations in the Complaint and asserting various defenses and counterclaims.

On October 10, 2008, the plaintiffs filed a motion for summary judgment of infringement in this case, pursuant to a schedule previously established by the Court. We have filed our response to this motion and briefing is now complete.

We believe that none of our products, including the OraQuick *ADVANCE*® HIV test, infringe the patent asserted in this lawsuit or any other party's intellectual property rights. We also believe that the patent asserted in this matter is invalid or unenforceable, and we intend to defend this lawsuit vigorously. We are unable at this time to determine the impact, if any, that this lawsuit may have on our business or prospects.

11. RETIREMENT PLANS:

Substantially all of our employees 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 $579,592, $477,390, and $397,970 in 2008, 2007, and 2006, respectively.

12. OTHER INCOME:

On January 11, 2008, we entered into a settlement and license agreement with Schering-Plough Healthcare Products, Inc. ("Schering") to resolve our patent infringement litigation against Schering. Under the terms of the agreement, Schering was required to make a payment of $4,883,714 to us. This payment was received during the first quarter of 2008 and recorded in other income.

In January 2007, we sold our shares in a privately-held nonaffiliated company that had a carrying value of $337,252 and we received $1,765,943 for our ownership interest. Accordingly, in 2007, we recorded a $1,428,691 pre-tax gain on the sale of this investment in other income.

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):

	2008	2007	2006
United States	$57,391	$64,587	$56,780
Europe	7,746	9,618	9,521
Other regions	5,967	8,481	1,854
	$71,104	$82,686	$68,155

14. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2008 and 2007. 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).

	2008 Results				
	Three months ended				Year ended December 31, 2008
	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2008	
Revenues	$18,089	$18,946	$16,860	$ 17,209	$ 71,104
Costs and expenses	21,100	22,754	20,200	23,381	87,435
Operating loss	(3,011)	(3,808)	(3,340)	(6,172)	(16,331)
Other income, net	5,745	744	587	507	7,583
Income (loss) before income taxes	2,734	(3,064)	(2,753)	(5,665)	(8,748)
Income tax provision (benefit)	732	(820)	(991)	23,606	22,527
Net income (loss)	$ 2,002	$ (2,244)	$ (1,762)	$(29,271)	$(31,275)
Earnings (loss) per share(1)					
Basic	$ 0.04	$ (0.05)	$ (0.04)	$ (0.64)	$ (0.67)
Diluted	$ 0.04	$ (0.05)	$ (0.04)	$ (0.64)	$ (0.67)

	2008 Results				
	Three months ended				Year ended December 31, 2008
	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2008	
Revenues	$20,109	$21,352	$21,415	$19,810	$82,686
Costs and expenses	19,513	20,768	22,373	21,251	83,905
Operating income (loss)	596	584	(958)	(1,441)	(1,219)
Other income, net	2,389	970	1,086	1,068	5,513
Income (loss) before income taxes	2,985	1,554	128	(373)	4,294
Income tax provision (benefit)	1,499	599	124	(401)	1,821
Net income	$ 1,486	$ 955	$ 4	$ 28	$ 2,473
Earnings per share					
Basic	$ 0.03	$ 0.02	$ —	$ —	$ 0.05
Diluted	$ 0.03	$ 0.02	$ —	$ —	$ 0.05

(1) The summation of the quarterly amounts may not equal the year-end amounts due to the use of weighted-average shares for each period.

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