ORASURE TECHNOLOGIES INC
Form 10-K
March 15, 2010
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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)

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

For the fiscal year ended December 31, 2009

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 x

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 x

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 x No ¨

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). 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. x

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.

Large accelerated filer ¨	Accelerated filer x
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 x

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, 2009): $111,509,155

Indicate the number of shares outstanding of each of the Registrant s classes of common stock, as of March 11, 2010: 46,191,178 shares.

Documents Incorporated by Reference:

Portions of the Registrant s Definitive Proxy Statement for the 2010 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 used for the removal of 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 is sold in the over-the-counter (OTC) or consumer retail markets in North America, Europe, Central and South America, 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. 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. When combined with their ease of use, non-invasive nature, and cost effectiveness, our oral fluid tests represent a very competitive alternative to the more traditional testing methods in the diagnostic space.

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

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.

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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) 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. CE mark (European Union) approved. Also registered in various countries.	Marketed Marketed
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 are in process. Data from observed user study submitted to FDA.	Not Marketed
OraQuick® HCV	A rapid, point-of-care test for antibodies to the hepatitis C virus (HCV).	CE mark (European Union) approved. Individual country registrations in process. PMA submitted to FDA. Additional clinical studies are in process.	Marketed Not Marketed
OraSure®	Oral fluid collection device for the detection of antibodies to HIV-1 in an oral fluid sample in a laboratory setting.	PMA approved by FDA. FDA 510(k) cleared for use in detecting cocaine and cotinine (an indicator of nicotine) in oral fluid. CE marked and registered in various countries.	Marketed Marketed 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
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. Intercept® device and various assays CE marked and registered in certain countries.	Marketed Marketed
Homogeneous DOA Assays	Homogeneous fully-automated oral fluid DOA assays jointly developed with Roche Diagnostics for use with Intercept® collection device.	510(k) applications submitted to FDA for opiates, amphetamines, methamphetamines and PCP.	Not Marketed

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Product	Description	Regulatory Status	Commercial Status
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. CE marked and registered in certain countries.	Marketed 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 Freeze n Clear Skin Clinibrand. Registered in Canada. CE marked and registered in certain countries under Scholl Freeze Spray® and POINTTS® names.	Marketed Marketed Marketed

In addition to the above products, we also sell certain immunoassay tests and reagents for insurance risk assessment, substance abuse testing and forensic toxicology applications; an oral fluid Western blot HIV-1 confirmatory test 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.® rapid point-of-care saliva alcohol test.

OraQuick® Rapid HIV Test

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 generally 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 whole blood, venous whole blood and plasma. This test is available for use by laboratories located 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 numerous 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 certain countries and 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 received approval for the new dating in Europe. Additional real-time stability testing is being performed for this product, and we expect to seek future approval for shelf life extensions beyond 12 months in both the U.S. and international markets.

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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 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.

In past years, the HIV-1 EIA test approved by the FDA for use with our OraSure® device was manufactured and sold by bioMerieux, Inc. (BMX). In 2007, however, BMX discontinued this product. During 2009, Avioq, Inc., a company that had acquired a license from BMX to manufacture and sell a new HIV-1 EIA test originally developed by BMX, obtained FDA approval of this new product for use with the OraSure® test. This new HIV-1 EIA is now commercially available to our OraSure® customers.

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.

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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. This product was initially sold in the United States and Canadian OTC markets by a third party distributor under that party s trade name. As a result of the termination of our agreement with this party on December 31, 2007, we re-launched our OTC cryosurgical wart product in the U.S. in 2009 under our own new national brand called Freeze n Clear Skin Clinic .

Internationally, we distribute an OTC cryosurgical product through our distributor Genomma Labs, under the POINTTS tradename, in Mexico and a number of South and Central American countries. We also 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.

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. Our AUTO-LYTE® tests continue to face strong competition from cheaper home-brew tests developed internally 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

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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 could continue to manufacture and sell our oral fluid Western blot test. The antigen was historically manufactured by a subcontractor to BMX and we expect that this party will be able to meet our future needs for HIV-1 antigen.

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 in 2010 and 2011, 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 and other sample types. A PMA application for this test was originally submitted to the FDA in October 2008. In response to comments on our submission received from the FDA, we have provided additional clinical data to the FDA in support of a whole blood claim for this product. We are also conducting an additional clinical study requested by the FDA in support of oral fluid and finger-stick whole blood claims. In late 2009, we received authorization to affix a CE mark to this product for all sample types, and this product is now available for sale in Europe.

We have entered into agreements with Merck & Co. Inc. (Merck, formerly 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 Merck for a portion of our costs to develop the test and obtain regulatory approvals, and Merck 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

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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 collaborating on the development of additional drugs of abuse assays for use with our Intercept® collection device. Pursuant to a development agreement with Roche Diagnostics, homogeneous fully-automated oral fluid drugs of abuse assays are being developed for use with our Intercept® collection device. The assays use Roche s KIMs (kinetic interaction of micro-particles in solution) technology and 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. Applications for 510(k) clearance of assays to detect opiates, methamphetamine, amphetamine and PCP in oral samples collected with our Intercept® device have been submitted to the FDA, and we expect that submissions for assays detecting cocaine and cannabinoids (marijuana) will be filed in 2010. We have also entered into 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.

Research and Development

In 2009, our research and development activities focused primarily on clinical and regulatory activities related to obtaining PMA and CE approval for our OraQuick® HCV test, discussions and planning 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® and Intercept® product lines.

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

Research and development expenses were $13.4 million in 2009, $20.3 million in 2008 and $14.1 million in 2007. 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 collaborations 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 $62.2 million, $57.4 million and $64.6 million in 2009, 2008 and 2007, respectively. Revenues attributable to international customers amounted to $14.8 million, $13.7 million and $18.1 million, or 19%, 19% and 22% of our total revenues, in 2009, 2008 and 2007, respectively.

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Infectious Disease Testing

We market the OraQuick *ADVANCE*® rapid HIV-1/2 antibody test directly to customers in the public health market for HIV testing. This market consists of a broad range of clinics and laboratories and includes states, counties, and other governmental agencies, 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.

As a result of the termination of our agreement with Abbott Laboratories (Abbott) at the end of 2008 for the distribution of the OraQuick *ADVANCE*® HIV test primarily in U.S. hospitals, we are now selling OraQuick *ADVANCE*® directly to this market. 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 also sell OraQuick® to the U.S. physician market primarily through distributors.

We currently distribute our OraQuick® test in several foreign countries. During 2007, we obtained a CE mark for this product and have since launched sales in several European countries. 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 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.

A PMA application is pending for FDA approval of our OraQuick® HCV test, and we plan to apply for CLIA waiver for this product. In late 2009, we received approval to affix the CE mark to this test and intend to sell this product on a worldwide basis. We previously entered into agreements with Merck 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 Merck for a portion of our costs to develop the test and obtain regulatory approvals, and Merck 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 (CRL), and internationally for workplace, criminal justice and forensic toxicology testing through 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 Intercept® 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

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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. We recently entered into agreements with two manufacturers representative organizations under which a contract sales force will be provided to help our U.S. distributors promote and sell Histofreezer®. Internationally, we sell the Histofreezer® product through a network of distributors in more than 20 countries worldwide.

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. In early 2009, we re-launched our OTC cryosurgical wart product in the U.S. under our own proprietary national brand called Freeze n Clear Skin Clinic . This launch started with one major retailer, and we are beginning to expand to other retail outlets.

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 CRL. 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. We sell our OraSure® Western blot confirmatory test directly to insurance testing laboratories for use in confirming oral fluid specimens collected with our OraSure® device that initially test positive for HIV-1.

There exists a wide range of policy limits where our OraSure® product is being used. 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. 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.

We also sell our AUTO-LYTE® assays and reagents in the insurance testing market directly to laboratories, including Heritage Labs and CRL.

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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.

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 $43.8 million, $10.9 million and $11.7 million in 2009, $35.3 million, $10.7 million and $13.6 million in 2008 and $32.7 million, $23.5 million and $15.5 million in 2007, respectively.

We had one customer, Quest, which accounted for 9% of our total revenues during 2009. 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 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 14 to the financial statements, included elsewhere in this Annual Report.

Supply and Manufacturing

We manufacture the OraQuick *ADVANCE*® HIV test in our Bethlehem, Pennsylvania facility. In addition, we have contracted with a third party in Thailand for the assembly of the OraQuick® HIV 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. For the past ten years, we purchased the antigen from a single contract supplier under an exclusive long-term agreement. We recently negotiated a buy-out of our obligations under this agreement, including the right to purchase the antigen from other third parties. We are now purchasing the antigen from a subcontractor historically used by the original supplier, and we expect to enter into a long-term supply agreement with this subcontractor in the near future. We also purchase the nitrocellulose used in the test from a single vendor, under a supply agreement which was recently renewed through 2014. 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 could require significant time to complete and could disrupt our ability to manufacture and sell the OraQuick® device.

The OraQuick® HCV test that is available for sale in Europe is manufactured in our Bethlehem, Pennsylvania facility.

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We manufacture both the OraSure® and Intercept® collection devices and our assays 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. The antigen was historically manufactured by a subcontractor to BMX. We have continued to purchase antigen directly from this subcontractor and we expect that this party will be able to meet our future needs for this product.

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, 2009, we had 280 full-time employees, including 82 in sales, marketing and client services; 19 in research and development; 130 in operations, manufacturing, quality control, information systems, purchasing and shipping; 22 in regulatory affairs; and 27 in administration and finance. This compares to 287 employees as of December 31, 2008. Our employees are not currently represented by a collective bargaining agreement.

Competition

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

Important competitive factors for our products include product quality, 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);

Commercial execution and strength of distribution;

Access to adequate capital;

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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 HIV-1/2 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*® HIV 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 and Trinity Biotech sell rapid HIV-1/2 blood tests 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.

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The OraQuick® HCV test that is now available in Europe is expected to compete primarily against laboratory-based HCV blood tests. Major suppliers of these competing tests are Abbott Labs, Seimens, Ortho-Clinical Diagnostics, Roche and Bio-Rad. In non-U.S. countries outside of Europe, we expect that our OraQuick® HCV test will compete against other rapid HCV blood tests in addition to the laboratory-based tests.

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 and intend to commercialize 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 Merck under the Dr. Scholl ®s brand and by Prestige Brands 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 primary 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.

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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 nine 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 January 2013 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 three United States patents for our OraQuick® platform, and we have several related patent applications pending 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 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*® HIV 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 three 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 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 a number of trademarks, including 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

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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

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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 any facility that does laboratory testing on specimens derived from humans from 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 facility a certificate issued by the U.S. Department of Health and Human Services applicable to the category of examination or procedure performed. Tests may be waived from this regulatory oversight if they meet certain requirements established under CLIA. 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 applicable 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 OraQuick® rapid HCV 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.

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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 and Other Fraud and Abuse 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.

We are also subject to other federal and state laws targeting fraud and abuse in the healthcare industry, including false claims laws and marketing conduct laws and laws constraining the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements, including sales programs, with physicians, hospitals, laboratories and other potential purchasers of medical devices. Violations of these laws may be punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in government healthcare programs such as Medicare and Medicaid. These laws and regulations are wide ranging and subject to changing interpretation and application. In recent years, there has been greater scrutiny of marketing practices in the medical device industry which has resulted in several government investigations by various government authorities and the introduction and/or passage of federal and state legislation regulating interactions between medical device manufacturers and healthcare professionals and providers and requiring the disclosure by medical device manufacturers of gifts or other payments to healthcare professionals and providers. To be in compliance with such disclosure laws, we have implemented necessary systems for accurately tracking gifts and other payments.

We are in the process of adopting a written Policy on Interactions with Health Care Professionals and will train our personnel on this policy, which is based on the Code of Conduct for Interactions with Health Care Professionals promulgated by the Advanced Medical Technology Association, or AdvaMed, a leading trade association representing medical device manufacturers. The Policy is intended to comply with applicable state and federal laws, regulations and government guidance. The Policy addresses interactions related to sales and

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marketing practices, research and development, product training and education, grants and charitable contributions, support of third-party educational conferences, and consulting arrangements.

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. A regulatory authority may impose its own requirements as a condition to granting an approval or clearance, may include significant restrictions or limitations as part of any approval or clearance it grants and may delay or refuse to grant approval or clearance, even though a product has been approved without restrictions or limitations in another country or by another agency.

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The process required for approval or clearance of our new products can be lengthy and may increase the costs associated with developing those 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 and clearances 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. Since a rapid HIV test has never before been approved by the FDA for OTC use, its approval will depend on our further discussions with the FDA and its advisory committees. We have also conducted clinical trials and submitted a PMA application for FDA approval of our OraQuick® HCV test for professional use, and we are conducting an additional clinical study in response to feedback from the FDA for certain specimen applications. There can be no assurance that our clinical trials will support FDA approval of either product or that FDA approval will ultimately 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 and prospects.

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. 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. The failure to obtain or maintain the CE mark for one or more of our products could lead to the termination of strategic alliances and agreements for sales of those products 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.

In addition, the FDA and other regulatory authorities have the ability to change the requirements for obtaining product approval and/or impose new or additional requirements for such approval. These changes or new or additional requirements may occur after the completion of substantial clinical work and other costly development activities. The implementation of such changes or new or additional requirements may result in additional clinical trials and substantial additional costs and can delay or make it more difficult or complicated to obtain product approvals.

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

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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 and results of operations.

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.

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 revenues and results of operations.

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

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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.

Compliance With Regulations Governing Public Company Corporate Governance and Reporting is Complex and Expensive.

Many laws and regulations, notably those adopted in connection with the Sarbanes-Oxley Act of 2002 by the SEC and the NASDAQ Global Market, impose obligations on public companies, such as ours, which have increased the scope, complexity and cost of corporate governance, reporting and disclosure practices. Our implementation of these reforms and enhanced new disclosures has required and will continue to require substantial management time and oversight and requires us to incur significant additional accounting and legal costs.

Federal and State Laws Pertaining to Healthcare Fraud and Abuse Could Materially Adversely Affect Our Business, Financial Condition and Results of Operations.

We are subject to various federal and state laws targeting fraud and abuse in the healthcare industry, including anti-kickback laws, false claims laws and marketing conduct laws, including laws constraining the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements, including sales programs, with physicians, hospitals, laboratories and other potential purchasers of medical devices. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in government healthcare programs such as Medicare and Medicaid. Many of the existing requirements are new and have not been definitively interpreted by state authorities or courts, and available guidance is limited. Unless and until we are in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity, all of which could materially harm our business. In addition, changes in these laws, regulations, or administrative or judicial interpretations, may require us to further change our business practices or subject our existing business practices to legal challenges, which could have a material adverse effect on our business, financial condition and results of operations.

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. We may also be required to increase our marketing efforts in order to compete effectively, which would increase our costs and reduce our margins.

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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 or enhanced products. The research and development process generally takes a significant amount of time from product inception to commercial 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 new or enhanced product in which we have invested substantial time and money.

During 2009, 2008 and 2007, we incurred $13.4 million, $20.3 million and $14.1 million, respectively, in research and development expenses. We expect to continue to incur significant costs related to 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 can be required before any regulatory authority will review them. As noted above, regulatory authorities may not approve these products for commercial sale or can substantially delay approval. 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 and 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 flow 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 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 or enhanced 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 a sufficient number of qualified employees in the future due to the intense competition for qualified personnel among medical products and other life science businesses. We generally do not enter into employment agreements requiring our employees to work for us for any specified period.

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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 research, development and clinical 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 or consistent with our objectives;
- We may be unable to successfully integrate an acquired company s personnel, assets, management systems, products and/or 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 and other 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 our or the acquired company s key personnel, customers, distributors or suppliers;
- 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 and 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

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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.

Changes in Healthcare Regulation Could Affect Our Revenues, Costs and Financial Condition.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs. Similar reforms may occur internationally.

Legislative and regulatory bodies are likely to continue to pursue healthcare reform initiatives and may continue to reduce the funding of the Medicare and Medicaid programs, including Medicare Advantage, in an effort to reduce overall federal healthcare spending. In addition, some of the proposed reform legislation in the U.S. contains taxes on medical device manufacturers as a way to help pay for the costs of reform.

The ultimate content or timing of any future healthcare reform legislation, and its impact on us, is impossible to predict. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may increase our costs or otherwise have an adverse effect on our financial condition and results of operations.

Increases in Demand for Our Products Could Require Us to Expend Considerable Resources 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 may 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

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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, or our inability to quickly and cost-effectively obtain alternative sources for this supply, could have a material adverse effect on our total revenues 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

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 currently 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 flow and business.

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 and distribution abilities of the companies with which we collaborate.

Relying on distributors or others to market and sell our products could harm our business for various reasons, including:

- 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;
- Agreements with distributors may terminate prematurely due to disagreements or may result in litigation between the parties;
- We may not be able to renew existing distribution agreements on acceptable terms or at all;
- Our distributors may not designate sufficient resources or priority to the sale of our products;
- Our existing distributor relationships or contracts may preclude or limit us from entering into additional future arrangements with other distributors; and
- We may not be able to negotiate future distribution agreements on acceptable terms or at all.

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 do so or that new distribution channels will be available on satisfactory terms. As a result, our revenues and business could be adversely affected.

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Some of our distributors have also consolidated 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 Unavailability of an FDA-Approved HIV-1 EIA Screening Test 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® collection device. Historically, BMX manufactured and sold the only oral fluid HIV-1 EIA screening test approved by the FDA for use in detecting HIV-1 in an oral fluid specimen collected with our OraSure® collection device. However, BMX discontinued manufacturing the HIV-1 EIA screening test in 2007.

During 2009, Avioq, Inc., a company that had acquired a license to produce a new HIV-1 EIA test originally developed by BMX, obtained FDA approval of the new product for use with our OraSure® device. The Avioq HIV-1 EIA is now the only such screening test approved for use with the OraSure® device.

If at some point in the future our customers cannot purchase the Avioq HIV-1 EIA or otherwise obtain an HIV-1 EIA screening 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. Relying on collaborative relationships could be risky to our business for a number of reasons, including:

- We may be required to transfer material rights to such strategic partners, licensees and others;
- Our collaborators may not devote sufficient resources to the success of our collaboration;
- Our collaborators may not obtain regulatory approvals necessary to continue the collaborations in a timely manner;
- Our collaborators may be acquired by another company and decide to terminate our collaborative arrangement or become insolvent;
- Our collaborators may develop technologies or components competitive with our products;
- Disagreements with collaborators could result in the termination of the relationship or litigation;
- Collaborators may not have sufficient capital resources; and
- We may not be able to negotiate future collaborative arrangements, or renewals of existing collaborative agreements, on acceptable terms.

While we expect that our current and future collaborative partners 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.

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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 an OraQuick® HIV OTC test, we and/or our distributors may need to invest significantly in advertising and promotion in order to sell this product. 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 and profits from 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. Our employees and third party consultants also sign agreements requiring that they assign to us interests in inventions and original expressions and any patents or copyrights arising from their work. However, these parties may not honor these agreements.

We cannot guarantee that the process of filing patents, the laws governing trade secrets and proprietary information, or any agreements we enter into with employees, consultants, advisors or collaborators will provide adequate protection of our intellectual property rights. Moreover, issued patents remain in effect for a fixed period and after expiration will not provide protection of the inventions they cover. We may also 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.

Some 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

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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. In addition, governmental agencies could commence investigations or criminal proceedings against our employees or us relating to claims of misuse or misappropriation of another party s proprietary rights.

Our involvement in litigation or other legal proceedings with respect to patents or other intellectual property and 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. These other parties may also not be required or financially able to indemnify us in the event that an infringement or misappropriation claim is asserted against us.

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The Sales Potential for Our OraQuick® Products Could be Affected by Our Ability to Obtain Certain Licenses and by 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. There are also patents that cover the type of analyte (i.e., HIV-1, HIV-2, HCV, etc.) which our OraQuick® test is designed to detect. Some of these patents may broadly cover the aspects of our 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, and assays directed at specific analytes, 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.

If we are unable to successfully defend against or resolve patent infringement 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 and develop and commercialize new applications using the same technology 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 flow 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® HIV OTC test, an OraQuick® HCV test, 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. In addition, governmental funding for the purchase of our products may be needed to help create market acceptance and expand the use of our products.

There may be limited evidence on which to evaluate the market reaction to products that may be developed and our marketing efforts for new products may not be successful. It is also possible that governmental funding may not be available for new products, such as an OraQuick® HCV test. As such, 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.

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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 and OraQuick® HCV tests, 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 Inability to Carry Out Certain of Our Marketing and Sales Plans May Make it Difficult for Us to Grow or Maintain Our Business.

We have implemented in the past, and we intend to implement in the future, an aggressive sales and marketing plan to expand sales of our products. Specifically, we will continue to expand the reach of our direct field sales force, use third party distributors and implement other sales and marketing programs. If we are unable to successfully implement these programs, we may be unable to grow and our business could suffer.

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 or public health 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 governmental 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. There is no assurance that we would be successful in defending any product liability lawsuits brought against us. Regardless of merit or eventual outcome, product liability claims could result in:

- Decreased demand for our products;
- Lost revenues;
- Damage to our image or reputation;
- Costs related to litigation; and
- Incurrence of damages payable to plaintiffs.

We are selling cryosurgical wart removal products in the consumer or OTC market in the U.S. and certain other 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.

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The Insurance We Purchase to Cover Our Potential Business Risks May be Inadequate.

Although we believe that our present product liability and other insurance coverage is sufficient to cover our current estimated exposures, we cannot be sure that we will not incur liabilities in excess of our policy limits. In addition, although we believe that we will be able to continue to obtain adequate coverage in the future, there is no assurance that we will be able to do so at acceptable costs.

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 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 $14.8 million or 19% of total revenues for 2009, $13.7 million or 19% of total revenues for 2008 and $18.1 million or 22% of total revenues for 2007.

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 could lower our sales;

- The inability to obtain or 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 or other country-specific registrations may preclude or delay our ability to sell products in the European Union;

The uncertainty of foreign laws and the inconsistent imposition of legal and regulatory requirements may make it more difficult to sell our products internationally;

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- 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, political instability, 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

Continued Economic Volatility and Disruption Could Adversely Affect Our Results of Operations, Cash Flow and Financial Condition or Those of Our Customers and Suppliers.

Capital and credit markets have been experiencing a period of unprecedented turmoil and upheaval, characterized by the bankruptcy, failure, collapse or sale of various financial institutions and substantial

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intervention by the U.S. government. These conditions could adversely affect the demand for our products and services and, therefore, reduce purchases by our customers, which would negatively affect our revenues and profitability. In addition, interest rate fluctuations, financial market volatility or credit market disruptions may limit our access to capital, and may also negatively affect our customers and our suppliers ability to obtain credit to finance their businesses on acceptable terms. As a result, our customers needs and ability to purchase our products or services may decrease, and our suppliers may increase their prices, reduce their output or change their terms of sale. If our customers or suppliers operating and financial performance deteriorates, or if they are unable to make scheduled payments or obtain credit, our customers may not be able to pay, or may delay payment of, accounts receivable owed to us, and our suppliers may restrict credit or impose different payment terms. Any inability of customers to pay us for our products and services, or any demands by suppliers for different payment terms, may adversely affect our earnings and cash flow.

Additionally, both state and federal government sponsored payers, as a result of budget deficits or reductions, may seek to reduce their health care expenditures by reducing their purchases of our products or renegotiating their contracts with us. Any reduction in payments by such government sponsored payers may adversely affect our earnings and cash flow.

The current economic circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct acquisitions and make other discretionary investments. Declining economic conditions may also increase our costs. If the economic conditions do not improve or continue to deteriorate, our results of operations or financial condition could be adversely affected.

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 net losses in 2008 and 2009. In addition, as of December 31, 2009, the Company had an accumulated deficit of $135.1 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 in the United States and internationally;

- 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;

- Our ability to successfully launch new products after receipt of required regulatory approvals including our OraQuick® rapid HCV test;

- 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;

- Whether we are successful in obtaining and maintaining required regulatory approvals and registrations for our new 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;

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Changes in economic conditions in domestic or international markets, such as economic downturns, reduced demand, inflation and currency fluctuations;

Failure to achieve our targets for growth in revenues;

Changes in distributor buying patterns or a buildup of significant quantities in our distributors inventories or distribution channels; and

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 continued volatility and disruption in economic conditions and other circumstances 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, 2009, we had $79.7 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.

All of the cash equivalents and marketable securities are treated as available-for-sale. 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. The market value of our investments could also be reduced as a result of market and other conditions or events, such as the recent U.S. sub-prime mortgage defaults and resulting credit and liquidity issues. Due in part to these factors, our future investment income may fall short of expectations. 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 or other factors. However, because any debt securities we hold are classified as available-for-sale, no gains or losses are recognized unless such securities are sold prior to maturity.

Our Estimates or Judgments Relating to Critical Accounting Policies Are Based on Assumptions That Can Change or Prove to be Incorrect.

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;

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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.

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 time, cost and degree of success of conducting clinical trials and obtaining regulatory approvals;

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 or enhanced products gain market acceptance;

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 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;

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, or at all.

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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, our products, our competitors or our industry;

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

Status of clinical studies and pending submissions for required regulatory approvals;

The gain or loss of significant contracts;

Delays in the development or commercialization of new or enhanced products;

Legislative developments;

Disputes or developments with key customers, distributors or suppliers;

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;

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.

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In addition, the stock market in general has experienced extreme price and volume fluctuations that have affected the market price of our Common Stock, as well as the stock of many companies in the diagnostics and life sciences industries. Often, price fluctuations are unrelated to operating performance of the specific companies whose stock is affected.

In the past, following periods of volatility in the market price of a company s stock, securities class action litigation has occurred against the issuing company. If we were subject to this type of litigation in the future, we could incur substantial costs and a diversion of our management s attention and resources, each of which could have a material adverse effect on our revenue and earnings. Any adverse determination in this type of litigation could also subject us to significant liabilities.

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 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. We also could conclude that our internal control over financial reporting is not effective. These events 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.

Because We Do Not Intend to Pay Cash Dividends on Our Common Stock, an Investor in Our Common Stock Will Benefit Only if it Appreciates in Value.

We currently intend to retain our current earnings and future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends on our Common Stock in the foreseeable future. As a

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result, the success of an investment in our Common Stock will depend entirely upon any future appreciation. There is no guarantee that our Common Stock will appreciate in value or even maintain the price at which investors purchased their shares.

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.

Future Sales of Shares of Our Common Stock or the Issuance of Securities Senior to Our Common Stock Could Adversely Affect the Trading Price of Our Common Stock and Our Ability to Raise Funds in New Equity Offerings.

Future sales of a substantial number of our shares of Common Stock or equity-related securities in the public market or privately, or the perception that such sales may occur, could adversely affect prevailing trading prices of our Common Stock, and could impair our ability to raise capital through future offerings of equity or equity-related securities. No prediction can be made as to the effect, if any, that future sales of shares of Common Stock or the availability of shares of Common Stock for future sale will have on the trading price 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 also rent additional warehouse space on an as-needed basis.

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

ITEM 3. Legal Proceedings.

Lateral Flow Patent Infringement Litigation

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 referred to our OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test. The complaint sought injunctive relief, damages and an award of attorneys fees. We aggressively defended against this lawsuit and asserted various defenses and counterclaims.

In November 2009, the parties entered into several agreements to settle this lawsuit, pursuant to which we paid Inverness $3 million, Inverness granted us non-exclusive, worldwide licenses to certain lateral flow patents, we and Inverness granted certain product distribution rights to each other, and we granted a limited right of first

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negotiation for the worldwide rights to market and distribute our OraQuick® HIV OTC test to the consumer diagnostics joint venture between Inverness and Proctor & Gamble. As a result of the settlement, the lawsuit and the claims of each party were dismissed by the Court with prejudice.

Cryosurgical Patent Infringement Litigation

In December 2009, we filed legal proceedings in the Patents Court of the High Court of England and Wales against D.D.D. Limited, DioMed Developments Limited and Sixtem Life Srl, alleging that the import and/or sale of the Bazuka Sub-Zero OTC cryosurgical product by the defendants in the United Kingdom infringes our European Patent (UK) 0 608 954. We are seeking injunctive relief and damages, among other remedies, in this matter. The defendants have filed a response denying infringement and alleging that our patent is invalid.

ITEM 4. (Removed and Reserved).

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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,			
	2009		2008	
	High	Low	High	Low
First Quarter	$ 3.82	$ 2.16	$ 9.23	$ 6.37
Second Quarter	4.09	2.41	7.81	3.74
Third Quarter	3.55	2.35	6.25	3.69
Fourth Quarter	5.25	2.80	4.96	2.18

On March 9, 2010, there were 551 holders of record and approximately 11,300 holders in street name of our Common Stock, and the closing price of our Common Stock was $5.35 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

Pursuant to our 2000 Stock Award Plan and in connection with the vesting of restricted shares, we retired 2,825 shares to satisfy minimum tax withholding obligations during the three months ended December 31, 2009. No shares were repurchased under our $25.0 million share repurchase program during this same period.

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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, 2004 through December 31, 2009. The graph assumes that $100 was invested on December 31, 2004 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 12/31/04 in stock or index, including reinvestment of dividends. Fiscal year ended December 31.

	12/04	12/05	12/06	12/07	12/08	12/09
OraSure Technologies, Inc.	**100.00**	**131.25**	**122.92**	**132.29**	**54.76**	**75.60**
NASDAQ Composite	**100.00**	**101.33**	**114.01**	**123.71**	**73.11**	**105.61**
NASDAQ Biotechnology	**100.00**	**117.54**	**117.37**	**121.37**	**113.41**	**124.58**

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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,				
	2009	**2008**	**2007**	**2006**	**2005**
Operating Results:					
Revenues	$ 77,026	$ 71,104	$ 82,686	$ 68,155	$ 69,366
Costs and expenses	85,819	82,551	83,905	62,692	61,793
Operating income (loss)	(8,793)	(11,447)	(1,219)	5,463	7,573
Other income, net	357	2,699	5,513	3,599	2,146
Income tax provision (benefit)	(622)	22,527[1]	1,821	3,794	(17,729)[2]
Net income (loss)	(7,813)	(31,275)[1]	2,472	5,268	27,448[2]
Earnings (loss) per share					
Basic	$ (0.17)	$ (0.67)	$ 0.05	$ 0.11	$ 0.61
Diluted	$ (0.17)	$ (0.67)	$ 0.05	$ 0.11	$ 0.59
Shares used in computing earnings (loss) per share					
Basic	45,878	46,550	46,325	45,910	45,110
Diluted	45,878	46,550	46,878	46,580	46,147
Cash Flow:					
Cash flows provided by (used in) operating activities	$ (293)	$ (2,460)	$ 11,584	$ 16,886	$ 10,392

	December 31,				
	2009	**2008**	**2007**	**2006**	**2005**
Financial Position:					
Cash, cash equivalents, and short-term investments	$ 79,670	$ 82,523	$ 95,566	$ 91,001	$ 77,620
Working capital	89,435	90,936	105,620	95,979	90,670
Deferred tax assets			22,327	23,522	26,708
Total assets	126,991	131,918	167,353	156,565	130,747
Long-term debt, excluding current portion	7,792	8,301	8,818	10,031	884
Accumulated deficit	(135,088)	(127,275)	(96,000)	(98,414)	(103,682)
Stockholders equity	103,807	108,325	140,055	129,504	118,919

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 9 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.

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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. We undertake no duty to update any forward-looking statements made herein after the date of this Annual Report.

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 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 is sold in the OTC or consumer retail market in North America, Europe, Central and South America, 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. 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 marketplace.

We rely heavily on distributors to purchase and resell many of our products. For example, Genomma Labs has exclusive rights to our wart removal product in the OTC market in Mexico, Argentina, Brazil, and various other Central and South American countries and SSL has similar rights to our wart removal product in the OTC footcare market in Europe, Australia and New Zealand. 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 also use distributors to sell our Histofreezer® product into the domestic and international physician office markets. We expect to enter into additional distribution agreements for existing and future products 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.

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*® HIV-1/2 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 or if the related products supplied by third parties become unavailable, the time required to develop replacements and obtain the required FDA approvals could disrupt our ability to sell the affected products.

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Competitive and Economic Outlook

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

The current economic downturn, including disruptions in the capital and credit markets, may continue for the foreseeable future 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 or funding available to 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. In addition, demand for our products by consumers may also be adversely affected by the economic downturn.

Current Financial Results

During the year ended December 31, 2009, our total revenues were $77.0 million, which represents an 8% increase from the same period in 2008. Our net loss for the year ended December 31, 2009 was $7.8 million or $0.17 per share, compared to a net loss of $31.3 million or $0.67 per share for the year ended December 31, 2008. Our net loss in 2009 included a $3.0 million pre-tax charge for the impairment of patents and product rights and a $1.5 million pre-tax charge for the settlement of a patent infringement lawsuit. Our net loss in 2008 included a $4.9 million pre-tax payment received in connection with the settlement of a patent infringement lawsuit and an income tax charge of $26.0 million recorded to establish a full valuation allowance against our net deferred tax asset.

Cash flow used in operating activities for the year ended December 31, 2009 was $293,000, an improvement of $2.2 million compared to the $2.5 million used in operating activities for the year ended December 31, 2008. As of December 31, 2009, we had $79.7 million in cash, cash equivalents and short-term investments, compared to $82.5 million at December 31, 2008.

2009 and More Recent Developments

OraQuick® HCV Test

During the fourth quarter of 2009, we received approval to affix the CE mark to our OraQuick® rapid HCV test. CE mark approval is the first step required in order to allow us to sell our HCV test in the 27 countries that make up the European Union. Our HCV test is the first and only rapid HCV test bearing a CE mark that can be used with oral fluid. We are currently pursuing certain additional registrations in specific European countries where required.

During the fourth quarter of 2008, we filed a PMA with the FDA for our OraQuick® HCV test for use in the U.S. professional market. The application sought approval for use of the product with multiple specimen types, including venous whole blood, fingerstick whole blood and oral fluid. The clinical study data submitted in the PMA showed a high degree of correlation to a comparator assay conducted at a central laboratory.

During its review of the PMA, the FDA indicated that our clinical data could potentially have been affected by bias because the same operators performed the test and interpreted the results on multiple specimen types derived from the same patient. The FDA had previously reviewed and concurred with our original clinical trial protocol. As a result, in the second quarter of 2009, the FDA concluded that additional clinical testing would be required to obtain approval of the PMA for a venous whole blood claim, and that a new clinical study would be required for approval of claims for oral fluid and other sample types. Although we believe the clinical data

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originally submitted to the FDA is sufficient to support approval of our PMA, we agreed to conduct the additional clinical testing and study mandated by the FDA in order to obtain approved claims for oral fluid, venous whole blood, and fingerstick whole blood.

In December 2009, we filed a PMA amendment with the FDA which contains the additional clinical data requested for use of the test in detecting HCV antibodies in venous whole blood samples. We continue to work on the additional clinical study required to obtain approval of the HCV test for use with oral fluid and fingerstick whole blood. We expect this clinical study to be completed during the first half of 2010.

OraQuick® HIV OTC Test

In August 2008, we submitted the results of our observed use study to the FDA as part of our efforts to obtain approval for an OraQuick® rapid HIV OTC test. The observed use study was designed to assess an individual s ability to interact with the product packaging, comprehend the instructions for use, take the test and interpret the results while a trained professional observed those activities. The observed use study was stopped after testing was completed for the first 1,000 subjects, because data from the study met the success criteria initially established in the study protocol for this phase of the trials.

During the second quarter of 2009, the FDA reviewed the data from the observed use study at a meeting of its senior management. Following this meeting, the FDA contacted us and indicated that both the results of the observed use study and our remaining clinical activities should also be reviewed and approved by the Blood Products Advisory Committee (BPAC), an advisory committee to the FDA, before proceeding. In November 2009, we attended a BPAC meeting in which we reviewed the results of our ongoing clinical studies related to our HIV OTC test. We received feedback from the BPAC which will be used to continue our efforts to seek FDA approval of our HIV OTC test.

OraQuick® HIV Manufacturing

During the second quarter of 2009, we experienced difficulty manufacturing a component for our OraQuick® rapid HIV-1/2 antibody test in accordance with our internal quality requirements. A multi-functional team was organized and worked aggressively with the assistance of outside consultants to resolve this manufacturing issue. As the second quarter progressed, this manufacturing issue remained unresolved and our inventory levels became depleted. As a result, we were required to allocate available product across our customer base and this resulted in a $2.2 million order backlog at June 30, 2009. We provided some customers with free OraSure® oral fluid collection devices in order to help them meet their HIV testing needs during this period.

Early in the third quarter of 2009, we identified the root cause of the manufacturing issue and implemented corrective action. We resumed full-scale production of our OraQuick® rapid HIV-1/2 antibody test, fulfilled the $2.2 million backlog, and replenished our finished goods inventories for this product.

Availability of HIV-1 Antigen and Screening Tests

In past years, bioMérieux, Inc. (BMX) manufactured and sold the only oral fluid HIV-1 enzyme immunoassay screening test (EIA) 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 and our agreement with BMX for the supply of HIV-1 antigen terminated on December 31, 2007. As a result, we purchased a two-year supply of the antigen from BMX as permitted under the agreement.

During the third quarter of 2009, we made arrangements to purchase additional HIV-1 antigen from a third party subcontractor that historically had been used by BMX to manufacture this product for resale to us by BMX. We believe this subcontractor can supply our future requirements for the HIV-1 antigen.

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As previously disclosed, we had initially planned to conduct clinical trials and seek FDA approval of an alternate HIV-1 EIA for use in testing oral fluid samples collected with our OraSure® collection device. However, in mid-2009 we learned that, Avioq Inc., who had acquired a license from BMX to produce a new HIV-1 EIA test originally developed by BMX, obtained FDA approval of this product for use with our OraSure® device. As a result, we no longer intend to conduct our own clinical trials or seek FDA approval for an alternate HIV-1 EIA, as originally planned.

Substance Abuse Testing

In January 2010, we signed an agreement with Roche Diagnostics for the worldwide commercialization of homogeneous, fully-automated oral fluid drugs of abuse assays with our Intercept® oral specimen collection device. The oral fluid assays are being jointly developed under a development agreement previously executed with Roche. The oral fluid assays are designed to run on various clinical chemistry automated analyzers, which is intended to allow oral fluid samples to be processed with the same efficiency currently provided by fully-automated, urine-based drug tests. The commercialization agreement is structured to take advantage of each party s respective distribution strengths, including our established market presence with oral fluid testing and Roche s established base of analyzers and broad marketing capabilities.

Settlement of Patent Infringement Lawsuit

In November 2009, we settled a patent infringement lawsuit filed against us by Inverness Medical and Church & Dwight that primarily targeted our OraQuick *ADVANCE*® HIV test. Pursuant to the terms of the settlement, we paid Inverness $3.0 million. We recorded $1.5 million of the $3.0 million payment as litigation settlement expense in our statement of operations. The remaining $1.5 million was recorded as prepaid royalties and will be expensed to cost of goods sold based on OraQuick® revenues through December 31, 2012. For additional information regarding the terms of this settlement, please see the Section entitled, Legal Proceedings, in this Annual Report.

Termination of Royalty Agreement

In July 2009, we entered into a termination and release agreement with the third party from whom we had previously purchased certain patents, trademarks, copyrights and technology related to our cryosurgical systems product line. Pursuant to this agreement, we made a one-time payment of $643,050 in full consideration of the termination of the original asset purchase agreement we executed with this third party in June 1998, and its related royalty obligations, which would have extended until December 2011. We recorded this payment, net of the royalties previously accrued, as prepaid royalties, which will be expensed in relation to cryosurgical revenues through December 31, 2011.

Termination of License and Supply Agreement

In January 2010, we entered into an agreement with the supplier of certain HIV peptides used in the manufacture of our OraQuick HIV 1/2 test. This agreement was executed in connection with the supplier s bankruptcy and terminated our obligation to exclusively purchase peptides from the supplier and pay royalties on worldwide sales of our OraQuick® HIV tests. Pursuant to this agreement, we made a one-time payment of $2.1 million to the supplier in full consideration of the termination of the original agreement with this supplier and satisfaction of our royalty and purchase obligations. We also received a fully paid-up worldwide, non-exclusive license to the supplier s patent rights related to the peptides. We recorded the payment, net of royalties previously accrued, as prepaid royalties, which will be expensed in relation to OraQuick® sales through June 30, 2011.

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Results of Operations

Year Ended December 31, 2009 Compared to December 31, 2008

Total revenues increased 8% to $77.0 million in 2009 from $71.1 million in 2008. Increased sales in the infectious disease, cryosurgical systems and insurance risk assessment markets were partially offset by declines in sales of our substance abuse testing products and a reduction in licensing and product development revenues. Revenues derived from products sold to customers outside the United States were $14.8 million and $13.7 million or 19% of total revenues for the years ended December 31, 2009 and 2008, respectively. The majority of our international sales are denominated in U.S. dollars. As such, the impact of foreign currencies was not 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	2009	2008	Change	2009	2008
Infectious disease testing	$ 46,098	$ 38,096	21%	60%	54%
Substance abuse testing	12,026	14,006	(14)	16	20
Cryosurgical systems	10,888	10,655	2	14	15
Insurance risk assessment	6,157	6,085	1	8	8
Product revenues	75,169	68,842	9	98	97
Licensing and product development	1,857	2,262	(18)	2	3
Total revenues	$ 77,026	$ 71,104	8%	100%	100%

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 21% to $46.1 million in 2009, primarily as a result of our switch to a direct sales model for the U.S. hospital market which allowed us to realize a higher average selling price for these customers. Higher volumes in the U.S. public health market and higher international sales also contributed to the increase. OraQuick® and OraSure® sales during 2009 totaled $43.8 million and $2.3 million, respectively, as compared to $35.3 million and $2.8 million in 2008, respectively.

The table below shows a breakdown of our total OraQuick® revenues (in thousands, except %) during 2009 and 2008.

	Year ended December 31,		
Customers	2009	2008	% Change
Direct to U.S. Public Health	$ 28,308	$ 25,450	11%
Hospital Market	10,998	6,625	66
International	4,511	3,234	39
Total OraQuick® revenues	$ 43,817	$ 35,309	24%

During 2009, OraQuick® sales to the U.S. public health market increased by 11% as compared to 2008. This increase was caused by higher purchase volumes due in part to the fact that a number of our hospital customers are procuring OraQuick® product through public health channels in lieu of purchasing the test directly from us. We believe this pattern is the result of increased public health support of testing initiatives by hospitals across the country. As a result, sales to the hospital market are being redirected to the U.S. public health market, thereby increasing revenues within that customer category. We expect this trend to continue in 2010.

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Sales into the hospital market increased 66% to $11.0 million during 2009, compared to $6.6 million in 2008. In January 2009, we switched to a direct sales model for U.S. hospitals as a result of the termination of our distribution agreement with Abbott Laboratories at the end of 2008. The increase in revenues in the hospital market is primarily due to a higher average selling price realized under our direct sales model.

International sales of our OraQuick® test increased to $4.5 million in 2009 from $3.2 million in 2008. This 39% increase reflects higher sales into Latin America, Europe and Asia. Sales into Africa remained flat at $2.3 million in both 2009 and 2008.

We continue to see evidence that sales of our OraQuick *ADVANCE*® HIV test are negatively impacting sales of our OraSure® oral fluid collection device in the infectious disease testing market in the U.S. During 2009, sales of OraSure® declined $506,000 from $2.8 million in 2008 to $2.3 million in 2009. Some customers who have purchased our OraSure® device for laboratory HIV-1 testing in the past are 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 ultimate impact of such ongoing change in purchasing patterns, we believe OraSure® sales will continue to decrease in 2010.

Substance Abuse Testing Market

Sales to the substance abuse testing market decreased 14% in 2009 primarily as a result of lower sales of our Intercept® collection devices and oral fluid assays. The table below shows a breakdown of our total Intercept® revenues (in thousands, except %) generated in each market during 2009 and 2008.

	Year ended December 31,		%
Market	**2009**	**2008**	**Change**
Workplace testing	$ 3,895	$ 4,750	(18)%
Criminal justice	2,593	2,663	(3)
International	2,003	2,168	(8)
Direct	917	1,204	(24)
Total Intercept® revenues	$ 9,408	$ 10,785	(13)%

Our workplace testing business decreased 18% from $4.8 million in 2008 to $3.9 million in 2009. Pre-employment drug screening represents over 50% of our workplace testing business and the current recession in the domestic economy and high unemployment levels have had a significant negative impact on this part of our business, as well as on our direct sales to small and mid-size companies. Revenues in our workplace testing business are not expected to increase until employment rates begin to improve.

Sales to the criminal justice market decreased 3% from $2.7 million in 2008 to $2.6 million in 2009, primarily as a result of the availability of competing lower priced drug testing products. International sales of Intercept® devices and assays decreased 8% to $2.0 million in 2009 from $2.2 million in 2008, also as a result of competition from lower priced drug testing products outside of the U.S.

We do not expect renewed growth in Intercept® sales until employment conditions in the U.S. recover and overall economic conditions improve. In addition, the microplate oral fluid drug assays, which are sold for use with the Intercept® collection device, have come under increasing competitive pressure from home-brew assays developed internally by our laboratory customers and 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. Pursuant to a development agreement with Roche Diagnostics, homogenous fully-automated oral fluid

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drugs of abuse assays are being developed for use with our Intercept® collection device. The assays use Roche s technology and 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. We have also entered into a commercialization agreement with Roche pursuant to which a drug testing system comprised of our Intercept® device and the newly developed homogenous assays will be marketed and sold on a worldwide basis.

Cryosurgical Systems Market

Sales of our products in the cryosurgical systems market (which includes both the physicians office and OTC markets) increased 2% to $10.9 million in 2009 from $10.7 million in 2008. This increase was primarily caused by higher sales to our Latin American OTC distributor, Genomma, partially offset by lower sales to our European OTC distributor, SSL, and decreased Histofreezer® sales in international professional markets.

The table below shows a breakdown of our total cryosurgery revenues (in thousands, except %) generated in each market during 2009 and 2008.

	Year ended December 31,		%
Market	**2009**	**2008**	**Change**
Professional domestic	$ 3,902	$ 3,911	0%
Professional international	1,919	2,529	(24)
OTC domestic	144		N/A
OTC international	4,923	4,215	17
Total cryosurgical systems revenues	$ 10,888	$ 10,655	2%

Sales to Genomma for the year ended December 31, 2009 increased to $2.3 million, compared to $401,000 during the year ended December 31, 2008. During 2008, Genomma reduced its purchases in response to an increase in product returns from retailers in Mexico who overstocked during the winter months of 2007. Throughout 2008 and early in 2009, Genomma worked through its excess inventory levels and resumed purchasing product during the second quarter of 2009. In addition, Genomma launched our cryosurgical wart removal product in Brazil and we completed our first shipment to Brazil in September 2009. We expect sales to Genomma to increase during 2010.

The increased sales to Latin America were partially offset by a decrease in sales to SSL. Sales to SSL were $2.6 million and $3.8 million in 2009 and 2008, respectively. The decrease in revenues from SSL resulted from a reduction in the transfer price paid by SSL and a decrease in units purchased as a result of increased competition in the wart removal market in Europe. We expect this increased competition to continue and sales to SSL to decline in 2010.

During the first quarter of 2009, we reentered the U.S. OTC cryosurgery marketplace through the launch of our own cryosurgical wart removal product under our new national brand, Freeze n Clear Skin Clinic . Commencing in February 2009, we shipped product to one major retailer and we plan to expand distribution to other retailers in the future. During the year ended December 31, 2009, we recorded $1.2 million in revenues from Freeze n Clear Skin Clinic . However, these revenues were offset by $1.0 million in promotional rebates, advertising, slotting and return allowances provided to the retail trade, which we netted against the revenues in accordance with U.S. generally accepted accounting principles. We believe our participation in these promotional and advertising programs, which were executed and controlled by the retail trade, was necessary in order to increase initial awareness and implement the launch of our product within the OTC market. It is not possible to predict at this time how successful our new brand will perform in the domestic OTC marketplace or whether we will need to participate in future retail promotional and advertising programs at comparable levels.

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Sales of our Histofreezer® product to physicians offices in the United States were $3.9 million in both 2009 and 2008. Sales of Histofreezer® in the professional international market decreased 24% to $1.9 million in 2009, as compared to $2.5 million in 2008. 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 and early 2009, 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. Although we tried to aggressively address this diversion issue, we believe it negatively impacted sales in the domestic physicians office market during 2009 and may continue to do so until the supply of diverted product is exhausted. The decline in Histofreezer® revenues in the professional international market in 2009 is largely due to a reduction of sales to distributors that we believe were diverting product to the U.S. market.

In early 2010, we signed agreements with two manufacturer s sales representative organizations to support sales of our Histofreezer® product in the U.S. Under these arrangements, over 40 additional sale representatives will be working with our physicians office distributors throughout the United States. The addition of these sale representatives is expected to contribute to domestic Histofreezer® sales growth in 2010.

We see evidence that sales of 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 domestic professional market. Furthermore, in the European professional marketplace, there is increasing pressure to change or exclude healthcare reimbursement for certain treatment types, including treatments for common warts. The reduction in or elimination of reimbursement for wart treatments could negatively affect international sales of our Histofreezer® product. However, it is not possible at this time to estimate the likelihood or financial impact of these changes.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market increased 1% from $6.1 million in 2008 to $6.2 million in 2009, due to variations in laboratory ordering patterns and an increase in purchases of lower face value insurance policies for which insurers use our oral fluid screening device. Overall, we expect our 2010 revenues in this market will remain at levels comparable to those attained in 2009.

Licensing and Product Development

Licensing and product development revenues decreased to $1.9 million in 2009, from $2.3 million in 2008. In January 2008, we entered into a license and settlement agreement with Merck & Co. Inc. (Merck , formerly called Schering-Plough) in which Merck agreed to pay us royalties on U.S. sales of their Freeze Away™ OTC cryosurgical wart removal product. Licensing revenues represent these royalties from Merck in 2009 and 2008.

We expect licensing and product development revenues to increase in 2010, primarily due to the anticipated achievement of certain regulatory milestones under our international collaboration agreement with Merck for the development and promotion of a rapid HCV oral fluid test. Payments received from Merck upon reaching the defined milestones will be recorded as licensing and product development revenues.

Gross Margin

The Company s gross margin was 61% in 2009, compared to 58% in 2008. Gross margin was favorably impacted during 2009 primarily by our switch in January 2009 to a direct sales model for our OraQuick *ADVANCE*® HIV-1/2 test in the U.S. hospital market. Also contributing to the increase was an improvement in manufacturing efficiency in 2009.

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Operating Expenses

Research and development expenses decreased 34% to $13.4 million in 2009, from $20.3 million in 2008, primarily as a result of decreased clinical trial spending for our OraQuick® HIV OTC test and OraQuick® HCV test. The majority of the initial product development and clinical costs associated with the OraQuick® HCV device and related PMA submission was incurred during 2008. A decrease in staffing costs resulting from organizational changes made during the fourth quarter of 2008 also contributed to the current period decrease. Expenses in 2008 also included a $1.0 million patent license milestone payment required as a result of our filing of a PMA submission with the FDA for our OraQuick® HCV device, while 2009 expenses did not include any such payment. We expect our research and development costs will increase in 2010 as we continue clinical trials for the HIV OTC test and OraQuick® HCV product and develop other new products.

Sales and marketing expenses increased 1% to $21.2 million in 2009 from $20.9 million in 2008. Staffing costs increased in 2009 as a result of hiring a new sales force in support of our direct sales model for the U.S. hospital market, as well as hiring, compensation, and relocation costs associated with new senior-level sales and marketing personnel. Market research and consulting expenses related to our cryosurgical products also increased during 2009.

These increases were offset by a decrease in reimbursement of distributor advertising expenses. We expect 2010 sales and marketing expenses to increase from 2009 levels as we incur full-year staffing expenses for the new senior-level sales and marketing personnel hired in 2009 and we launch our OraQuick® HCV test in the European market.

General and administrative expenses increased 3% to $16.9 million in 2009 from $16.3 million in 2008. This increase was primarily attributable to increased staffing costs as well as legal expenses associated with the patent infringement lawsuit related to our OraQuick *ADVANCE*® HIV test filed against us by Inverness Medical and Church & Dwight, which was settled in the fourth quarter of 2009**.** We expect 2010 general and administrative expenses to remain at approximately 2009 levels as decreases in legal expenses are expected to be largely offset by increased consulting costs.

In November 2009, we settled the patent infringement lawsuit filed by Inverness and Church & Dwight. Pursuant to the settlement we paid Inverness $3.0 million. We recorded $1.5 million of the $3.0 million payment as litigation settlement expense in our Statement of Operations. The remaining $1.5 million was recorded as prepaid royalties and will be expensed in cost of goods sold in relation to OraQuick® revenues generated through December 31, 2012.

In the first quarter of 2008, we received a payment of $4.9 million as a result of the settlement of patent infringement litigation we had previously filed against Merck. In response to a comment letter received from the SEC dated August 31, 2009, we reclassified our patent litigation settlement of $4.9 million received in January 2008 from other income in our Statement of Operations to a reduction of operating expenses.

During the second quarter of 2009, we recorded an impairment charge of $3.0 million related to license payments for certain HCV patents, which we previously capitalized. Management s intent in capitalizing these payments was to utilize this license in certain developing countries for the marketing and sale of an existing rapid HCV test supplied by a third party manufacturer. However, we were unable to penetrate this international marketplace with the third-party s rapid HCV test. Furthermore, given the impact of the current global recession and the deteriorating status of certain third-world economies, we no longer believed that we would be successful in selling a third-party s rapid HCV test in the foreseeable future. Accordingly, we recorded a non-cash impairment charge for the remaining unamortized book value of the patent and product rights in the second quarter of 2009.

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Other Income/Expense

Interest expense increased to $361,000 in 2009 from $346,000 in 2008. Interest income decreased to $738,000 in 2009 from $3.1 million in 2008 primarily as a result of lower yields earned on our investment portfolio, lower investment balances, and an overall conservative, shorter-term investment approach.

Income Taxes

In November 2009, *The Worker, Homeownership, and Business Assistance Act of 2009* was enacted. This new law extends the carryback period for a net operating loss (NOL) from two years up to a maximum of five years. The carryback of the NOL can be applied to both regular tax NOLs and alternative minimum tax (AMT) NOLs. The new law also eliminates the 90% limitation on the use of any AMT NOLs. As a result of the elimination of the 90% limitations, we have elected to carryback our 2008 AMT NOL to our 2007, 2006, and 2005 tax years and apply for a refund of the AMT taxes paid for those years. As such, in the fourth quarter of 2009, we recorded a $632,000 federal tax benefit associated with this AMT NOL carryback. Offsetting this benefit was a nominal amount of state income taxes.

During 2008, we 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, which would result in a net cumulative three-year loss, we determined that it was more likely than not that we would not realize the benefits associated with our net deferred tax assets in the immediate future. Accordingly, in accordance with Financial Accounting Standards Board (FASB) guidance, 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.

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 was not 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%

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Infectious Disease Testing Market

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.

	Year ended December 31,		
Customers	**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.

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.

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.

During 2008, sales of our OraSure® collection device declined $348,000 from $3.1 million in 2007 to $2.8 million in 2008.

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Substance Abuse Testing Market

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.

	Year ended December 31,		
Market	**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)%

Cryosurgical Systems Market

Sales to 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.

	Year ended December 31,		
Market	**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 Brands, 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.

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 2008 was due to lower than expected outsales by SSL in key markets outside 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.

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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.

Insurance Risk Assessment Market

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. At the end of 2007, BMX discontinued the distribution of our Western blot HIV-1 confirmatory test and, as a result, in 2008 we began and are now selling this product directly to our laboratory customers.

Licensing and Product Development

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 Merck (formerly, Schering-Plough) in which Merck agreed to pay us royalties on U.S. sales of its Freeze Away™ OTC cryosurgical wart removal product. Pursuant to the terms of that agreement, during 2008, we recorded $2.3 million in royalty payments from Merck.

In December 2006, we entered into a collaboration agreement with Merck 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.

Gross Margin

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.

Operating Expenses

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 our 2008 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.

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.

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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.

As a result of the license and settlement agreement we entered into with Merck to resolve our patent infringement litigation, we received a payment of $4.9 million during the first quarter of 2008.

Other Income/Expense

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.

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. Although the majority of our international sales are denominated in United States dollars, as a result of the weakness of the 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.

Income Taxes

During 2008, we 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, which would result in a net cumulative three-year loss, we determined that it was more likely than not that we would not realize the benefits associated with our net deferred tax assets in the immediate future. Accordingly, in accordance with FASB accounting guidance, 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.

Liquidity and Capital Resources

	December 31,	
	2009	2008
	(In thousands)	
Cash and cash equivalents	$ 74,934	$ 39,565
Short-term investments	4,737	42,957
Working capital	89,435	90,936

Our cash, cash equivalents and short-term investments decreased $2.8 million at December 31, 2008 to $79.7 million at December 31, 2009, primarily as a result of using $293,000 to fund operations, $1.2 million for

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property and equipment purchases, $558,000 for debt repayments, $309,000 to buy back shares under our stock repurchase plan and $392,000 for the retirement of common stock to pay minimum tax withholding obligations on the vesting of restricted shares.

Net cash used in operating activities was $293,000 in 2009, resulting from our net loss of $7.8 million and a reduced provision for scrap and spoilage of $228,000 for the year, partially offset by non-cash charges of $3.0 million associated with the impairment of the HCV patent rights, stock-based compensation expense of $4.0 million and depreciation and amortization of $3.0 million. Also contributing to net cash used in operations were increases in accounts receivable and prepaid expenses of $2.1 million and $2.4 million, respectively. Accounts receivable increased primarily due to the change in 2009 to a direct sales model in the U.S. hospital market and an increase in hospital sales in the fourth quarter of 2009 when compared to 2008. Prepaid expenses include $1.5 million and $643,000 in prepaid royalties associated with payments made pursuant to our Inverness settlement and the termination and release agreement related to our cryosurgical product line, respectively. Other current assets increased as a result of the $632,000 in refundable AMT taxes recorded at the end of 2009. An additional use of cash during 2009 was related to a decrease in accounts payable of $501,000. Offsetting these uses of cash during the year was a $2.1 million decrease in inventory related to the utilization of a significant amount of cryosurgical raw material inventory for the Latin America OTC market and an increase in accrued expenses of $707,000, primarily related to increases in our year end management incentive bonus accrual and our royalty obligations.

Net cash provided by investing activities during 2009 was $36.9 million. Payments of $1.2 million for additions to property and equipment, were offset by $38.1 million of net proceeds from maturities and redemptions of short-term investments.

During the year ending December 31, 2010, we expect to invest approximately $6.0 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 $1.2 million for the year ended December 31, 2009 primarily as a result of $558,000 in loan principal repayments and $392,000 used for the withholding and retirement of common stock. During the year, we also used $309,000 to purchase 108,293 shares of common stock under our stock repurchase plan and we received $25,000 in cash proceeds from the exercise of stock options.

At December 31, 2009, we had in place a $10,000,000 credit advance with Comerica Bank (Comerica). Pursuant to the terms of the advance, principal, and interest fixed at 4.15%, are payable monthly through June 2011, at which time the remaining unpaid principal balance is payable. As of December 31, 2009, we had $8.3 million in outstanding borrowings under this advance.

On June 29, 2009, our $4,000,000 working capital line of credit with Comerica expired. We elected not to renew this working capital line of credit, since our facility advance matures in June 2011 and we had in excess of $79.0 million of cash, cash equivalents and short-term investments available as of June 30, 2009 to fund our ongoing operations and capital needs.

All borrowings from Comerica 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. The Comerica agreement 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, 2009. The agreement 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.

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At December 31, 2009, we had NOL carryforwards of $54.1 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 and short-term investments is expected to be more than sufficient to fund our operating and capital needs through at least the end of 2010. 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 cost of any future litigation, 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, the impact of the ongoing economic downturn and other factors.

Contractual Obligations and Commercial Commitments

The following sets forth our approximate aggregate obligations at December 31, 2009 for future payments under contracts and other contingent commitments, for the year 2010 and beyond:

		Payments due by December 31,					
Contractual Obligations	**Total**	**2010**	**2011**	**2012**	**2013**	**2014**	**Thereafter**
Long-term debt[1]	$ 8,301,440	$ 509,761	$ 7,791,679	$	$	$	$
Operating leases[2]	136,340	136,340					
Employment contracts[3]	1,788,500	1,526,000	262,500				
Purchase obligations[4]	3,578,021	2,223,346	1,354,675				
Minimum commitments under contracts[5]	4,291,667	500,000	500,000	500,000	500,000	500,000	1,791,667
Total contractual obligations	$ 18,095,968	$ 4,895,447	$ 9,908,854	$ 500,000	$ 500,000	$ 500,000	$ 1,791,667

1 Represents principal repayments required under notes payable to our lenders. See Note 8 to the financial statements included herein.
2 Represents payments required under our operating leases.
3 Represents salary payments payable under the terms of employment agreements executed by us with certain executives. See Note 11 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 11 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 11 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.

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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 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 and return rights granted to retail customers for our domestic cryosurgical wart removal product. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred. For our cryosurgical product sold in the retail market, a provision for estimated product returns is recorded as a reduction of revenue in the same period in which the revenue is recognized. In addition, revenue from retail sales is also recorded net of promotional, advertising, and slotting allowances granted to the retail trade.

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.

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 approximately $257,000 at December 31, 2009. While credit losses have been within our expectations and the allowance provided, these losses can vary from period to period. 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

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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 2009, 2008 and 2007, we wrote-off inventory which had a cost of $1.2 million, $1.6 million and $922,000, respectively, as a result of quality, 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 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 $20.8 million, or 16% of our total assets, at December 31, 2009. 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. An impairment of long-lived or intangible assets could occur whenever events or changes in circumstances indicate that the net book value of our assets may not be recoverable. Events which could trigger asset impairment include significant underperformance relative to 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. During the second quarter of 2009, we recorded an impairment charge of $3.0 million related to license payments for certain HCV patents, which were previously capitalized. Management s intent in capitalizing these payments was to utilize this license in certain developing countries for the marketing and sale of an existing rapid HCV test supplied by a third party manufacturer. However, we were unable to penetrate this international marketplace with the third-party s rapid HCV test. Furthermore, given the impact of the current global recession and the deteriorating status of certain third-world economies, we no longer believed that we would be successful in selling a third-party s rapid HCV test in the foreseeable future. We currently believe the future cash flows to be received from all remaining long-lived and intangible assets at December 31, 2009 will exceed their book value. We did not recognize any impairment losses for the years ended December 31, 2008 and 2007. 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, 2009, we had federal NOL carryforwards of $54.1 million. The deferred tax assets, before a full valuation allowance, associated with these NOLs and other temporary differences was $27.5 million at December 31, 2009. 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.

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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 pursuant to FASB accounting guidance. A cumulative loss in recent years is a 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, which would result in a net cumulative three-year loss, we determined that it was more likely than not that we would not realize the benefits associated with our net deferred tax asset in the immediate future. Accordingly, we recorded an income tax charge of $26.0 million in the fourth quarter of 2008 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 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.

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The majority of our assets is comprised of cash and cash equivalents and as a result we have little exposure to market risks associated with available-for-sale securities.

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

As of December 31, 2009, 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 were minimal compared to our total revenues for the year ended December 31, 2009. We do not expect the risk of foreign currency fluctuations to be material to us 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, 2009. Based on that evaluation, the Company s management, including such officers, concluded that as of December 31, 2009 the Company s disclosure controls and procedures were 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, 2009.

The effectiveness of our internal control over financial reporting as of December 31, 2009 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report, which is included below.

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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, 2009 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, 2009, 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, 2009, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

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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, 2009 and 2008, 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, 2009, and our report dated March 15, 2010 expressed an unqualified opinion on those financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania

March 15, 2010

ITEM 9B. Other Information.
Not applicable.

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PART III

We have omitted from Part III the information that will appear in our Definitive Proxy Statement for our 2010 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, 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.

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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.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 15, 2010.

ORASURE TECHNOLOGIES, INC.

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on March 15, 2010, by the following persons on behalf of the Registrant and in the capacities indicated.

SIGNATURE	TITLE
/s/ DOUGLAS A. MICHELS	President, Chief Executive Officer and Director
Douglas A. Michels	(Principal Executive Officer)
/s/ RONALD H. SPAIR	Chief Operating Officer, Chief Financial Officer and
Ronald H. Spair	Director (Principal Financial Officer)
/s/ MARK L. KUNA	Senior Vice President, Finance and Controller
Mark L. Kuna	(Principal Accounting Officer)
*MICHAEL CELANO	Director
Michael Celano	
*JACK GOLDSTEIN, PH.D.	Director
Jack Goldstein, Ph.D.	
*RONNY B. LANCASTER	Director
Ronny B. Lancaster	
*CHARLES W. PATRICK	Director
Charles W. Patrick	
*ROGER L. PRINGLE	Director
Roger L. Pringle	
*DOUGLAS G. WATSON	Director
Douglas G. Watson	

*By: /s/ JACK E. JERRETT
Jack E. Jerrett

(Attorney-in-Fact)

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INDEX TO FINANCIAL STATEMENTS

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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, 2009 and 2008, 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, 2009. 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, 2009 and 2008, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2009, 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, 2009, 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 15, 2010 expressed an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania

March 15, 2010

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ORASURE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31, 2009	2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 74,933,630	$ 39,565,218
Short-term investments	4,736,730	42,957,467
Accounts receivable, net of allowance for doubtful accounts of $256,572 and $163,100	13,693,340	11,571,048
Inventories	8,844,492	10,704,088
Prepaid expenses and other	2,609,518	1,418,171
Total current assets	104,817,710	106,215,992
PROPERTY AND EQUIPMENT, net	20,014,466	21,235,367
PATENTS AND PRODUCT RIGHTS, net	809,252	4,380,540
OTHER ASSETS	1,349,319	86,290
	$ 126,990,747	$ 131,918,189
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 509,761	$ 557,897
Accounts payable	3,370,604	3,925,662
Accrued expenses and other	11,502,802	10,795,955
Total current liabilities	15,383,167	15,279,514
LONG-TERM DEBT	7,791,679	8,301,440
OTHER LIABILITIES	8,911	11,985
COMMITMENTS AND CONTINGENCIES (Note 11)		
STOCKHOLDERS EQUITY:		
Preferred stock, par value $.000001, 25,000,000 shares authorized, none issued		
Common stock, par value $.000001, 120,000,000 shares authorized, 45,929,511 and 45,769,221 shares issued and outstanding	46	46
Additional paid-in capital	239,126,422	235,862,999
Accumulated other comprehensive loss	(230,992)	(262,442)
Accumulated deficit	(135,088,486)	(127,275,353)
Total stockholders equity	103,806,990	108,325,250
	$ 126,990,747	$ 131,918,189

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

	For the year ended December 31,		
	2009	**2008**	**2007**
REVENUES:			
Product	$ 75,168,959	$ 68,842,755	$ 80,576,622
Licensing and product development	1,857,267	2,261,712	2,109,254
	77,026,226	71,104,467	82,685,876
COST OF PRODUCTS SOLD	29,895,832	29,976,120	32,402,794
Gross profit	47,130,394	41,128,347	50,283,082
OPERATING EXPENSES:			
Research and development	13,371,358	20,255,451	14,136,019
Sales and marketing	21,224,125	20,916,718	20,061,685
General and administrative	16,847,920	16,286,907	17,304,615
Litigation settlement (recovery)	1,451,183	(4,883,714)	
Impairment of patent and product rights	3,028,375		
	55,922,961	52,575,362	51,502,319
Operating loss	(8,792,567)	(11,447,015)	(1,219,237)
INTEREST EXPENSE	(361,188)	(345,767)	(520,002)
INTEREST INCOME	737,892	3,080,950	4,709,771
OTHER INCOME			1,428,691
FOREIGN CURRENCY LOSS	(19,554)	(36,136)	(105,448)
Income (loss) before income taxes	(8,435,417)	(8,747,968)	4,293,775
INCOME TAX PROVISION (BENEFIT)	(622,284)	22,527,334	1,821,336
NET INCOME (LOSS)	$ (7,813,133)	$ (31,275,302)	$ 2,472,439
EARNINGS (LOSS) PER SHARE:			
BASIC	$ (0.17)	$ (0.67)	$ 0.05
DILUTED	$ (0.17)	$ (0.67)	$ 0.05
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:			
BASIC	45,877,843	46,549,739	46,325,338
DILUTED	45,877,843	46,549,739	46,878,143

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.

STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME (LOSS)

For the years ended December 31, 2009, 2008 and 2007

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at January 1, 2007	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 treasury shares	(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 treasury shares	(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
Common stock issued upon exercise of options	30,911		24,807			24,807
Vesting of restricted stock	370,457					
Purchase and retirement of treasury shares	(132,785)		(391,590)			(391,590)
Shares purchased and retired pursuant to the stock repurchase plan	(108,293)		(308,605)			(308,605)
Compensation cost for restricted stock			2,621,723			2,621,723
Compensation cost for stock option grants			1,317,088			1,317,088
Comprehensive loss:						
Net loss					(7,813,133)	(7,813,133)
Currency translation adjustment				34,513		34,513
Unrealized loss on marketable securities				(3,063)		(3,063)
Total comprehensive loss						(7,781,683)

Balance at December 31, 2009	45,929,511	$ 46	$ 239,126,422	$ (230,992)	$ (135,088,486)	$ 103,806,990

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.

STATEMENTS OF CASH FLOWS

	For the year ended December 31,		
	2009	**2008**	**2007**
OPERATING ACTIVITIES:			
Net income (loss)	$ (7,813,133)	$ (31,275,302)	$ 2,472,439
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)
Impairment of patent and product rights	3,028,375		
Deferred income taxes		22,305,250	1,313,839
Stock-based compensation	3,935,737	5,456,135	5,830,770
Depreciation and amortization	3,049,962	3,386,670	2,735,999
Acquired in-process technology		1,000,000	
Reserve for excess and obsolete inventories	(228,417)	(919,925)	922,433
Changes in assets and liabilities:			
Accounts receivable	(2,116,410)	(274,284)	(937,622)
Inventories	2,088,013	(374,420)	(4,797,609)
Prepaid expenses and other	(2,442,562)	1,070,168	(463,674)
Accounts payable	(501,177)	(1,686,143)	2,584,439
Accrued expenses and other liabilities	706,847	(1,148,491)	3,351,556
Net cash provided by (used in) operating activities	(292,765)	(2,460,342)	11,583,879
INVESTING ACTIVITIES:			
Purchase of property and equipment	(1,199,551)	(2,643,270)	(5,503,770)
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)
Purchase of short-term investments	(5,986,000)	(67,125,962)	(93,953,103)
Proceeds from maturities and redemptions of short-term investments	44,090,000	87,315,645	101,526,541
Net cash provided by (used in) investing activities	36,904,449	16,346,413	(364,389)
FINANCING ACTIVITIES:			
Repayments of long-term debt	(557,897)	(515,083)	(1,264,716)
Proceeds from issuance of common stock	24,807	92,517	3,100,037
Purchase and retirement of common stock	(308,605)	(5,121,108)	
Withholding and retirement of common stock	(391,590)	(995,367)	(785,908)
Net cash provided by (used in) financing activities	(1,233,285)	(6,539,041)	1,049,413
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(9,987)	(11,509)	10,973
NET INCREASE IN CASH AND CASH EQUIVALENTS	35,368,412	7,335,521	12,279,876
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	39,565,218	32,229,697	19,949,821
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 74,933,630	$ 39,565,218	$ 32,229,697

The accompanying notes are an integral part of these statements.

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ORASURE TECHNOLOGIES, INC.

NOTES TO THE FINANCIAL 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. They 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. The current weak 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, 2009 and 2008, 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. These securities are comprised of certificates of deposits, commercial paper, U.S. government and agency obligations, and corporate bonds, all

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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, 2009 in a continuous unrealized loss position for twelve or more months.

The following is a summary of our available-for-sale securities at December 31, 2009 and 2008:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2009				
Certificates of deposit	$ 3,986,000	$	$	$ 3,986,000
Commercial paper				
Government and agency bonds				
Corporate bonds	750,278	452		750,730
Total available-for-sale securities	$ 4,736,278	$ 452	$	$ 4,736,730
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
At December 31, 2009, maturities of our available-for-sale securities were as follows:				
Less than one year	$ 2,741,278	$ 452	$	$ 2,741,730
One to two years	1,995,000			1,995,000
Total available-for-sale securities	$ 4,736,278	$ 452	$	$ 4,736,730

Supplemental Cash Flow Information

In 2009, 2008 and 2007, we paid interest of $361,121, $409,902, and $663,127, respectively. In 2008 and 2007, we capitalized interest of $47,463 and $131,738, respectively.

In 2009, 2008 and 2007, we paid federal and state income taxes of $16,461, $381,950, and $500,529, respectively.

In 2009, 2008 and 2007, we recorded through the statement of operations an increase in our allowance for doubtful accounts of $93,472, $78,044 and $27,288, respectively. We had write-offs of $101,412 and $40,914 against the allowance for doubtful accounts in 2008 and 2007, respectively. We had no write-offs against the allowance for doubtful accounts in 2009.

In 2008 and 2007, we recorded accruals for purchases of property and equipment of $25,250 and $66,053, respectively. We had no accruals for purchases of property and equipment in 2009.

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.

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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 twenty to forty 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

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.

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 and return rights granted to retail customers for our domestic cryosurgical wart removal product.

Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred. For our cryosurgical product sold in the retail market, a provision for estimated product returns is recorded as a reduction of revenue in the same period in which the revenue is recognized. In addition, revenue from retail sales is also recorded net of promotional, advertising, and slotting allowances granted to the retail trade.

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.

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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	**2009**	**2008**	**2007**
Quest Diagnostics, Incorporated	9%	10%	11%
Abbott Laboratories		10	10

	Percentage of Accounts Receivable at December 31,	
	2009	**2008**
SSL International plc	3%	10%
National Aids Control Program	11	15

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. As a result, we had no sales to Abbott during the year ended December 31, 2009.

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 CROs based on purchase order estimates provided by the CROs. 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 2009, 2008, and 2007, we incurred $165,394, $893,279, and $1,261,356, respectively, in advertising expenses. Included in advertising expenses for 2008 and 2007 were $687,308 and $1,164,294, 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. We have elected to recognize compensation expense for stock option awards issued to employees and directors on a

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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.

We assess the realizability of our net deferred tax assets on a quarterly basis. 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 we reduce our net deferred tax assets by a valuation allowance. 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.

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

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,		
	2009	**2008**	**2007**
Net income (loss)	$ (7,813,133)	$ (31,275,302)	$ 2,472,439
Weighted average shares of common stock outstanding:			
Basic	45,877,843	46,549,739	46,325,338
Dilutive effect of stock options, warrants and restricted stock			552,805
Diluted	45,877,843	46,549,739	46,878,143
Earnings (loss) per share:			
Basic	$ (0.17)	$ (0.67)	$ 0.05
Diluted	$ (0.17)	$ (0.67)	$ 0.05

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For the years ended December 31, 2009, 2008, and 2007, outstanding common stock options and unvested restricted stock representing 6,033,966, 5,403,228, and 2,751,325 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 classify 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, 2009, 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.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to 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.

Reclassification

In response to a comment letter received from the SEC dated August 31, 2009, we reclassified our patent litigation settlement of $4.9 million received in January 2008 from Other Income in the Statement of Operations to a reduction of operating expenses.

Recent Accounting Pronouncements

In April 2009, the FASB added additional disclosures requirements under FASB ASC 825-10-65 Financial Instruments, to require disclosures about fair value of financial instruments in interim financial statements as well as in annual financial statements, effective for interim reporting periods ending after June 15, 2009. FASB ASC 825-10-65 also requires those disclosures in summarized financial information in interim financial statements. These additional disclosure requirements did not have a material impact on our financial statements.

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3. INVENTORIES:

	December 31, 2009	December 31, 2008
Raw materials	$ 4,911,570	$ 6,721,102
Work in process	334,452	390,259
Finished goods	3,598,470	3,592,727
	$ 8,844,492	$ 10,704,088

4. PROPERTY AND EQUIPMENT:

	December 31, 2009	December 31, 2008
Land	$ 1,117,788	$ 1,117,788
Buildings and improvements	15,730,546	15,571,279
Machinery and equipment	14,705,102	14,383,479
Computer equipment and software	3,982,769	3,791,012
Furniture and fixtures	1,469,785	1,455,965
Construction in progress	772,840	682,955
	37,778,830	37,002,478
Less accumulated depreciation	(17,764,364)	(15,767,111)
	$ 20,014,466	$ 21,235,367

Depreciation expense was $2,395,202, $2,278,257, and $1,687,126 for 2009, 2008, and 2007, respectively.

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

Patents product rights and licenses were as follows:

	December 31, 2009	December 31, 2008
HIV-related	$ 1,900,000	$ 1,900,000
HCV-related		4,500,000
Lateral flow-related	1,500,000	1,500,000
Cryosurgery-related	2,548,620	2,548,620
	5,948,620	10,448,620
Less accumulated amortization	(5,139,368)	(6,068,080)
	$ 809,252	$ 4,380,540

Amortization expense for 2009, 2008, and 2007 was $542,913, $898,931, and $1,048,873, respectively.

Amortization expense for each of the three succeeding fiscal years is estimated as $294,000 in both 2010 and 2011 and $221,252 in 2012.

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.

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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 was to provide for various alternatives of the licensed patents, one of which was the marketing and sale of an existing rapid HCV test supplied by a third party manufacturer in certain developing countries. Based on management s estimate of the cash flows to be received from future product sales in these international markets, we capitalized both the $1,500,000 and $3,000,000 payments. We were amortizing these amounts to cost of products sold on a straight-line basis over ten years, which represented management s estimate of the remaining useful life of the licensed patents.

However, we have been unable to penetrate the international marketplace with this third-party s rapid HCV test. In addition, given the impact of the current global recession and the deteriorating status of certain third-world economies, we no longer believe that we will be successful in selling a third-party s rapid HCV test in the foreseeable future. As a result, during the second quarter of 2009, we recorded an impairment charge of $3,028,375 which represented the remaining net book value of the HCV license, patents and product rights.

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 which was allocated 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.

6. PREPAID EXPENSES AND OTHER NONCURRENT ASSETS:

In July 2009, we entered into a termination and release agreement with the third party from whom we purchased certain patents, trademarks, copyrights and technology related to our Histofreezer® product line. Pursuant to this termination and release agreement, we made a one-time payment of $643,050 to this third party in full consideration of the termination of the original asset purchase agreement we executed with this third party in June 1998, and its related royalty obligations, which extended until December 2011. We recorded this

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payment, net of the royalties previously accrued, as prepaid royalties, which will be expensed in relation to Histofreezer® revenues through December 31, 2011.

In August 2008, a complaint was filed against the Company in the US District Court for the District of New Jersey by Inverness Medical Innovations, Inc., and Inverness Medical Switzerland GmbH (collectively, Inverness) and Church & Dwight Co. Inc., alleging that the Company s OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test infringed US Patent No. 6,485,982 (the 982 Patent). In November 2009, the Company entered into a settlement agreement with Inverness and Church & Dwight and the litigation was dismissed with prejudice. Under the settlement agreement, the Company made a $3,000,000 payment to Inverness. Inverness granted the Company nonexclusive, worldwide, royalty-bearing, non-transferable and nonsublicensable (sub)licenses to certain patent rights, including the 982 Patent. In addition, each party received limited supply and distribution rights to certain other products developed by the other party. We allocated the $3,000,000 payment based upon the relative fair values of the litigation settlement, of which, $1,451,183 was immediately expensed in our statement of operations and $1,548,817 was recorded as prepaid royalties and will be expensed to cost of goods sold, based on future OraQuick® revenues through December 31, 2012. As of December 31, 2009, $1,055,049 of prepaid royalties were included in other assets on the accompanying balance sheet with the balance in prepaid expenses.

7. ACCRUED EXPENSES AND OTHER:

	December 31,	
	2009	**2008**
Payroll and related benefits	$ 4,867,716	$ 3,513,124
Royalties	3,394,991	2,481,466
Deferred revenue	1,618,798	1,951,921
Professional fees	290,208	472,969
Advertising		365,313
Clinical research obligations	658,605	348,459
Other	672,484	1,662,703
	$ 11,502,802	$ 10,795,955

Deferred revenue includes customer prepayments of $1,501,598 and $1,824,721 at December 31, 2009 and 2008, respectively.

8. LONG-TERM DEBT:

	December 31,	
	2009	**2008**
Note payable to bank, 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.	$ 8,291,679	$ 8,791,679
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.	9,761	67,658
	8,301,440	8,859,337
Less current portion	(509,761)	(557,897)
	$ 7,791,679	$ 8,301,440

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At December 31, 2009, we had in place a $10,000,000 facility advance (the Credit Facility) with Comerica Bank (Comerica). Pursuant to the terms of the facility advance, principal, and interest fixed at 4.15%, are payable monthly through June 2011, at which time the remaining unpaid principal balance is payable. As of December 31, 2009, we had $8,291,679 in outstanding borrowings under this facility advance.

On June 29, 2009, our $4,000,000 working capital line of credit with Comerica expired. We elected not to renew this working capital line of credit, since our Credit Facility matures in June 2011 and we had in excess of $79.0 million of cash, cash equivalents and short-term investments available as of June 30, 2009 to fund our ongoing operation and capital needs.

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. 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, 2009. 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.

The maturities of our long-term debt as of December 31, 2009 are $509,761 in 2010 and $7,791,679 in 2011.

9. INCOME TAXES:

The components of the income tax provision (benefit) for the years ended December 31, 2009, 2008 and 2007 are as follows:

	2009	2008	2007
Current			
Federal	$ (631,688)	$ 9,590	$ 137,520
State	9,404	212,494	369,977
	(622,284)	222,084	507,497
Deferred			
Federal	(2,115,338)	(3,200,853)	1,417,925
State	(35,591)	(472,064)	(104,086)
	(2,150,929)	(3,672,917)	1,313,839
Change in valuation allowance	2,150,929	25,978,167	
		22,305,250	1,313,839
Total income tax provision (benefit)	$ (622,284)	$ 22,527,334	$ 1,821,336

In November 2009, The Worker, Homeownership, and Business Assistance Act of 2009 was enacted. This new law extended the carryback period for a net operating loss (NOL) from two years up to a maximum of five years. The carryback of the NOL can be applied to both regular tax NOLs and alternative minimum tax NOLs (AMT NOL). The new law also eliminates the 90% limitation on the use of any AMT NOLs. As a result of the elimination of the 90% limitations, we have elected to carryback our 2008 AMT NOL to our 2007, 2006, and 2005 tax years and apply for a refund of the AMT taxes paid for those years. As such, in the fourth quarter of 2009, we recorded a $632,000 federal and benefit associated with the AMT NOL carryback.

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A reconciliation of the statutory United States federal income tax rate to our effective tax rate for each of the years ended December 31, 2009, 2008, and 2007 is as follows:

	2009	2008	2007
Statutory U.S. federal income tax rate	34.0%	34.0%	34.0%
State income taxes, net of federal benefit	0.2	2.8	4.1
Nondeductible expenses and other	(3.1)	(3.4)	11.0
Research and development credits	1.8	6.1	(6.7)
Change in valuation allowance, federal and state	(25.5)	(297.0)	
Effective tax rate	7.4%	(257.5)%	42.4%

Deferred income taxes reflect the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting purposes and tax purposes, and net operating loss and tax credit carryforwards. Significant components of our total deferred tax asset as of December 31, 2009 and 2008 are as follows:

	2009	2008
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 18,740,789	$ 17,006,767
Inventory	1,047,607	1,424,523
Capitalized research and development costs	1,179,422	1,445,495
Accruals and reserves currently not deductible	1,185,360	657,761
Patent costs	2,078,303	1,193,265
Depreciation and amortization	(1,077,860)	(451,061)
Stock-based compensation	3,361,386	3,240,047
Research and development tax credit carryforward	980,410	827,689
Alternative minimum tax credit carryforwards		633,681
Net deferred tax asset	27,495,417	25,978,167
Valuation allowance	(27,495,417)	(25,978,167)
Net deferred tax asset	$	$

In assessing the realizability of our net deferred tax asset, we consider all relevant positive and negative evidence in determining whether 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.

Pursuant to FASB accounting guidance, a cumulative loss in recent years is a significant piece of negative evidence to be considered when evaluating the need for a valuation allowance and this evidence is difficult to overcome. Based upon our pre-tax loss in 2008, and our projection of a pre-tax loss in 2009, which would result in a net cumulative three-year loss and the volatility and uncertainty in the global economy, we determined that it was more likely than not that our net deferred tax assets would not be realized in the immediate future. Accordingly, we recorded an income tax charge of $25,978,167 in the fourth quarter of 2008 to establish a full valuation allowance against our net deferred tax asset. During 2009 we continued to reevaluate our valuation allowance position and believe that it is more likely than not that our deferred income tax asset will not be realized in the immediate future. As such, we maintained a full valuation allowance against our net deferred tax assets as of December 31, 2009.

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Our federal NOL carryforwards expire as follows:

Year of Expiration	NOLs
2011	$ 5,765,731
2017-2021	30,428,371
2022-2029	17,925,009
	$ 54,119,111

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 $2,044,929 and $2,184,370 as of December 31, 2009 and 2008, respectively, which if recognized, $2,019,203 and $2,151,345, respectively, would result in a reduction to our effective tax rate. Interest and penalties were immaterial at December 31, 2009 and 2008. 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 2009.

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

	2009	2008	2007
Balance at January 1	$ 2,184,370	$ 2,370,526	$ 2,370,300
Additions based on tax positions related to the current period	10,121	46,836	40,000
Additions for tax positions of prior periods		28,021	60,226
Reductions for tax positions of prior periods	(149,562)	(105,729)	(100,000)
Settlements		(155,284)	
Balance at December 31	$ 2,044,929	$ 2,184,370	$ 2,370,526

10. 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

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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.

As of December 31, 2009, 3,031,540 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	**2009**	**2008**	**2007**
Risk-free interest rate[1]	1.50%	2.50%	4.79%
Expected dividend yield			
Expected stock price volatility[2]	53%	46%	49%
Expected life of stock options (in years)[3]	4	4	4

(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, 2009, 2008 and 2007 was $1.22, $2.84 and $3.62, respectively.

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

	Year Ended December 31,		
	2009	**2008**	**2007**
Total compensation cost during the year	$ 1,314,014	$ 2,103,259	$ 2,953,307
Amounts capitalized into inventory during the year	(55,381)	(142,965)	(303,472)
Amounts recognized in cost of products sold for amounts previously capitalized	128,805	229,860	280,283
Amounts charged against income, before income tax benefit	$ 1,387,438	$ 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, 2009, 2008 and 2007 was $79,884, $31,037, and $1,284,319, respectively.

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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, 2007	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		
Granted	681,708	2.89		
Exercised	(30,911)	0.80		
Forfeited	(349,839)	6.61		
Balance, December 31, 2009	5,431,665	$ 7.09	5.68	$ 1,716,663
Vested or expected to vest as of December 31, 2009	5,336,288	$ 7.09	5.68	$ 1,686,519
Exercisable on December 31, 2009	4,484,524	$ 7.64	5.03	$ 261,421

As of December 31, 2009, there was $1,645,902 of unrecognized compensation expense related to unvested option awards that is expected to be recognized over a weighted-average period of 1.8 years.

Net cash proceeds from the exercise of stock options were $24,807, $92,517 and $3,100,037 for the years ended December 31, 2009, 2008 and 2007, 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, 2009:

	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
$2.55 $3.31	554,790	9.13	$ 2.82		$
$3.34 $5.60	817,871	9.09	4.86	685,692	5.03
$5.76 $6.96	837,280	2.70	6.50	836,577	6.50
$6.98 $7.77	672,965	3.53	7.52	671,298	7.52
$7.90 $8.18	477,692	7.47	8.05	334,275	8.05
$8.20	586,736	4.04	8.20	586,736	8.20
$8.28 $8.97	589,659	6.25	8.48	518,063	8.51
$9.04 $9.56	551,712	5.86	9.40	509,341	9.42
$9.78 $10.99	337,960	2.51	10.57	337,542	10.57
$12.69	5,000	1.68	12.69	5,000	12.69

5,431,665	5.68	$ 7.09	4,484,524	$ 7.64

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The 2000 Plan also permits us to grant restricted shares of our common stock to eligible employees, including officers, and our outside directors. Generally, these shares are nontransferable until vested and are subject to vesting requirements and/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 $2,621,723, $3,352,876 and $2,877,463 related to restricted shares was recognized during the years ended December 31, 2009, 2008 and 2007, 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, 2007	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
Granted	429,870	2.82
Vested	(370,457)	8.39
Forfeited	(71,024)	5.38
Issued and unvested, December 31, 2009	819,877	$ 5.44
Issued and expected to vest, December 31, 2009	819,877	$ 5.44

As of December 31, 2009, there was $2,531,778 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 2.6 years.

In connection with the vesting of restricted shares during the years ended December 31, 2009, 2008 and 2007, we purchased and immediately retired 132,785, 135,432 and 90,446 shares with aggregate values of $391,590, $995,367 and $785,908, respectively, in satisfaction of minimum tax withholding obligations.

Certain of our share-based payment arrangements are vested stock options held by certain nonemployee consultants and are accounted for as liability-classified awards. 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 2009 or 2008. As of December 31, 2009 and 2008, $8,911 and $11,985, respectively, was included in other liabilities for stock options to acquire 58,000 and 63,000 shares, respectively, of common stock which remain unexercised. For the years ended December 31, 2009, 2008 and 2007, the mark-to-market adjustment recorded as a reduction of compensation costs in the statements of operations was $3,074, $137,332 and $27,608, 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, 2009, we purchased and retired 108,293 shares of common stock at an average price of $2.85 per share. 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.

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11. 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:

2010	$ 500,000
2011	500,000
2012	500,000
2013	500,000
2014	500,000
Thereafter	1,791,667
	$ 4,291,667

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 were required under this agreement in 2009 or are required 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 $136,340 for 2010.

Rent expense for 2009, 2008 and 2007 was $181,124, $184,128, and $186,714, respectively.

Purchase Commitments

As of December 31, 2009, we had outstanding non-cancelable purchase commitments in the amount of $3,578,021 related to inventory, capital expenditures, and other goods or services.

Employment Agreements

Under terms of employment agreements with certain executive officers, extending through 2011, we are required to pay each individual a base salary for continuing employment with us. The agreements require payments of $1,526,000 and $262,500 in 2010 and 2011, 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.

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12. 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 $563,017, $579,592, and $477,390 in 2009, 2008, and 2007, respectively.

13. OTHER INCOME:

In January 2008, we entered into a settlement and license agreement with Merck to resolve our patent infringement litigation against Merck. Under the terms of the agreement, Merck was required to make a payment of $4,883,714 to us. This payment was received during the first quarter of 2008 and recorded as a reduction of operating expenses.

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.

14. GEOGRAPHIC 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):

	2009	2008	2007
United States	$ 62,209	$ 57,391	$ 64,587
Europe	6,592	7,746	9,618
Other regions	8,225	5,967	8,481
	$ 77,026	$ 71,104	$ 82,686

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15. QUARTERLY DATA (Unaudited):

The following tables summarize the quarterly results of operations for each of the quarters in 2009 and 2008. 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).

	2009 Results				
	Three months ended				Year ended
	March 31, 2009	June 30, 2009	September 30, 2009	December 31, 2009	December 31, 2009
Revenues	$ 17,256	$ 17,274	$ 21,609	$ 20,887	$ 77,026
Costs and expenses	19,116	22,579	19,834	24,289	85,818
Operating income (loss)	(1,860)	(5,305)	1,775	(3,402)	(8,792)
Other income (expense), net	242	145	24	(54)	357
Income (loss) before income taxes	(1,618)	(5,160)	1,799	(3,456)	(8,435)
Income tax benefit				(622)	(622)
Net income (loss)	$ (1,618)	$ (5,160)	$ 1,799	$ (2,834)	$ (7,813)
Earnings (loss) per share					
Basic	$ (0.04)	$ (0.11)	$ 0.04	$ (0.06)	$ (0.17)
Diluted	$ (0.04)	$ (0.11)	$ 0.04	$ (0.06)	$ (0.17)

	2008 Results				
	Three months ended				Year ended
	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2008	December 31, 2008
Revenues	$ 18,089	$ 18,946	$ 16,860	$ 17,209	$ 71,104
Costs and expenses	16,216	22,754	20,200	23,381	82,551
Operating income (loss)	1,873	(3,808)	(3,340)	(6,172)	(11,447)
Other income, net	861	744	587	507	2,699
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)

(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.

16. SUBSEQUENT EVENTS:

In January 2010, we entered into an agreement with the supplier of HIV peptides used in the manufacture of our OraQuick HIV 1/2 test. This agreement was executed in connection with the supplier s bankruptcy and terminated our obligation to exclusively purchase peptides from the supplier and pay royalties on worldwide sales of our OraQuick® tests. Pursuant to this agreement, we made a one-time payment of $2.1 million to the supplier in full consideration of the termination of the original agreement with this supplier and satisfaction of our royalty and purchase obligations. We also received a fully paid-up worldwide, non-exclusive license to the supplier s patent rights related to the peptides. We recorded the payment, net of royalties previously accrued, as prepaid royalties, which will be expensed in relation to OraQuick® sales through June 30, 2011.

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INDEX TO EXHIBITS

Exhibit Number	Exhibit
3.1.1	Certificate of Incorporation of OraSure Technologies, Inc. is incorporated by reference to Exhibit 3.1 to the Company s Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
3.1.2	Certificate of Amendment to Certificate of Incorporation dated May 23, 2000 is incorporated by reference to Exhibit 3.1.1 to the Company s Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
3.1.3	Certificate of Designation of Series A Preferred Stock of OraSure Technologies (filed as Exhibit A to the Rights Agreement referred to in Exhibit 4.1).
3.2	Bylaws of OraSure Technologies, amended and restated as of August 18, 2008, are incorporated by reference to Exhibit 3 to the Company s Current Report on Form 8-K filed August 22, 2008.
4.1	Rights Agreement, dated as of May 6, 2000, between OraSure Technologies, Inc. and ChaseMellon Shareholder Service, L.L.C. (now called BNY Mellon Shareowner Services), as Rights Agent, is incorporated by reference to Exhibit 4.2 to Amendment No. 1 to the Company s Registration Statement on Form S-4 (No. 333-39210), filed August 8, 2000.
10.1	Form of Indemnification Agreement (and list of parties to such agreement) is incorporated by reference to Exhibit 10.1 to Amendment No. 3 to the Company s Registration Statement on Form S-4 (No. 333-39210), filed August 30, 2000.*
10.2	Employment Agreement, dated as of June 22, 2004, between OraSure Technologies, Inc. and Douglas A. Michels, is incorporated by reference to Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.3	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Douglas A. Michels, is incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed December 19, 2008.*
10.4	Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and Ronald H. Spair, is incorporated by reference to Exhibit 10.4 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.5	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Ronald H. Spair, is incorporated by reference to Exhibit 10.3 to the Company s Current Report on Form 8-K filed December 19, 2008.*
10.6	Employment Agreement, dated September 23, 2005, between OraSure Technologies, Inc. and Stephen R. Lee, Ph.D., is incorporated herein by reference to Exhibit 99 to the Company s Current Report on Form 8-K filed September 28, 2005.*
10.7	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Stephen R. Lee, Ph.D., is incorporated by reference to Exhibit 10.5 to the Company s Current Report on Form 8-K filed December 19, 2008.*
10.8	Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and P. Michael Formica, is incorporated by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.9	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and P. Michael Formica, is incorporated by reference to Exhibit 10.4 to the Company s Current Report on Form 8-K filed December 19, 2008.*
10.10	Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and Jack E. Jerrett, is incorporated by reference to Exhibit 10.7 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*

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Exhibit Number	Exhibit
10.11	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Jack E. Jerrett, is incorporated by reference to Exhibit 10.6 to the Company s Current Report on Form 8-K filed December 19, 2008.*
10.12	Employment Agreement, dated as of October 2, 2006, between Mark L. Kuna and OraSure Technologies, Inc., is incorporated by reference to Exhibit 99.1 to the Company s Current Report on Form 8-K filed October 5, 2006.*
10.13	Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Mark L. Kuna, is incorporated by reference to Exhibit 10.7 to the Company s Current Report on Form 8-K filed December 19, 2008.*
10.14	Description of Non-employee Director Compensation Policy, as amended as of February 1, 2007, is incorporated by reference to Exhibit 10.9 to the Company s Annual Report on Form 10-K for the year ended December 31, 2007.*
10.15	Description of Non-employee Director Compensation Policy, as amended as of February 15, 2010.*
10.16	Amended and Restated Epitope, Inc. 1991 Stock Award Plan is incorporated by reference to Exhibit 10.9 to the Company s Annual Report on Form 10-K for the year ended December 31, 2002.*
10.17	OraSure Technologies, Inc. Employee Incentive and Non-Qualified Stock Option Plan, as amended and restated effective September 29, 2000, is incorporated by reference to Exhibit 10.12 to the Company s Annual Report on Form 10-K for the year ended December 31, 2000.*
10.18	OraSure Technologies, Inc. 2000 Stock Award Plan, as amended and restated effective as of May 13, 2008, is incorporated by reference to Exhibit 10 to the Company s Current Report on Form 8-K filed May 19, 2008.*
10.19	Form of Restricted Share Grant Agreement (Officers and Employees) is incorporated by reference to Exhibit 10.2.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
10.20	Form of Restricted Share Grant Agreement (Non-Employee Directors) is incorporated by reference to Exhibit 10.19 to the Company s Annual Report on Form 10-K for the year ended December 31, 2008.*
10.21	Incentive Stock Option General Terms and Conditions (Officers and Employees) is incorporated by reference to Exhibit 10.12 to the Company s Annual Report on Form 10-K for the year ended December 31, 2004.*
10.22	Nonqualified Stock Option Award General Terms and Conditions (Officers and Employees) is incorporated by reference to Exhibit 10.13 to the Company s Annual Report on Form 10-K for the year ended December 31, 2004.*
10.23	Nonqualified Stock Option Award General Terms and Conditions (Non-Employee Directors) is incorporated by reference to Exhibit 10.14 to the Company s Annual Report on Form 10-K for the year ended December 31, 2004.*
10.24	Description of the OraSure Technologies, Inc. 2010 Management Incentive Plan is incorporated by reference to Item 5.02 to the Company s Current Report on Form 8-K filed February 19 2010.*
10.25	Description of the OraSure Technologies, Inc. 2009 Self-Funding Management Incentive Plan is incorporated by reference to Item 5.02 to the Company s Current Report on Form 8-K filed February 24, 2009.*
10.26	Description of the OraSure Technologies, Inc. 2010 Stock Award Guidelines is incorporated by reference to Item 5.02 to the Company s Current Report on Form 8-K filed February 19, 2010.*

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Exhibit Number	Exhibit
10.27	Description of the OraSure Technologies, Inc. 2009 Stock Award Guidelines is incorporated by reference to Item 5.02 to the Company s Current Report on Form 8-K filed February 24, 2009.*
10.28	Loan and Security Agreement, dated as of September 10, 2002, between Comerica Bank California and OraSure Technologies, Inc., is incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
10.29	First Amendment to Loan and Security Agreement, dated as of May 23, 2003, between OraSure Technologies, Inc. and Comerica Bank California, is incorporated by reference to Exhibit 10.24 to the Company s Annual Report on Form 10-K for the year ended December 31, 2003.
10.30	Second Amendment to Loan and Security Agreement, dated as of September 12, 2003, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 99.1 to the Company s Current Report on Form 8-K, dated September 17, 2003.
10.31	Third Amendment to Loan and Security Agreement, dated as of April 21, 2005, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 10 to the Company s Current Report on Form 8-K filed April 27, 2005.
10.32	Fourth Amendment to Loan and Security Agreement, dated as of June 27, 2006, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 10 to the Company s Current Report on Form 8-K filed June 30, 2006.
10.33	Fifth Amendment to Loan and Security Agreement, dated as of June 28, 2007, between OraSure Technologies, Inc. and Comerica Bank, is incorporated by reference to Exhibit 10 to the Company s Current Report on Form 8-K filed July 5, 2007.
10.34	Settlement Agreement, effective as of November 17, 2009, by and among Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and OraSure Technologies, Inc.
10.35	License Agreement, effective as of November 17, 2009, by and among Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and OraSure Technologies, Inc.**
23	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
24	Powers of Attorney.
31.1	Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management contract or compensatory plan or arrangement.

** Portions of this exhibit were omitted pursuant to an application for confidential treatment and filed separately with the Securities and Exchange Commission.