ORASURE TECHNOLOGIES INC
Form 10-K
March 12, 2008
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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, 2007

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 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 definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer 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, 2007): $375,625,477

Indicate the number of shares outstanding of each of the Registrant s classes of common stock, as of March 5, 2008: 46,838,669 shares.

Documents Incorporated by Reference:

Portions of the Registrant s Definitive Proxy Statement for the 2008 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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

Forward-looking statements are not guarantees of future performance or results. Known and unknown factors could cause actual performance or results to be materially different from those expressed or implied in these statements. Factors that could affect our results are discussed more fully under Item 1A., entitled Risk Factors, and elsewhere in this Annual Report. Although forward-looking statements help to provide complete information about us, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this Annual Report and we undertake no duty to update these statements.

PART I

ITEM 1. Business.

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

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

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

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

Additional information about us can be found on our website. Our website address is www.orasure.com. We make available free of charge through a link provided at such website our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and our other filings with the Securities and

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Exchange Commission (SEC), as well as any amendments to those Reports and filings. These Reports and filings are made available as soon as reasonably practicable after they are filed or furnished to the SEC. Our Internet website and the information contained in or connected to that website are not intended to be incorporated by reference into this Annual Report.

Products

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

Product	Description	Regulatory Status	Commercial Status
OraQuick *ADVANCE*® HIV-1/2	A rapid, point-of-care test for antibodies to the Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2 and together with HIV-1, HIV-1/2) that can be visually read at the point of care in approximately 20 minutes.	Premarket approval (PMA) approved by the U.S. Food and Drug Administration (FDA) for use with oral fluid, finger-stick and venous whole blood, and plasma. CLIA (Clinical Laboratory Improvement Amendments of 1988) waived for use with oral fluid, finger-stick and venous whole blood.	Marketed
		CE mark approved.	Marketed
		Registered in Mexico, Brazil and Peru.	Marketed
OraQuick® HIV-1/2 OTC		Clinical trials initiated.	Pending
OraQuick® HCV	A rapid, point-of-care test for antibodies to the hepatitis C virus (HCV)	Clinical trials initiated.	Pending
OraSure®	Oral fluid collection device for the detection of antibodies to HIV-1 in an oral fluid sample in a laboratory setting.	PMA approved by FDA.	Marketed
		Also FDA 510(k) cleared for use in detecting cocaine and cotinine (an indicator of nicotine) in oral fluid.	Marketed
		CE marked and registered in the United Kingdom. Also registered in Mexico, Canada, Columbia, South Africa, Afghanistan, Argentina, Brazil and Trinidad.	Marketed
Intercept®	Oral fluid collection device, along with nine related immunoassays, for oral fluid drugs of abuse (DOA) testing in a laboratory setting.	Collection device FDA 510(k) cleared.	Marketed
MICRO-PLATE DOA Assays	Used to detect the following drugs in an oral fluid sample: marijuana, cocaine, opiates, amphetamines, methamphetamines, PCP, benzodiazepines, barbiturates and methadone.	Nine drug assays FDA 510(k) cleared.	Marketed
		Intercept® device CE marked and registered in the United Kingdom.	Marketed
		Various assays are CE marked and registered in the United Kingdom, Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Mexico, Netherlands, Portugal, Spain, Sweden, Korea, Canada, Afghanistan and Brazil.	

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Product	Description	Regulatory Status	Commercial Status
Homogeneous DOA Assays	Homogeneous fully-automated oral fluid DOA assays.	In development.	Pending
Cryosurgical Systems Professional	Cryosurgical system for the removal of warts and other benign skin lesions, marketed under the Histofreezer® tradename primarily to the physicians office market.	Nine indications FDA 510(k) cleared.	Marketed
		CE marked and registered in Europe, Venezuela, Thailand, New Zealand, Hong Kong, Brazil, Mexico, Canada and Afghanistan.	Marketed
Cryosurgical Systems OTC	Cryosurgical (freezing) system for the removal of common and plantar warts, sold in various OTC markets.	FDA 510(k) cleared. Registered in Canada.	
		CE marked and registered in several European countries under Scholl Freeze Spray name.	Marketed
		Registered in Mexico under POINTTS name.	Marketed
		Registrations applied for under POINTTS name in certain South and Central American countries and South Africa.	Pending
Cryosurgical Systems OTC Product Line Extensions	Cryosurgical system for an indication other than common warts or plantar warts.	FDA 510(k) filed.	Pending

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

OraQuick® Rapid Test Platform

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

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

On the international front, we have obtained a CE mark for our OraQuick *ADVANCE*® test so that we can sell this product in Europe and other countries accepting the CE mark for commercialization. We have

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distributors in place for the United Kingdom, Ireland and Spain and are pursuing distribution arrangements in several additional European countries. We are selling OraQuick® in Mexico and Africa and are completing registrations of our OraQuick® test in several countries in Latin America, Asia, the Middle East and Russia. We are aggressively seeking to expand our distribution network for this product throughout the world.

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. Demand for OraQuick *ADVANCE*® has grown since the launch of that product in late 2004.

OraSure®/Intercept® Collection Devices

Our OraSure® oral fluid collection device is used in conjunction with screening and confirmatory tests for HIV-1 antibodies and other analytes. This device consists of a small, treated cotton-fiber pad on a handle that is placed in a person s mouth for two to five minutes. The device collects oral mucosal transudate (OMT), a serum-derived fluid that contains higher concentrations of certain antibodies and analytes than saliva. As a result, OMT testing is a highly accurate method for detecting HIV-1 infection and other analytes.

We believe that oral fluid testing has several significant advantages over blood or urine-based systems for infectious disease testing, for both health care professionals and the individuals being tested. These advantages include eliminating the risk of needle-stick accidents, providing a non-invasive collection technique, requiring minimal training to administer, providing rapid and efficient collection in almost any setting, and reducing the cost of administration by a trained health care professional.

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

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

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

We have received premarket approval from the FDA to sell the OraSure® collection device for use with a laboratory-based EIA screening test for HIV-1 antibody detection. This EIA screening test was manufactured and sold by bioMerieux, Inc. (BMX). We have also received FDA 510(k) clearance for use of the OraSure® collection device with EIAs to test for cocaine and cotinine (a metabolite of nicotine) in oral fluid specimens primarily for insurance risk assessment purposes.

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

A collection device that is substantially similar to the OraSure® device is sold 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.

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

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

Cryosurgical Systems (Skin Lesion Removal Products)

The Histofreezer® cryosurgical removal system is a low-cost alternative to liquid nitrogen and other methods for removal of warts and other benign skin lesions by physicians. The Histofreezer® product mixes three environmentally friendly cryogenic gases in a small aerosol canister. When released, these gases are delivered to a specially designed foam bud, cooling the bud to a maximum of 50°C to 55°C. The frozen bud is then applied to the wart or lesion for 15 to 40 seconds (depending on the type of lesion) creating localized destruction of the target area by freezing. We have received 510(k) clearance for use of the Histofreezer® product to remove common warts and eight other types of benign skin lesions, and this product has been CE marked and registered for distribution in Canada, throughout Europe and in certain other foreign countries.

We have also received FDA 510(k) clearance to market and sell a cryosurgical product similar to the Histofreezer® product in the OTC or retail market for the removal of common and plantar warts only. This product was previously distributed in the United States and Canadian OTC markets under the name Freeze Off® by Prestige Brands Holdings, Inc. (Prestige), the owner of the Compound W® line of wart removal products. As a result of the decision in the arbitration proceedings with respect to Prestige s acquisition of the competing Wartner® cryosurgical product line, our agreement with Prestige terminated on December 31, 2007. We are currently evaluating alternative strategies for the distribution of this product in the United States and Canada.

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

Immunoassay Tests and Reagents

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

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

AUTO-LYTE® tests are sold in the form of bottles of liquid reagents. These reagents are run on commercially available laboratory-based automated analytical instruments, which are manufactured by a variety

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of third parties. AUTO-LYTE® is typically used in high volume, automated, commercial reference insurance laboratories to detect certain drugs or chemicals in urine. Test results are produced quickly, allowing for high throughput. In recent years, sales of our AUTO-LYTE® tests have been substantially reduced largely because of competition from cheaper home-brew tests used by our laboratory customers. As a result, we expect to eventually stop selling our AUTO-LYTE® tests.

Western blot HIV-1 Confirmatory Test

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

In March 2007, BMX notified us that it would not renew the agreement under which it supplies the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test or the agreement under which it distributed that product on an exclusive, world-wide basis. As a result, these agreements terminated on December 31, 2007 and we are now supplying this test directly to our laboratory customers. Pursuant to the terms of the antigen supply agreement, we have purchased an additional two-year supply of the antigen from BMX so that we can continue to manufacture and sell our oral fluid Western blot test. When this additional two-year supply is combined with our existing inventory of the HIV-1 antigen, we believe we have a sufficient supply of HIV-1 antigen to meet the demand for our Western blot test for at least the next three to four years.

Q.E.D.® Saliva Alcohol Test

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

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

Products Under Development

OraQuick® Platform

We believe that OraQuick® has significant potential as a point-of-care testing platform for clinics and other public health entities, hospitals, physicians offices and other markets. Because the OraQuick® platform is simple to use and can operate in a non-invasive manner with oral fluid, we believe it will be suitable for use by consumers without the assistance of a doctor or other medical professional. We also believe that OraQuick® provides a platform technology that can be modified for detection of a variety of infectious diseases in addition to HIV, such as viral hepatitis and certain sexually transmitted diseases.

We are currently devoting significant resources to obtaining FDA approval to sell our OraQuick® HIV-1/2 test in the United States OTC market. We have completed several laboratory-based operational and label comprehension studies and will continue to perform additional clinical studies in support of our application for FDA approval. We have developed an information and referral system and product packaging and labeling suitable for the OTC market, all of which will be key components of our clinical studies. We expect this clinical work to continue through 2008, and we intend to submit an application for FDA approval after our clinical studies are completed.

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We have developed a rapid test on the OraQuick® platform which can detect antibodies to the Hepatitis C virus, or HCV, in oral fluid, blood, serum and plasma samples. Clinical trials have commenced to obtain pre-market approval of this test from the FDA. These trials are expected be completed in 2008, after which we intend to file submissions for FDA approval and a CE mark and seek CLIA waiver for this product. We are also in negotiations to obtain rights to a rapid HCV test manufactured by a third party for distribution into certain developing foreign countries, which we intend to secure by mid 2008.

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

OraSure®/Intercept® Applications

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

In 2004, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued proposed regulations for oral fluid drug testing for federal workers. These proposed regulations have since been withdrawn. If and when reissued in final form, these regulations may require certain modifications to our Intercept® product in order to permit its use by federal workers. As a result, we are developing modifications to the Intercept® collection device that we anticipate will be required by these regulations or are otherwise likely to be desired by our customers.

We are also currently developing additional drugs of abuse assays for use with our Intercept® collection device. In October 2006, we signed a letter of intent with Roche Diagnostics to negotiate a joint development and commercialization agreement for homogeneous fully-automated oral fluid drugs of abuse assays that can be run on random access chemistry analyzers. The oral fluid assays are being developed for use with our Intercept® collection device and Roche s KIMS (kinetic information of microparticles in solution) technology. The assays will run on various automated analyzers to allow oral fluid samples to be processed with the same efficiency currently achieved with urine-based drug tests. Prototype assays for cocaine, opiates, methamphetamine and amphetamine have been developed and the development of assays for PCP and cannabinoids (marijuana) continues to progress.

OTC Cryosurgical Systems Products

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

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

Business Strategy

We have adopted a multi-part growth strategy, pursuant to which we intend to leverage our extensive diagnostic experience in order to maximize the available opportunities from our existing products and

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technologies, and supplement our existing product pipeline by accessing other technologies and products. We intend to follow a disciplined approach to maximize the value of our business for the benefit of our stockholders.

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

Extension of Base Businesses. We intend to maximize the sales potential of our existing product lines and technologies in the markets where they are currently sold, with a focus on expanding, where possible, the number of our oral fluid product offerings. Under this part of the strategy, we intend to fully capitalize on the potential market reach of our OraQuick®, OraSure®, Intercept®, Histofreezer® and OTC cryosurgical products by investing in our sales and marketing efforts where appropriate, making product improvements and enhancements, and optimizing our distribution channels. We also intend to expand the reach of our existing products and technology platforms into new markets and will focus specifically on expanding into international markets.

Infectious Disease Testing. We will pursue new products and technology platforms in the infectious disease, point-of-care testing business to supplement our existing product pipeline. This may include either the development of new infectious disease products or the acquisition of new technologies or products. An important new product under clinical development is a rapid HCV test on our OraQuick® platform.

OTC Opportunities. We intend to identify or develop products that can be sold in the OTC or retail marketplace. A significant opportunity that we are pursuing under this part of our strategy is to seek FDA approval to sell our OraQuick® rapid HIV-1/2 antibody test in the United States OTC market. We are also working to expand the international distribution of our OTC cryosurgical product.

Operational Improvements. We intend to remain focused on the continuous improvement of our operations. These improvements will include, but not be limited to, expanding the use of automated manufacturing for our product lines as demand increases, expanding the global sourcing of components and assemblies to achieve efficiencies and cost improvements, making infrastructure and information technology investments as needed to improve effectiveness and productivity, and modifying our processes in order to continuously improve quality and the effectiveness of our operations.

Research and Development

In 2007, our research and development activities focused primarily on the development of a rapid HCV test using our OraQuick® technology platform, clinical and regulatory activities related to obtaining a CE mark for the OraQuick *ADVANCE*® test, clinical work to obtain FDA approval for use of OraQuick® in the United States OTC market, and development of certain improvements to existing products in the OraQuick®, Intercept® and cryosurgical wart removal product lines.

From time to time, we supplement our own research and development activities by funding external research at universities and certain other entities. We may continue to fund external research.

Research and development expenses totaled $14.1 million in 2007, $8.6 million in 2006 and $5.3 million in 2005. These expenses include the costs associated with research and development, regulatory affairs, clinical trials and product support.

Sales and Marketing

We attempt to reach our major target markets through a combination of direct sales, strategic partnerships and independent distributors. Our marketing strategy is to raise awareness through a full array of marketing activities, which include trade shows, print advertising, special programs and distributor promotions, to support sales in each target market.

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We market our products in the United States and internationally. Revenues attributable to customers in the United States were $64.6 million, $56.8 million and $59.9 million in 2007, 2006 and 2005, respectively. Revenues attributable to international customers amounted to $18.1 million, $11.4 million and $9.5 million, or 22%, 17% and 14% of our total revenues, in 2007, 2006 and 2005, respectively.

Infectious Disease Testing

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

Abbott Laboratories (Abbott) is our exclusive distributor of OraQuick *ADVANCE*® in the U.S. hospital market and non-exclusive distributor in the U.S. physicians office marketplace. As our exclusive distributor to hospitals, Abbott sells OraQuick *ADVANCE*® to federal hospitals under the terms of our Federal Supply Schedule on file with the General Services Administration. Under our agreement with Abbott, we have retained exclusive rights for all other markets, including sales to the public health and criminal justice markets, the military, the CDC, SAMHSA and other governmental agencies. We have a small sales force that supports Abbott in order to maximize the penetration of OraQuick *ADVANCE*® in the hospital market. The initial term of our agreement with Abbott expired at the end of 2007, and the agreement has been extended for 2008 pursuant to its annual renewal terms.

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

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

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

Substance Abuse Testing

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

We have entered into agreements for the distribution of Intercept® collection devices and associated MICRO-PLATE assays for drugs-of-abuse testing in the workplace testing market in the United States and Canada through several laboratory distributors, including Quest Diagnostics (Quest) and Clinical Reference Laboratory, and internationally for workplace, criminal justice and forensic toxicology testing through Bio-Rad Laboratories, Concateno (which acquired our prior distributor, Altrix HealthCare, plc) and other distributors. In

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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.

The forensic toxicology market in the United States for our substance abuse testing products consists of several hundred laboratories including federal, state and county crime laboratories, medical examiner laboratories and reference laboratories. The criminal justice market consists of a wide variety of entities in the criminal justice system that require drug screening, such as pre-trial services, parole and probation officials, police forces, drug courts, prisons, drug treatment programs and community/family service programs.

We also distribute our Q.E.D.® saliva alcohol test primarily through various distributors in the United States and internationally. The markets for alcohol testing are relatively small and fragmented with a broad range of legal and procedural barriers to entry. Markets range from law enforcement testing to workplace testing of employees in safety sensitive occupations. Typical usage situations include pre-employment, random, post-accident, reasonable-cause and return-to-duty testing.

Cryosurgical Systems

Most of our Histofreezer® sales occur in the United States to distributors that, in turn, resell the product to primary care physicians and podiatrists in the United States. Major U.S. distributors include Cardinal Healthcare, McKesson HBOC, Physicians Sales & Service, AmerisourceBergen Corporation, and Henry Schein. Internationally, we have a sales office in Reeuwijk, The Netherlands, and sell the Histofreezer® product through a network of distributors in more than 20 countries worldwide.

In past years, we sold a cryosurgical wart removal product similar to Histofreezer® in the OTC market in the United States and Canada pursuant to a distribution agreement with Prestige, the owner of the Compound W® line of wart removal products. That distribution agreement terminated at the end of 2007, and we are currently evaluating alternative strategies for the distribution of this product in the United States and Canada. Additionally, we distribute cryosurgical wart removal products in the OTC footcare market in Europe, Australia and New Zealand through our distributor, SSL, under its Scholl and Dr. Scholl tradenames, and in the OTC market in Mexico under the POINTTS tradename through our distributor, Genomma Labs. We have also entered into new agreements with Genomma Labs for distribution of our OTC cryosurgical wart product in several Central and South American countries and in South Africa.

Insurance Risk Assessment

We currently market the OraSure® oral fluid collection device for use in screening life insurance applicants in the United States and internationally to test for three of the most important underwriting risk factors: HIV-1, cocaine and cotinine (a metabolite of nicotine). Devices are sold to insurance testing laboratories, including Quest, Heritage Labs and Clinical Reference Laboratory. These laboratories in turn provide the devices to insurance companies, usually in combination with testing services.

We also maintain a direct sales force that promotes use of the OraSure® device directly to insurance companies for life insurance risk assessment. Insurance companies then make their own decision regarding which laboratory to use to supply their collection devices and testing services. Our OraSure® Western blot confirmatory test was previously distributed through BMX to laboratories and is used to confirm oral fluid specimens collected with our OraSure® device that initially test positive for HIV-1. Because BMX elected not to renew the Western blot agreements after December 31, 2007, we now distribute the Western blot test directly to our laboratory customers.

Because insurance companies are in various stages of their adoption of the OraSure® device, there exists a wide range of policy limits where the product is being applied. Some insurance companies have chosen to extend their testing to lower policy limits where they did not test at all before, while others have used OraSure® to

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replace some of their blood and urine-based testing. In general, most of our insurance company customers use the OraSure® device in connection with life insurance policies having face amounts of up to $250,000, with some customers using the device for policies of up to $500,000 in amount.

In recent years, we have experienced a decline in sales of OraSure® and related assays for insurance testing, primarily due to a reduction in the number of applications for life insurance policies and changes in underwriting requirements, as well as some consolidation in the industry leading to a reevaluation of testing methods.

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

International Markets

We sell most of our products into international markets primarily through distributors with knowledge of their local markets. Principal markets include foreign governments, physicians offices, insurance risk assessment, substance abuse, public health and laboratory testing.

We assist our international distributors in registering the products and obtaining required regulatory approvals in each country, and we provide training and support materials. Our international marketing program includes direct assistance to distributors in arranging for laboratory services, cooperation from screening test manufacturers and performance of Western blot confirmatory tests when necessary.

Significant Products and Customers

Several different products have contributed significantly to our financial performance, accounting for 10% or more of 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 $32.7 million, $23.5 million and $15.5 million in 2007, $25.6 million, $17.3 million and $15.1 million in 2006, and $21.6 million, $22.7 million and $15.9 million in 2005, respectively. As new products are developed and commercialized, we expect to receive a greater portion of our revenues from these products.

We currently have two customers, Quest and Abbott, which accounted for 11% and 10% of our total revenues, respectively, during 2007. The loss of Quest or Abbott, or a significant decrease in the volume of products purchased by either customer, could have a material adverse effect on our results.

Revenue by Segment

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

Supply and Manufacturing

We manufacture our OraQuick *ADVANCE*® test in our Bethlehem, Pennsylvania facility. In addition, we have entered into a supply agreement for the assembly of the OraQuick® device in Thailand, in order to supply certain international markets. This supply agreement had an initial term of one year, and automatically renews for additional annual periods unless either party provides a timely notice of termination prior to the end of an annual period. We believe that other firms would be able to manufacture the OraQuick® test on terms no less favorable than those set forth in the agreement if the Thailand contractor would be unable or unwilling to continue manufacturing this product.

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We can purchase the HIV antigen and the nitrocellulose required for the OraQuick® test only from a limited number of sources. The antigen is currently purchased from a single contract supplier under a long-term agreement with an initial term ending in January 2010 and one-year automatic renewal terms thereafter. The nitrocellulose used in the test is also provided by a single contract supplier, under a supply agreement with a five-year term ending in 2009. If for any reason these suppliers are unwilling or no longer able to supply our antigen or nitrocellulose needs, we believe that alternative supplies could be obtained at a competitive cost. However, a change in the antigen or nitrocellulose would require FDA approval and some additional development work. This in turn would require significant time to complete and could disrupt our ability to manufacture and sell the OraQuick® device.

We manufacture both the OraSure® and Intercept® collection devices in our Bethlehem, Pennsylvania facility, and we expect to continue to do so for the foreseeable future.

The oral fluid Western blot HIV-1 confirmatory test is currently manufactured in our Bethlehem, Pennsylvania facility. The HIV antigen needed to manufacture the Western blot test is currently available from only a limited number of sources. For many years, we purchased the antigen for this product from BMX on an exclusive basis. Our agreement with BMX for the supply of HIV-1 antigen terminated on December 31, 2007. As a result, we purchased an additional two-year supply of the antigen from BMX as permitted under the agreement. When this additional supply is combined with our existing inventory of the HIV-1 antigen, we believe we have a sufficient supply of the HIV-1 antigen to meet the demand for our Western blot test for at least the next three to four years.

Histofreezer® is assembled in The Netherlands by Koninklijke, Utermöhlen, N.V. (Utermöhlen), the company from which we acquired the product in 1998. We purchase the product pursuant to an exclusive production agreement. The cryosurgical wart removal products distributed in OTC markets are supplied by vendors located in the United States. We believe that additional suppliers of all of our cryosurgical products are available on terms no less favorable than the terms of our existing supply agreements in the event that our current suppliers would be unable or unwilling to continue manufacturing these products.

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

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

Employees

As of December 31, 2007, we had 282 full-time employees, including 70 in sales, marketing and client services; 24 in research and development; 134 in operations, manufacturing, quality control, information systems, purchasing and shipping; 28 in regulatory affairs; and 26 in administration and finance. This compares to 250 employees as of December 31, 2006. 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.

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Important competitive factors for our products include product quality, performance, price, ease of use, customer service and reputation. Industry competition is based on the following:

- Scientific and technological capability;
- Proprietary know-how;
- The ability to develop and market products and processes;
- The ability to obtain FDA or other regulatory approvals;
- The ability to manufacture products that meet applicable FDA requirements (i.e., good manufacturing practices);
- Access to adequate capital;
- The ability to attract and retain qualified personnel; and
- The availability of patent protection.

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

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

We expect competition to intensify as technological advances are made and become more widely known, and as new products reach the market. Furthermore, new testing methodologies could be developed in the future that render our products impractical, uneconomical or obsolete. There can be no assurance that our competitors will not succeed in developing or marketing technologies and products that are more effective than those we develop or that would render our technologies and products obsolete or otherwise commercially unattractive. In addition, there can be no assurance that our competitors will not succeed in obtaining regulatory approval for these products, or introduce or commercialize them before we can do so. These developments could have a material adverse effect on our business, financial condition and results of operations.

Several companies market or have announced plans to market oral specimen collection devices and tests both within and outside the United States. We expect the number of devices competing with our Intercept®, OraQuick® and OraSure® devices to increase as the benefits of oral specimen-based testing become more widely accepted.

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

Significant competitors for our OraQuick *ADVANCE*® rapid test, such as the Ortho Diagnostics division of Johnson & Johnson, Bio-Rad Laboratories 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 or 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

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others, may continue to expand the bodily fluids with which a rapid HIV test may be performed, or develop and commercialize new rapid HIV tests, which would provide further competition for our OraQuick *ADVANCE*® test. We believe other companies may also seek FDA approval to sell competing rapid HIV tests in the future.

Internationally, our OraQuick *ADVANCE*® test competes against rapid HIV tests sold by a number of other entities, and often these competing tests are sold at prices substantially below the prices we charge for our OraQuick *ADVANCE*® test. Inverness Medical sells a rapid HIV-1/2 blood test outside the United States and Calypte has developed a rapid oral fluid HIV test which is now being sold in certain foreign countries.

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

Our MICRO-PLATE oral fluid drug assays, which are sold for use with the Intercept® and OraSure® collection devices, are expected to come under increasing competitive pressure from home-brew assays developed internally by our laboratory customers. Our oral fluid MICRO-PLATE assays also compete with urine-based homogeneous assays that are run on fully-automated, random access analyzers. These tests provide strong competitive pressure because they provide the benefits of automation, including lower costs and short turn-around times. In addition, we believe our competitors are developing oral fluid tests suitable for use on these fully automated homogeneous assay systems and these assays, if and when they are developed and commercialized, will represent a significant competitive threat to our oral fluid MICRO-PLATE business. In order to meet this competition, we are developing fully-automated homogeneous oral fluid drugs of abuse assays with Roche Diagnostics for use with our Intercept® device.

Our MICRO-PLATE drugs-of-abuse reagents sold in the forensic toxicology market are targeted to forensic testing laboratories where sensitivity, automation and system solutions are important. In the past, these laboratories have typically had to rely on radioimmunoassay test methods to provide an adequate level of sensitivity. Radioimmunoassays require radioactive materials, which have a short shelf-life and disposal problems. Our MICRO-PLATE tests meet the laboratories sensitivity needs, run on automated equipment, are not radioimmunoassays, and are offered to the laboratory as a complete system solution of reagents, instrumentation and software to meet the specific needs of each customer. We compete with both homogeneous and heterogeneous tests manufactured by many companies. Significant competitors in the market for these assays include Microgenics, Inc., Roche Diagnostics and Immunalysis.

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

The Histofreezer® product s delivery system and operating temperature, which is warmer than liquid nitrogen, provide us with the opportunity to target sales to primary care physicians, such as family practitioners, pediatricians and podiatrists. We do not generally target sales to dermatologists because they have the volume of patients required to support the capital costs associated with a liquid nitrogen delivery system, which is also used to remove warts and other benign skin lesions. Major competitors for the Histofreezer® product include Cryosurgery, Inc. in the United States and Wartner in Europe.

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

Q.E.D.® has two direct competitors, Ansys Technologies, Inc. and Chematics. These companies offer semi-quantitative saliva-based alcohol tests and have received DOT approval. Indirect competitors who offer breath

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testing equipment include Intoximeters, Dräger and CMI. Although there are lower priced tests on the market that use oral fluid or breath as a test medium, these tests are qualitative tests that are believed to be substantially lower in quality and provide fewer benefits than our Q.E.D.® test.

Patents and Proprietary Information

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

We have ten United States patents and numerous foreign patents for the OraSure® and Intercept® collection devices and technology relating to oral fluid collection, containers for oral fluids, methods to test oral fluid, formulations for the manufacture of synthetic oral fluid, and methods to control the volume of oral fluid collected and dispersed. The patents expire from April 2009 to March 2018. We have also applied for additional patents, in both the United States and certain foreign countries, on such products and technology.

We have two United States patents for our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test, and we have several related patent applications pending for this product in the United States and internationally. The patents expire from March to April 2019. We have obtained licenses to certain lateral flow patents and to certain HIV-1 and HIV-2 patents held by other parties. We also have obtained a license to certain HCV patents which we intend to use to manufacture and sell a rapid HCV test on the OraQuick® or other technology platform. We obtained these licenses through the payment of certain upfront fees and an agreement to pay ongoing royalties. We believe these fees and royalties are comparable to those generally paid by other companies under similar arrangements.

We may need to obtain licenses or other rights under, or enter into distribution or other business arrangements in connection with, certain other intellectual property patents in order to manufacture and sell the OraQuick *ADVANCE*® test 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 five United States patents and numerous foreign patents issued for apparatuses and methods for the topical removal of skin lesions relating to our cryosurgical wart removal products, and we have a pending patent application related to these products in the United States and in certain foreign countries. The patents expire from March 2008 to August 2013. We have also licensed another patent relating to apparatuses and methods for the topical removal of skin lesions relating to our cryosurgical wart removal products.

We have four United States patents and numerous foreign patents and patent applications for the technology used in the Q.E.D.® test. These patents expire from July 2008 to August 2009. These patents are related to the analog-to-digital technology color control systems and methods, systems and devices for the test, and detection of biochemical molecules.

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

We own rights to trademarks and service marks that we believe are necessary to conduct our business as currently operated. In the United States, we own the OraSure® , Intercept®, OraQuick®, OraQuick *ADVANCE*®,

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Histofreezer®, Q.E.D.® and AUTO-LYTE® trademarks. We also own many of these marks and others in several foreign countries. With respect to our international OTC cryosurgical products, the Scholl and Dr. Scholl tradenames are owned by SSL in Europe, Australia, New Zealand and other countries outside North and South America, and the POINTTS tradename is owned by Genomma Labs.

Although important, the issuance of a patent or existence of trademark or trade secret protection does not in itself ensure the success of our business. Competitors may be able to produce products competing with our patented products without infringing our patent rights. Issuance of a patent in one country generally does not prevent manufacture or sale of the patented product in other countries. The issuance of a patent is not conclusive as to validity or as to the enforceable scope of the patent. The validity or enforceability of a patent can be challenged by litigation after its issuance. If the outcome of such litigation is adverse to the owner of the patent, the owner s rights could be diminished or withdrawn. Trade secret protection does not prevent independent discovery and exploitation of the secret product or technique.

Government Regulation

General

Most of our products are regulated by the FDA, certain state and local agencies and comparable regulatory bodies in other countries. This regulated environment governs almost all aspects of development, production and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing and recordkeeping.

All of our FDA-regulated products require some form of action by the FDA before they can be marketed in the United States. After approval or clearance by the FDA, we must continue to comply with other FDA requirements applicable to marketed products. Both before and after approval or clearance, failure to comply with the FDA s requirements can lead to significant penalties or could disrupt our ability to manufacture and sell these products. In addition, the FDA could refuse permission to obtain certificates needed to export our products if the agency determines that we are not in compliance.

Domestic Regulation

Most of our products are regulated in the United States as medical devices.

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

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

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

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

The Clinical Laboratory Improvements Amendments of 1988, or CLIA, prohibit laboratories from performing tests for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of human beings, unless there is in effect for such laboratories a certificate issued by the U.S. Department of Health and Human Services applicable to the category of examination or procedure performed. We consider the applicability of the requirements of CLIA in the design and development of our products. We have obtained a waiver of the CLIA requirements for both our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test and our Q.E.D.® alcohol saliva test and may seek similar waivers for certain other products. A CLIA waiver allows certain customers to use the waived products that may not have been able to use them without complying with certain quality control and other requirements.

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

International

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

The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies from some 130 countries, established in 1947. The mission of the ISO is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services. ISO certification is a pre-requisite to use of the CE mark and indicates that our quality system complies with standards applicable to activities ranging from initial product design and development through production and distribution. The CE mark is a European Union (EU) requirement to sell products that fall under the scope of the Medical Devices Directive (MDD) and the In Vitro Diagnostic Directive (IVDD). The CE mark is evidence that the manufacturer and the product meet the requirements of all applicable directives, including the MDD and IVDD.

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

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

Anti-Kickback Laws

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

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

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

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

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

Foreign Corrupt Practices Act

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

Environmental Regulation

Because of the nature of our current and proposed research, development, and manufacturing processes, we are subject to stringent federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge and handling and disposal of materials and wastes.

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

Many of our proposed and existing products are subject to regulation by the FDA and other governmental or public health agencies. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products. In addition, we are often required to obtain approval or registration with foreign governments or regulatory bodies before we can import and sell our products in foreign countries.

The process of obtaining required approvals or clearances from governmental or public health agencies can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities and other costly, time-consuming procedures. These approvals can require the submission of a large amount of clinical data which may require significant time to obtain. It is also possible that a product will not perform at a level needed to generate the clinical data required to obtain an approval or clearance. The submission of an application to the FDA or other international regulatory authority does not guarantee that an approval or clearance to market the product will be received. Each authority may impose its own requirements and delay or refuse to grant approval or clearance, even though a product has been approved in another country or by another agency.

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

We are in the process of 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 and our OraQuick® HCV test for professional use. There can be no assurance that these clinical trials will generate sufficient data to support FDA approval of either product or that FDA approval will be obtained. Failure to obtain or any delay in obtaining FDA approval for either product could significantly reduce future revenues, increase our costs and adversely affect our financial performance.

Newly promulgated or changed regulations could also require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. For example, during 2004 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

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the final SAMHSA regulations permit the sale of our oral fluid drug tests for use with federal workers may influence whether customers in the workplace, criminal justice or other unregulated markets use our products.

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

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

The Inability to Extend the Shelf Life of Our OraQuick ADVANCE® HIV-1/2 Test Could Adversely Affect Our Business.

The shelf life of a product is the period of time from the date of manufacture during which the product is expected to perform in accordance with its specifications and labeling. In order to successfully sell our products, they need to have a shelf life that is long enough to cover the time required to distribute the product to a customer and provide the customer with a reasonable period to use that product.

Where a product has a short shelf life, our ability to sell that product may be adversely affected. In order to extend the shelf life, we may be required to submit real time stability data supporting such an extension to the FDA for approval.

Our OraQuick *ADVANCE®* HIV-1/2 test currently has a shelf life of six months. While this shelf life has not prevented us from selling into the public health and hospital markets in the United States, it has limited our ability to sell that test internationally. We also believe a shelf life of at least 12 months will be required to sell the OraQuick® HIV-1/2 test successfully into the United States OTC market.

We are working to extend the shelf life of our OraQuick *ADVANCE®* test. However, there can be no assurance that we will be successful in obtaining such an extension or its approval by the FDA or regulatory authorities in foreign countries, or that such extension will occur within a time frame consistent with our objectives. If we are unsuccessful or delayed in obtaining a shelf life extension, our ability to sell the OraQuick® test may be adversely affected and we may not be able to sell it successfully into the United States OTC market.

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

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

Although we believe that we have adequate processes in place to ensure compliance with these requirements, the FDA or other regulatory bodies could force us to stop manufacturing, selling or exporting our products if it concludes that we are out of compliance with applicable regulations. The FDA and other regulatory bodies could also require us to recall products if we fail to comply with applicable regulations, which could force us to stop manufacturing such products. Such actions by the FDA could adversely affect our revenues. See the Section entitled Government Regulation in Item 1 of this Annual Report for a further discussion of applicable regulatory requirements.

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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, numerous laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, disposal of hazardous substances and labor or employment practices impact our business operations. Compliance with these laws or any new or changed laws regulating our business could result in substantial costs. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of these requirements. To the extent the costs and procedures associated with complying with these laws and requirements are substantial or it is determined that we do not comply, our business and results of operations could be adversely affected.

Risks Relating to Our Industry, Business and Strategy

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

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

We also face competition from products which may be sold at a lower price. To the extent this competition arises, customers may choose to buy lower cost products from third parties or we may be forced to sell our products at a lower price, both of which could result in a loss of revenues or a lower gross margin contribution from the sale of our products.

In addition, the development and commercialization of products outside of the diagnostics industry could adversely affect sales of our product. For example, the development of a safe and effective vaccine to prevent HIV or preventative treatments for other diseases or conditions that our products are designed to detect, could reduce, or eventually eliminate, the demand for our HIV or other diagnostic products and thereby result in a loss of revenues.

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

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

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

During 2007, 2006 and 2005, we incurred $14.1 million, $8.6 million and $5.3 million, respectively, in research and development expenses. We expect to continue to incur significant costs from our research and development activities.

Successful products require significant development and investment, including testing, to demonstrate their cost-effectiveness or other benefits prior to commercialization. In addition, regulatory approval must be obtained

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before most products may be sold. Additional development efforts on these products will be required before any regulatory authority will review them. Regulatory authorities may not approve these products for commercial sale. In addition, even if a product is developed and all applicable regulatory approvals are obtained, there may be little or no market for the product. Accordingly, if we fail to develop or gain commercial acceptance for our products, or if competitors develop more effective products or a greater number of successful new products, customers may decide to use products developed by our competitors. This would result in a loss of revenues and adversely affect our results of operations, cash flows and business.

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

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

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

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

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

Suitable acquisitions or investments may not be found or consummated on terms or schedules that are satisfactory to us;

We may be unable to successfully integrate an acquired company s personnel, assets, management systems and technology into our business;

Acquisitions may require substantial expense and management time and could disrupt our business;

An acquisition and subsequent integration activities may require greater capital resources than originally anticipated at the time of acquisition;

An acquisition may result in the incurrence of unexpected expenses, the dilution of our earnings or our existing stockholders percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business;

An acquisition may result in the loss of existing key personnel or customers or the loss of the acquired company s key personnel or customers;

The benefits expected to be derived from an acquisition may not materialize and could be affected by numerous factors, such as regulatory developments, general economic conditions and increased competition; and

An acquisition of a foreign business may involve additional risks, including, but not limited to, foreign currency exposure, liability under foreign laws or regulations and not being able to successfully assimilate differences in foreign business practices or overcome language or cultural barriers.

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

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

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

If we experience significant or unexpected increases in the demand for our products, we and our suppliers may not be able to meet that demand without expending additional capital resources. These capital resources could involve the cost of new machinery or even the cost of new manufacturing facilities. This would increase our capital costs, which could adversely affect our earnings. Our suppliers may be unable or unwilling to expend the necessary capital resources or otherwise expand their capacity. In addition, new manufacturing equipment or facilities may require FDA approval before they can be used to manufacture our products. To the extent we are unable to obtain or are delayed in obtaining such approvals, our ability to meet the demand for our products could be adversely affected.

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

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

Risks Relating to Collaborators

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

We have marketed many of our products by collaborating with laboratories, diagnostic companies and distributors. Our sales depend to a substantial degree on our ability to sell products to these customers and on the marketing abilities of the companies with which we collaborate.

Some of our distributors or other customers may not fulfill their contractual obligations to us. Although we will try to maintain and expand our business with distributors and customers and require that they fulfill their

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contractual obligations, there can be no assurance that such companies will continue to purchase or distribute our products, maintain historic order volumes or otherwise meet their purchase or other obligations, or that new distribution channels will be available on satisfactory terms. The failure of these distributors or other customers to purchase our products could adversely affect our revenues.

We previously distributed a cryosurgical wart removal product in the United States OTC market under a distribution agreement with Prestige Brands. As a result of a dispute with Prestige during 2007, this agreement has terminated and we are currently evaluating alternative strategies for the OTC distribution of this product in the United States and Canada. Sales of our cryosurgical product in the United States OTC market totaled $6.2 million during 2007. Failure or delay in finding a new distributor for this product will adversely affect our ability to replace the revenues previously generated from sales to Prestige.

Some of our distributors have also consolidated in recent years and such consolidation has had, and may continue to have, an adverse impact on the level of orders for our products. In addition, some distributors have experienced, and may continue to experience, pressure from their customers to reduce the price of their products and testing services. For example, several of our insurance testing laboratories are facing this pressure and are using lower cost home brew insurance testing assays that they have developed internally or purchased from our competitors. This has reduced our assay sales and is expected to lower sales of these products in 2008 and beyond.

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

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

If these suppliers are unable or unwilling to supply the required component or if they make changes in the component or do not supply materials meeting our specifications, we may need to find another source and perform additional development work. We may also need to obtain FDA or other regulatory approvals for the use of the alternative component for our products. Completing that development and obtaining such approvals could require significant time and may not occur at all. The availability of critical components from sole supply sources or other third parties could also reduce our control over pricing, quality and timely delivery. These events could either disrupt our ability to manufacture and sell certain of our products, or completely prevent us from doing so or increase our costs. Any such event could have a material adverse effect on our results of operations, cash flows and business.

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

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

Historically, BMX manufactured and sold the only oral fluid HIV-1 EIA screening test that has received FDA approval for use in detecting HIV-1 in an oral fluid specimen collected with our OraSure® collection device. BMX also supplied the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and was the exclusive world-wide distributor of that product.

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BMX discontinued manufacturing the HIV-1 EIA screening test in 2007. As a result, we intend to seek FDA approval of an alternative HIV-1 EIA screening test for use with oral fluid samples collected with our OraSure® device.

On December 31, 2007, the agreements under which BMX supplies the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and distributed that product on an exclusive, world-wide basis, terminated. As a result, we are now supplying this confirmatory test directly to our laboratory customers. Pursuant to the terms of the antigen supply agreement with BMX, we purchased an additional two-year supply of the antigen from BMX so that we can continue to manufacture and sell our oral fluid Western blot test. When this additional two-year supply is combined with our existing inventory of the HIV-1 antigen, we believe we have a sufficient supply of HIV-1 antigen to meet the demand for our Western blot test for the next three to four years.

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

We May Need Strategic Partners to Assist in Developing and Commercializing Some of Our Diagnostic Products.

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

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

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

We Have a History of Losses Prior to 2005.

We achieved our first full years of profitability in 2005, 2006 and 2007. However, as of December 31, 2007, the Company had an accumulated deficit of $96.0 million. Even though we achieved profitability in the past, there can be no assurance that we will be able to sustain such profitability in the future.

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

- Creating market acceptance for and selling increasing volumes of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test, Intercept® drug testing product, cryosurgical products and OraSure® collection device;

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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 able to extend the shelf life of our OraQuick *ADVANCE*® HIV-1/2 test;

Our ability to successfully resolve claims or litigation, including patent infringement litigation;

The level of expenditures we are required to make in order to develop and obtain regulatory approvals for our new products, including our OraQuick® HIV-1/2 test for use in the OTC market and an OraQuick® HCV test for professional use;

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

Achieving growth in sales of our wart removal products in the OTC market and selling other products, such as our OraQuick ® HIV-1/2 test, in the OTC market;

Whether we are able to find and obtain FDA approval of a replacement for the BMX HIV-1 EIA screening test for use in connection with oral fluid samples collected with our OraSure® device;

Achieving growth in international markets with our OraQuick *ADVANCE*® HIV-1/2 test, cryosurgical wart removal products and other products;

Changes in the level of competition, such as would occur if larger and financially stronger competitors introduced new or lower priced products to compete with our products;

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

Failure to achieve our targets for growth in revenues;

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

Commercially developing, and obtaining regulatory approvals and creating market acceptance for new products in a time frame consistent with our objectives.

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 estimated demand for our products. However, sales to our distributors and other customers may fall short of expectations because of less than estimated customer demand or other factors, including those described elsewhere in this Annual Report. Infrequent, unusual or unexpected revenues or costs could also contribute to the variability of our financial results. In addition, our products provide different contributions to our gross margin and our operating results could also fluctuate and be affected depending on the mix of products sold and the relative prices and gross margin contribution of those products. Failure to achieve operating results consistent with the expectations of investors and securities analysts could adversely affect our reputation and the price of our common stock.

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

At December 31, 2007, we had $95.6 million in cash, cash equivalents and short-term investments. We invest our cash in a variety of financial instruments, consisting principally of investments in certificates of deposit, commercial paper, U.S. government and agency obligations, and U.S. corporate bonds. These investments are denominated in U.S. dollars.

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

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

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

As of December 31, 2007, we had federal net operating loss (NOL) carryforwards of $45.5 million for federal income tax purposes. The Tax Reform Act of 1986 contains provisions under Section 382 of the Internal Revenue Code that limit the NOLs that may be used in any given year in the event of specified occurrences, including significant ownership changes. If these specified events occur, we may lose some or all of the tax benefits of these carryforwards.

During 2005, we determined, based on our assessment of both positive and negative evidence, which takes into consideration our forecasted taxable income, that it was more likely than not that we will benefit from the use of a significant portion of our deferred tax assets, and therefore we reduced our valuation allowance on our deferred tax assets related to these NOLs and other items. If in the future we determine, based on our assessment of both positive and negative evidence, that it is more likely than not that we will not realize all or a portion of the deferred tax assets, we will record a valuation allowance on the deferred tax assets which would result in recognition of income tax expense.

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

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

- Revenue recognition;

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Allowance for uncollectible accounts receivable;

Reserve for inventory write-downs;

Stock-based compensation;

Potential impairment of long-lived and intangible assets;

Realization of deferred tax 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 costs and timing of the expansion of our manufacturing capacity;

The success of our research and product development efforts;

The magnitude of capital expenditures;

Changes in existing and potential relationships with distributors and other business partners;

The time and cost of conducting clinical trials and obtaining regulatory approvals;

The costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses;

The costs and liability associated with patent infringement or other types of litigation;

The costs and timing of expansion of sales and marketing activities;

The timing of the commercial launch of new products;

The extent to which existing and new products gain market acceptance;

The scope and results of clinical testing;

Competing technological and market developments; and

The scope and timing of strategic acquisitions.

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

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

Changes in economic conditions could adversely affect our business. A weakening business climate could cause longer sales cycles and slower growth, and could expose us to increased business or credit risk in dealing with customers or suppliers adversely affected by economic conditions.

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.

Risks Relating to Our Common Stock

Our Stock Price Could Continue to be Volatile.

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

Future announcements concerning us or our products;

Future announcements concerning our competitors or industry;

Developments in patent or other proprietary rights;

Litigation or threatened litigation;

Public concern as to the performance or safety of products that we or others have developed or sold;

Failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by securities analysts or major stockholders;

Governmental regulation;

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

Timing of completion of clinical studies and receipt of required regulatory approvals;

Changes in the level of competition;

Loss of or declines in sales to major distributors or customers or changes in the mix of products sold;

The relatively low trading volume for our Common Stock;

Period to period fluctuations in our operating results;

Additions or departures of key personnel;

General market and economic conditions; and

Terrorist attacks, civil unrest, war and national disasters.

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

Sales of our Common Stock in the public market, or the perception that such sales could occur, could negatively impact the market price of our Common Stock. We are unable to estimate the number of shares of our Common Stock that may actually be resold in the public market since this will depend on the market price for our Common Stock, the individual circumstances of the sellers and other factors.

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

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

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

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

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

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

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.

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

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

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

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

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

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

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

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

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

As is common with major litigation, it could consume a substantial portion of managerial and financial resources;

Its outcome would be uncertain and a court may find that our patents are invalid or unenforceable in response to claims by another party or that the third-party patent claims are valid and infringed by our products;

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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,