ORASURE TECHNOLOGIES INC
Form 10-K
March 16, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT

TO SECTIONS 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the fiscal year ended December 31, 2006

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No 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, 2006): $434,917,582

Indicate the number of shares outstanding of each of the Registrant s classes of common stock, as of March 12, 2007: 46,127,212 shares.

Documents Incorporated by Reference:

Portions of the Registrant s Definitive Proxy Statement for the 2007 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, 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 Report and we undertake no duty to update these statements.

PART I

ITEM 1. Business.

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

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

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

Our Company was formed in May 2000 under Delaware law solely for the purposes of combining two companies, STC Technologies, Inc. (STC or STC Technologies) and Epitope, Inc. (Epitope), and changing the state of incorporation of Epitope from Oregon to Delaware. STC Technologies and Epitope were merged into our Company on September 29, 2000. 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

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Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, as well as any amendments to those Reports. These Reports are made available as soon as reasonably practicable after they are filed or furnished to the Securities and Exchange Commission. Our Internet website and the information contained in or connected to that website are not intended to be incorporated by reference into this Annual Report.

Products

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

Product	Description	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) (March 2004 June 2004) for use with oral fluid, finger-stick and venous whole blood, and plasma. CLIA (Clinical Laboratory Improvement Amendments of 1988) waived for use with oral fluid, finger-stick and venous whole blood (June 2004).	Marketed
		CE mark application filed.	Pending
		Registered in Mexico.	Marketed
OraQuick *ADVANCE*® *OTC*		In development.	
OraQuick® HCV	A rapid, point-of-care test for antibodies to the hepatitis C virus (HCV)	In development.	
OraSure®	Oral fluid collection device for the detection of antibodies to HIV-1 in an oral fluid sample in a laboratory setting.	PMA approved by FDA in December 1994.	Marketed
		Also FDA 510(k) cleared for use 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 in 2000.	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 during 2000-2001.	Marketed
		Intercept® device CE marked and registered in the United Kingdom. Various assays are CE marked and registered in the United Kingdom, Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Mexico, Netherlands, Portugal, Spain, Sweden, Korea, Canada, Afghanistan and Brazil.	Marketed

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Product	Description	Regulatory Status	Commercial Status
Homogeneous DOA Assays	Homogeneous fully-automated oral fluid DOA assays.	In development.	
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 during 1991 1999.	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 the OTC markets in the United States and Canada under the Compound W Freeze Off® tradename by Prestige Brands Holdings, Inc., in Europe, Australia and New Zealand under the Scholl and Dr. Scholl Freeze Spray tradenames by SSL International plc. and in Mexico under the POINTTS tradename by Genomma Labs.	FDA 510(k) cleared for two Freeze Off® indications in February 2003.	Marketed
		Freeze Off® registered in Canada.	Marketed
		Scholl Freeze Spray CE marked and registered in several European countries.	Marketed
		POINTTS registered in Mexico.	Marketed
Cryosurgical Systems OTC Product Line Extensions	Cryosurgical system for an indication other than common warts or plantar warts.	In development.	
	Cryosurgical system combined with salicylic acid.	In development.	

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.

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On the international front, we are in the process of obtaining a CE mark for our OraQuick *ADVANCE*® test so that we will be able to sell this product in Europe. We have a distributor in place for the United Kingdom 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 quickly 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.

We have received premarket approval from the FDA to sell the OraSure® collection device for use with a laboratory-based enzyme immunoassay (EIA) screening test for HIV-1 antibody detection. This EIA screening test has been approved by the FDA for use with our OraSure® device and is manufactured and sold by bioMerieux, Inc. (BMX).

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

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

A trained health care professional then conveys test results and provides appropriate counseling to the individual who was tested. We have also received FDA 510(k) clearance for use of the OraSure® collection device with EIAs to test for cocaine and cotinine (a metabolite of nicotine) in oral fluid specimens primarily for insurance risk assessment purposes.

In late 2006, BMX announced that it will discontinue manufacturing the HIV-1 EIA screening test during 2007 and that, due to quality problems, it may have difficulty supplying this screening test prior to the time it ceases manufacturing. As a result, we are working with BMX, the FDA and Centers for Disease Control and Prevention (CDC), our major laboratory customers and other potential suppliers to find or develop an alternative HIV-1 EIA screening test that can be used 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

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Intercept® collection device with laboratory-based EIAs to test for drugs of abuse commonly identified by the National Institute for Drug Abuse (NIDA) as the NIDA-5 (i.e., cannabinoids (marijuana), cocaine, opiates, amphetamines/methamphetamines and phencyclidine (PCP)), and for barbiturates, methadone and benzodiazepines. Each of these EIAs is also FDA 510(k) cleared for use with the Intercept® device.

We have received a CE mark for the Intercept® and OraSure® devices and 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 two environmentally friendly cryogenic gases in a small aerosol canister. When released, these gases are delivered to a specially designed foam bud, cooling the bud to 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 throughout Europe.

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 is being 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. Prestige is the owner of both the Freeze Off® and Compound W® tradenames. In September 2006, Prestige announced that it had acquired the Wartner® cryosurgical wart removal product line, which competes with the Freeze Off® product in the U.S. and Canadian OTC markets. Because we believe that the Wartner acquisition constitutes a breach of our agreement with Prestige, we have initiated an arbitration proceeding against Prestige. As a result, it is uncertain whether Prestige will continue to distribute the Freeze Off® product after 2007. For a more detailed description of our dispute with Prestige, see Item 3, Legal Proceedings, in this Annual Report.

Internationally, we distribute a similar 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 have also launched an OTC cryosurgical product in Mexico through our distributor Genomma Labs, under the POINTTS tradename.

Immunoassay Tests and Reagents

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

In a MICRO-PLATE kit, the sample to be tested is placed into a small plastic receptacle, called a microwell, along with the reagents. The result of the test is determined by the color of the microwell upon completion of the reaction. Controlling the reaction involves the use of a variety of reagents by laboratory personnel. Test results

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are analyzed by any of a variety of commercially available laboratory instruments, which we may also provide to our laboratory customers. MICRO-PLATE tests can be performed on commonly used instruments and can detect drugs in urine, serum and sweat specimens. MICRO-PLATE tests are also used as part of the Intercept® product line to detect drugs of abuse in oral fluid specimens.

AUTO-LYTE® tests are sold in the form of bottles of liquid reagents. These reagents are run on commercially available laboratory-based automated analytical instruments, which are manufactured by a variety of third parties. AUTO-LYTE® is typically used in high volume, automated, commercial reference insurance laboratories to detect certain drugs or chemicals in urine. Test results are produced quickly, allowing for high throughput. In recent years, sales of our AUTO-LYTE® tests have been substantially reduced largely because of competition from cheaper home-brew tests used by our laboratory customers. As a result, we eventually expect to 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 is currently marketed under an exclusive arrangement with BMX.

In March 2007, BMX notified us that it will 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 distributes that product on an exclusive, world-wide basis. As a result, these agreements will terminate on December 31, 2007. Pursuant to the terms of the antigen supply agreement, we have the right to purchase an additional two-year supply of the antigen following termination 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 will have a sufficient supply of HIV-1 antigen to meet the demand for our Western blot test for three to four years after the agreement terminates. We also intend to pursue a long-term supply agreement directly with the vendor (a former affiliate of BMX) used by BMX to manufacture the HIV-1 antigen. During 2006, sales of our oral fluid Western blot HIV-1 confirmatory test totaled approximately $330,000.

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.

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We are currently devoting significant resources to obtaining FDA approval to sell our OraQuick *ADVANCE*® HIV-1/2 test in the United States OTC market. We have completed several laboratory-based operational studies and have initiated and will continue to perform additional clinical studies, including label comprehension studies, in support of our application for FDA approval. We are also developing a counseling 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 during 2007 and early 2008, after which we intend to submit an application for FDA approval.

During 2005, we obtained a license from Ortho-Clinical Diagnostics and Chiron Corporation to patents relating to the Hepatitis C virus, or HCV, and we have made substantial progress in developing a rapid HCV test using the OraQuick® platform. In addition, in late 2006 we entered into an agreement 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 our agreement, we will be reimbursed by Schering-Plough for a portion of our costs to develop the test, and Schering-Plough will provide detailing and other promotional support for the test in the U.S. physicians office market, once the test is approved by the FDA. We are also in negotiations to obtain rights to a rapid HCV test manufactured by a third party that we intend to distribute into international markets.

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. When issued in final form, these regulations may require certain modifications to our Intercept® product in order to permit its use by federal workers. As a result, we are developing modifications to the Intercept® collection device that we anticipate will be required by these regulations or are otherwise likely to be desired by our customers.

We are also currently developing additional drugs of abuse assays for use with our Intercept® collection device. 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 will be developed for use with our Intercept® collection device and Roche s KIMS (kinetic information of microparticles in solution) technology. The assays will be designed to run on various automated analyzers and to allow oral fluid samples to be processed with the same efficiency currently achieved with urine-based drug tests. The parties are in the process of negotiating a definitive joint development and commercialization agreement.

In light of BMX s announced decision to cease production of the HIV-1 EIA screening assay used with our OraSure® device, we are working with BMX, the FDA and CDC, our major laboratory customers and other potential suppliers to find or develop an alternative HIV-1 EIA screening test that can be used with our OraSure® device.

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.

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We believe that one or more of the seven remaining Histofreezer® indications may be attractive to the OTC market. We are developing an OTC cryosurgical product for one of these indications, and we intend to seek FDA 510(k) clearance of that product during 2007. In addition, we are developing an extension of our existing OTC cryosurgical wart removal product in order to sell that product in combination with salicylic acid for the treatment of common and plantar warts. We also intend to seek FDA clearance of this product extension in 2007.

Business Strategy

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

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

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

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

OTC Opportunities. We intend to identify or develop products that can be sold in the OTC or retail marketplace. A significant opportunity that we are pursuing under this part of our strategy is to seek FDA approval to sell our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test in the United States OTC market. We are also working to expand the distribution of our OTC cryosurgical product internationally beyond Europe, Australia, New Zealand and Mexico where the product is currently distributed.

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 2006, our research and development activities focused primarily on the development of a rapid HCV test using our OraQuick® technology platform, clinical and regulatory activities related to obtaining a CE mark for the OraQuick *ADVANCE*® test, preliminary work to obtain FDA approval for use of OraQuick *ADVANCE*® in the United States OTC market, and development of certain improvements to existing products in

both the Intercept® and cryosurgical wart removal product lines.

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.

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Research and development expenses totaled $8.6 million in 2006, $5.3 million in 2005 and $6.1 million in 2004. 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.

We market our products in the United States and internationally. Revenues attributable to customers in the United States were $56.8 million, $59.9 million and $47.8 million in 2006, 2005 and 2004, respectively. Revenues attributable to international customers amounted to $11.4 million, $9.5 million and $6.2 million, or 17%, 14% and 11% of our total revenues, in 2006, 2005 and 2004, 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 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) was appointed as our exclusive distributor in the U.S. hospital market and as a non-exclusive distributor in the U.S. physicians office marketplace. As our exclusive distributor to hospitals, Abbott sells OraQuick *ADVANCE*® to federal hospitals under the terms 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.

Abbott recently announced that it will sell part of its diagnostics business, including its rights to distribute OraQuick *ADVANCE*®, to General Electric (GE). This transaction is expected to close during the first half of 2007. We intend to meet with executives from GE to discuss their plans for the OraQuick *ADVANCE*® product.

We currently distribute our OraQuick® test in several foreign countries. We expect the number of countries to increase as we find new distributors, complete registrations in additional countries and obtain a CE mark for this product.

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.

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

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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 recently acquired Altrix HealthCare, plc) and other distributors. In some cases, we assist our laboratory customers in customizing their testing services by selling them equipment required to test oral fluid specimens collected with the Intercept® device.

The forensic toxicology market in the United States for our substance abuse testing products consists of 250 300 laboratories including federal, state and county crime laboratories, medical examiner laboratories and reference laboratories. The criminal justice market consists of a wide variety of entities in the criminal justice system that require drug screening, such as pre-trial services, parole and probation officials, police forces, drug courts, prisons, drug treatment programs and community/family service programs.

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

Cryosurgical Systems

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

We sell Freeze Off®, a product similar to Histofreezer®, in the OTC market in the U.S. and Canada pursuant to a distribution agreement with Prestige Brands, the owner of the Compound W® line of wart removal products. 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. For a description of our pending dispute with Prestige Brands, see Item 3, Legal Proceedings, in this Annual Report.

Insurance Risk Assessment

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

We also maintain a direct sales force that promotes use of the OraSure® device directly to insurance companies for life insurance risk assessment. Insurance companies then make their own decision regarding which laboratory to use to supply their collection devices and testing services. Our OraSure® Western blot confirmatory test is distributed through BMX to laboratories and is used to confirm oral fluid specimens collected with our OraSure® device that initially test positive for HIV-1. For a description of BMX s recent election not to renew the Western blot agreements after December 31, 2007, see the Section entitled, Western blot HIV-1 Confirmatory Test, in this Annual Report.

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. However, our sales force continues to encourage additional insurance companies to use OraSure® and to extend the use of the product by existing customers. We believe there are several factors which could help expand the use of our device, including increasing acceptance of the reliability of oral fluid testing, the high quality of test results, the low cost of oral fluid testing relative to blood tests and the ease of use of the OraSure® device.

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 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 OraSure® and Intercept® oral fluid collection devices, cryosurgical systems products, and OraQuick® rapid HIV test accounted for total revenues of $15.1 million, $17.3 million and $25.6 million in 2006, $15.9 million, $22.7 million and $21.6 million in 2005, and $14.6 million, $20.2 million and $10.2 million in 2004, respectively. As new products are developed and commercialized, we expect to receive a greater portion of our revenues from these new products.

We currently have two customers, Quest and Abbott, which accounted for 14% and 10% of our total revenues, respectively, during 2006. 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.

Supply and Manufacturing

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

We can purchase the HIV antigen and the nitrocellulose required for the OraQuick® test only from a limited number of sources. The antigen is currently purchased from a single contract supplier under a long-term agreement with an initial term ending in January 2010 and one-year automatic renewal terms thereafter. The

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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 have purchased the antigen for this product from BMX on an exclusive basis. BMX is also the exclusive distributor of the Western blot test kits. Our agreements with BMX provide for the supply by BMX of the HIV-1 antigen and distribution of the oral fluid Western blot product by BMX on an exclusive worldwide basis. In March 2007, BMX notified us that it will not renew the agreements under which it supplies the HIV-1 antigen and distributes that product on an exclusive, world-wide basis, beyond December 31, 2007. For a further description of BMX s election not to renew the Western blot agreements, see the Section entitled, Western blot HIV-1 Confirmatory Test, in this Annual Report.

Histofreezer® is assembled in The Netherlands by Koninklijke, Utermöhlen, N.V. (Utermöhlen), the company from which we acquired the product in 1998. We purchase the product pursuant to an exclusive production agreement. Utermöhlen also supplies Freeze Off®, the OTC cryosurgical product for the U.S. and Canadian markets. Assuming minimum purchase requirements are met, our agreement with Utermöhlen will terminate at the end of 2008 with respect to the Histofreezer® product. The Utermöhlen agreement was scheduled to terminate at the end of 2006 with respect to the Freeze Off® product, subject to a minimum purchase requirement. However, we did not meet that requirement by the end of 2006 due to unexpectedly low purchases of the product by our distributor, Prestige. As a result, we expect to continue to purchase product for the U.S. OTC market from Utermöhlen for the foreseeable future. The cryosurgical wart removal products distributed in international 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, 2006, we had 250 full-time employees, including 66 in sales, marketing and client services; 26 in research and development; 105 in operations, manufacturing, quality control, information systems, purchasing and shipping; 19 in regulatory affairs and

quality assurance, and 34 in administration and finance. This compares to 233 employees as of December 31, 2005. Our employees are not currently represented by a collective bargaining agreement.

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Competition

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

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

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

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

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

We expect competition to intensify as technological advances are made and become more widely known, and as new products reach the market. Furthermore, new testing methodologies could be developed in the future that render our products impractical, uneconomical or obsolete. There can be no assurance that our competitors will not succeed in developing or marketing technologies and products that are more effective than

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

Several companies market or have announced plans to market oral specimen collection devices and tests both within and outside the United States. We expect the number of devices competing with our Intercept®, 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.

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Significant competitors for our OraQuick *ADVANCE*® rapid test, such as the Ortho Diagnostics division of Johnson & Johnson, Bio-Rad Laboratories, Abbott and BMX, 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 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 Chembio have received CLIA waivers for their rapid HIV tests, and these tests compete with our OraQuick *ADVANCE*® test in the markets outside of the traditional hospital and laboratory settings. These companies, or others, may continue to expand the bodily fluids with which a rapid HIV test may be performed, or develop and commercialize new rapid HIV tests, which would provide further competition for our OraQuick *ADVANCE*® test. We believe other companies may also seek FDA approval to sell competing rapid HIV tests in the future.

Internationally, our OraQuick *ADVANCE*® test competes against rapid HIV tests sold by a number of other entities, and often these competing tests are sold at prices substantially below the prices we charge for our OraQuick *ADVANCE*® test. 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 executed a letter of intent with Roche Diagnostics in October 2006 to enter into an agreement for the joint development and commercialization of fully-automated homogeneous oral fluid drugs of abuse assays for use with our Intercept® device. We expect final agreements with Roche to be executed during the first half of 2007.

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 assays developed internally by our laboratory customers (i.e., home brews), which can be produced at a cost lower than the price typically paid for our products. Many of our customers no longer purchase our AUTO-LYTE® assays, and we eventually expect to stop selling this product line.

The Histofreezer® product s delivery system and operating temperature, which is warmer than liquid nitrogen, provide us with the opportunity to target sales to primary care physicians, such as family practitioners, pediatricians and podiatrists. We do not generally target sales to dermatologists because they have the volume of

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patients required to support the capital costs associated with a liquid nitrogen delivery system, which is also used to remove warts and other benign skin lesions. There is limited competition for convenient cryosurgical products for wart removal in the primary care physician market. Major competitors for the Histofreezer® product include Cryosurgery, Inc. in the United States and Wartner in Europe. Wartner may also eventually compete with Histofreezer® in the physician market in the United States.

The Freeze Off® product, sold by Prestige under its Compound W® tradename, competes with other OTC wart removal products in the United States. Schering-Plough sells a competing cryosurgical wart removal product under its Dr. Scholl s brand and another competing cryosurgical wart removal product is sold in the OTC market under the Wartner® name. Wartner also sells a product that competes with our cryosurgical product in the European OTC footcare market. During 2006, Prestige acquired the Wartner® product sold in the United States and Canada, and we believe this action constitutes a material breach of our agreement with Prestige. For a further discussion of our dispute with Prestige regarding this matter, see Item 3, Legal Proceedings, in this Annual Report.

Q.E.D.® has two direct competitors, Ansys Technologies, Inc. and Chematics. These companies offer semi-quantitative saliva-based alcohol tests and have received DOT approval. Indirect competitors who offer breath testing equipment include Intoximeters, Dräger and CMI. Although there are lower priced tests on the market that use oral fluid or breath as a test medium, these tests are qualitative tests that are believed to be substantially lower in quality and provide fewer benefits than our Q.E.D.® test.

Patents and Proprietary Information

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

We have 16 United States patents and numerous foreign patents for the OraSure® and Intercept® collection devices and technology relating to oral fluid collection, containers for oral fluids, methods to test oral fluid, formulations for the manufacture of synthetic oral fluid, and methods to control the volume of oral fluid collected and dispersed. We have also applied for additional patents, in both the United States and certain foreign countries, on such products and technology.

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

We may need to obtain licenses or other rights under, or enter into distribution or other business arrangements in connection with, certain other intellectual property patents in order to manufacture and sell the OraQuick *ADVANCE*® test 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

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application related to these products. We have also licensed another patent relating to apparatuses and methods for the topical removal of skin lesions relating to our cryosurgical wart removal products.

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

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

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

We own rights to trademarks and service marks that we believe are necessary to conduct our business as currently operated. In the United States, we own the OraSure®, Intercept®, OraQuick®, OraQuick *ADVANCE*®, Histofreezer®, Q.E.D.® and AUTO-LYTE® trademarks. We also own many of these marks and others in several foreign countries. The Compound W® and Freeze Off® trademarks are owned by Prestige, or its affiliates, in the United States and Canada, 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 in Mexico.

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

Government Regulation

General

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

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

Domestic Regulation

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

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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.

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

Every company that manufactures medical devices distributed in the United States must comply with the FDA s Quality System Regulations (QSRs). These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation and purchasing. In complying with QSRs, manufacturers must continue to expend time, money and effort in the area of production and quality assurance to ensure full technical compliance. Companies are also subject to other post-market and general requirements, including restrictions imposed on marketed products, promotional standards and requirements for recordkeeping and reporting of certain adverse reactions. If there are any modifications made to our marketed devices, a premarket notification or 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 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.

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International

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

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

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

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

Anti-Kickback Laws

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

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

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

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

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

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

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. We believe that we have complied with these laws and regulations in all material respects.

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

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

Regulatory Risks

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

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

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

The process of obtaining required approvals or clearances from governmental or public health agencies can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities and other costly, time- consuming procedures. 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 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.

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We are in the process of conducting clinical studies to support an application for FDA approval of our OraQuick *ADVANCE*® HIV-1/2 test for sale in the United States OTC market. We also expect to conduct clinical trials in support of our application for FDA approval of 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 and could 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 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 and we intend to CE mark our OraQuick *ADVANCE*® test and certain of our future products and are not aware of any material reason why we will be unable to do so. However, there can be no assurance that compliance with all provisions of the IVDD will be demonstrated and the CE mark will be obtained for all products that we desire to sell in the EU.

The Inability to Extend the Shelf Life of Our OraQuick ADVANCE® 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 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 *ADVANCE*® 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. If we are unsuccessful 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.

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

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

Although we believe that we have adequate processes in place to ensure compliance with these requirements, the FDA or other regulatory bodies could force us to stop manufacturing or selling our products if it concludes that we are out of compliance with applicable regulations. The FDA and other regulatory bodies could also require us to recall products if we fail to comply with applicable regulations, which could force us to stop manufacturing such products. 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.

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 2006, 2005 and 2004, we incurred $8.6 million, $5.3 million and $6.1 million, respectively, in research and development expenses. We expect to continue to incur significant costs from our research and development activities.

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

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

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

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

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

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

- Suitable acquisitions or investments may not be found or consummated on terms that are satisfactory to us;
- We may be unable to successfully integrate an acquired company s personnel, assets, management systems and technology into our business;
- Acquisitions may require substantial expense and management time and could disrupt our business;
- An acquisition and subsequent integration activities may require greater capital resources than originally anticipated at the time of acquisition;
- An acquisition may result in the incurrence of unexpected expenses, the dilution of our earnings or our existing stockholders percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business;

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

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

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

The occurrence of one or more of the above or other factors may prevent us from achieving all or a significant part of the benefits expected from an acquisition or investment. This may adversely affect our

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financial condition, results of operations and ability to grow our business or otherwise achieve our financial or strategic objectives.

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

The end-users of our products are expected to increasingly include hospitals, physicians and other healthcare providers. Use of our products could be adversely impacted if 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 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 net sales could be adversely affected. Failure to cost-effectively increase production volumes, if required, or lower than anticipated yields or production problems encountered as a result of changes that we or our suppliers make in our manufacturing processes to meet increased demand, could result in shipment delays or interruptions and increased manufacturing costs, which could also have a material adverse effect on our revenues and profitability.

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

Risks Relating to Collaborators

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

We have marketed many of our products by collaborating with laboratories, diagnostic companies and distributors. 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.

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We currently sell our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test to the diagnostics division of Abbott Laboratories for distribution into the United States hospital market on an exclusive basis. Abbott recently announced that it will sell a portion of its diagnostics business to General Electric (GE), including its rights to the OraQuick *ADVANCE*® product. This sale has not yet closed, and it is unclear what, if any, effect it may have on sales of our OraQuick *ADVANCE*® test in the hospital market.

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 our distributors and customers and require that they fulfill their contractual obligations, there can be no assurance that such companies will continue to purchase or distribute our products, maintain historic order volumes or otherwise meet their purchase or other obligations, or 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.

In September 2006, Prestige Brands, Inc., the domestic distributor of the Freeze Off® cryosurgical wart removal product, announced that it had acquired the Wartner® cryosurgical product, which directly competes with the Freeze Off® product in the United States and Canadian OTC markets. We believe this acquisition constitutes a material breach of our agreement with Prestige, and we are pursuing arbitration to resolve this matter. We believe we have already suffered significant damages from this breach and Prestige s actions may continue to impact future sales of the Freeze Off® product. If we are unable to successfully resolve this matter with Prestige or find an alternative arrangement for distributing our cryosurgical product into the United States and Canada OTC markets, our revenues could be negatively affected.

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 2007 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 to complete 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

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

BMX currently manufactures and sells 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 supplies the HIV-1 antigen used to manufacture our oral fluid Western blot HIV-1 confirmatory test and is the exclusive world-wide distributor of that product.

In late 2006, BMX announced that it will discontinue manufacturing the HIV-1 EIA screening test during 2007 and that, due to quality problems, it may have difficulty supplying this screening test prior to the time it ceases manufacturing. As a result, we are working with BMX, the FDA and CDC, our major laboratory customers and other potential suppliers to find or develop an alternative HIV-1 EIA screening test that can be used with oral fluid samples collected with our OraSure® device.

In March 2007, BMX notified us that it will 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 distributes that product on an exclusive, world-wide basis. As a result, these agreements will terminate on December 31, 2007. Pursuant to the terms of the antigen supply agreement, we have the right to purchase an additional two-year supply of the antigen following termination 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 will have a suffucient supply of HIV-1 antigen to meet the demand for our Western blot test for three to four years after the agreement terminates. We also intend to pursue a long-term supply agreement directly with the vendor (a former affiliate of BMX) used by BMX to manufacture the HIV-1 antigen. During 2006, sales of our oral fluid Western blot HIV-1 confirmatory test totaled approximately $330,000.

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 *ADVANCE*® HIV-1/2 test should we receive approval from the FDA for use in the United States OTC market. In order to successfully commercialize our OraQuick *ADVANCE*® test in the OTC market, we 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.

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

We Have a History of Losses Prior to 2005.

We achieved our first full years of profitability in 2005 and 2006. However, as of December 31, 2006, the Company had an accumulated deficit of $98.4 million.

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

- Creating market acceptance for and selling increasing volumes of our OraQuick *ADVANCE*® rapid HIV-1/2 antibody test, Intercept® drug testing product and OraSure® collection device;
- The degree to which certain of our new products may replace sales of our existing products and the financial impact of that change, including the degree to which our OraQuick *ADVANCE*® test will replace our OraSure® collection device for HIV-1 testing or sales of our cryosurgical wart removal products in the OTC market will replace sales of our Histofreezer® product to physicians offices or other professional markets;
- 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 *ADVANCE*® HIV-1/2 test for use in the OTC market and an OraQuick® HCV test for professional use;
- Achieving growth in sales of our wart removal products in the OTC market and selling other products, such as our OraQuick *ADVANCE*® HIV-1/2 test, in the OTC market;
- Whether we are able to find 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.

Even though we achieved profitability for 2005 and 2006, there can be no assurance that we will be able to sustain such profitability in the future.

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

As of December 31, 2006, we had federal net operating loss (NOL) carryforwards of $53.0 million for federal income tax purposes. The Tax Reform Act of 1986 contains provisions under Section 382 of the Internal

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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. If in the future we determine, based on our assessment of both positive and negative evidence, that it is more likely than not that we will not realize all or a portion of the deferred tax assets, we will record a valuation allowance on the deferred tax assets which would result in recognition of income tax expense.

We May Require Future Additional Capital.

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

- The costs and timing of the expansion of our manufacturing capacity;
- The success of our research and product development efforts;
- The magnitude of capital expenditures;
- Changes in existing and potential relationships with distributors and other business partners;
- The time and cost of obtaining regulatory approvals;
- The costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses;
- The costs and liability associated with patent infringement or other types of litigation;