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® te