ORASURE TECHNOLOGIES INC
Form S-3
July 03, 2003
Table of Contents

As filed with the Securities and Exchange Commission on July 3, 2003

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification Number)**

220 East First Street

Bethlehem, Pennsylvania 18015

(610) 882-1820

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant s Principal Executive Offices)

Jack E. Jerrett, Esquire

Senior Vice President, General Counsel and Secretary

OraSure Technologies, Inc.

220 East First Street

Bethlehem, Pennsylvania 18015

(610) 882-1820

(Name, Address, Including Zip Code, and Telephone Number,

Including Area Code, of Agent For Service)

COPIES TO:

Jeffrey P. Libson, Esquire

Steven J. Feder, Esquire

Pepper Hamilton LLP

400 Berwyn Park

899 Cassatt Road

Berwyn, PA 19312-1183

(610) 640-7800

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: *From time to time after the effective date of this Registration Statement, as determined by market conditions and other factors.*

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

Table of Contents

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered (1)	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee (3)
Common Stock, par value $.000001 per share (4)		
Preferred Stock, par value $.000001 per share		
Debt Securities		
Total	$ 75,000,000	$ 6,068

(1) There are being registered hereunder such indeterminate number of shares of common stock and preferred stock and such indeterminate principal amount of debt securities, as shall have an aggregate initial offering price not to exceed $75,000,000. If any debt securities are issued at an original issue discount, then the offering price of such debt securities shall be in such greater principal amount as shall result in an aggregate initial offering price not to exceed $75,000,000, less the aggregate dollar amount of all securities previously issued hereunder. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder. The securities registered also include such indeterminate amounts and numbers of common stock, preferred stock and debt securities as may be issued upon conversion of or exchange for preferred stock or debt securities that provide for conversion or exchange or pursuant to the antidilution provisions of any such securities.

(2) The proposed maximum aggregate offering price per class of security will be determined from time to time by the Registrant in connection with the issuance by the Registrant of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3 under the Securities Act of 1933, as amended.

(3) Calculated pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(4) Each share of the Registrant s common stock being registered hereunder, if issued prior to the termination by the Registrant of its rights plan, includes Series A preferred stock purchase rights. Prior to the occurrence of certain events, the Series A preferred stock purchase rights will not be exercisable or evidenced separately from the Registrant s common stock and have no value except as reflected in the market price of the shares to which they are attached.

Table of Contents

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

Table of Contents

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated July 3, 2003

PROSPECTUS

[GRAPHIC APPEARS HERE]

$75,000,000

Common Stock

Preferred Stock

Debt Securities

We may sell from time to time in one or more offerings, together or separately:

Common Stock

Preferred Stock

Debt Securities

in one or more series or issuances and their total offering price, in the aggregate, will not exceed $75,000,000. We will provide the specific terms of any securities we actually offer for sale in supplements to this prospectus. This prospectus may not be used to sell securities unless accompanied by a prospectus supplement. The net proceeds we expect to receive from such sales will be set forth in a prospectus supplement.

Our common stock is listed on the Nasdaq National Market under the symbol OSUR . On June 27, 2003, the reported last sale price of our common stock on the Nasdaq National Market was $7.77 per share. None of the other securities are currently publicly traded. We may sell these securities to or through underwriters and also to other purchasers or through agents. We will set forth the names of any underwriters or agents in the accompanying prospectus supplement.

Our principal offices are located at 220 East First Street, Bethlehem, Pennsylvania 18015, and our telephone number is (610) 882-1820.

INVESTING IN OUR SECURITIES INVOLVES RISKS. YOU SHOULD CAREFULLY CONSIDER THE RISK FACTORS BEGINNING ON PAGE 4 OF THIS PROSPECTUS BEFORE YOU DECIDE TO INVEST.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this Prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is July ____, 2003

Table of Contents

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus is part of a shelf registration statement that we filed with the Securities and Exchange Commission (the SEC). By using a shelf registration statement, we may sell, from time to time over the next two years, in one or more offerings, any combination of the securities described in this prospectus in a dollar amount that does not exceed $75,000,000. For further information about our business, and the securities, you should refer to the registration statement and its exhibits. The exhibits to our registration statement contain the full text of certain contracts and other important documents we have summarized in this prospectus. Since these summaries may not contain all the information that you may find important in deciding whether to purchase the securities we may offer, you should review the full text of these documents. The registration statement can be obtained from the SEC as indicated under the Section entitled, Where You Can Find More Information.

You should rely only on the information contained or incorporated by reference in this prospectus and the prospectus supplement. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We will not make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, as well as information we previously filed with the SEC and incorporated by reference in this prospectus, is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

Table of Contents

WHO WE ARE

General

As the market leader in oral fluid diagnostics, we develop, manufacture and market oral fluid specimen collection devices using our proprietary oral fluid technologies. In addition, we manufacture and sell proprietary diagnostic products including *in vitro* diagnostic tests, and other medical devices. Our diagnostic products include tests which are processed in a laboratory and tests which are performed on a rapid basis and read at the point of care. These products are sold in both the United States and certain foreign countries to various distributors, government agencies, clinical laboratories, physicians offices, hospitals, and commercial and industrial entities.

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 or diseases. *In vitro* diagnostic tests are performed outside the body, in contrast to *in vivo* tests, which are performed directly on or within the body.

Products

Our business includes the following principal products: (1) the OraQuick® rapid HIV-1 antibody test; (2) the OraSure® and Intercept® oral fluid collection devices; and (3) the Histofreezer® portable cryosurgical system. In addition, we sell certain immunoassay tests and reagents for insurance risk assessment, substance abuse and forensic toxicology applications; an oral fluid Western blot HIV-1 confirmatory test; and the Q.E.D.® saliva alcohol test.

OraQuick®. OraQuick® is the only rapid, point-of-care test for HIV-1 (the virus that causes AIDS) that has received U.S. Food and Drug Administration (FDA) approval and a waiver under the Clinical Laboratory Improvements Amendments of 1988 (CLIA). The OraQuick® test does not require a laboratory as it can be visually read at the point of care in approximately 20 minutes after the sample is collected. The initial FDA approval permits the use of the test in detecting antibodies to HIV-1 in finger stick whole blood samples. However, this test is designed for use with oral fluid (or saliva), venous whole blood and plasma samples as well. We have submitted an application for FDA approval of a venous whole blood claim and are currently performing clinical trials and intend to submit FDA applications later in 2003 for oral fluid and plasma claims.

Our OraQuick® test can be used by approximately 180,000 sites in the United States, including hospitals, outreach clinics, community-based organizations and physicians offices. OraQuick® is sold directly by OraSure Technologies primarily into the public health market, to the military and the Centers for Disease Control and Prevention, and to certain international markets. This product is also distributed indirectly in the United States through Abbott Laboratories on a co-exclusive basis with OraSure. Abbott is focusing its sales efforts primarily on the hospital and physicians office markets.

OraSure® and Intercept®. OraSure® is the only collection device approved by the FDA for the detection of antibodies to HIV-1 in a sample of oral fluid. We have also obtained FDA clearance for the use of this product for detecting cocaine and cotinine (an indicator for the use of nicotine) in oral fluid. Samples collected with an OraSure® device are processed in a laboratory. If an oral fluid sample tests positive for antibodies to HIV-1, this result must be confirmed with our oral fluid Western blot confirmatory test, which is the only HIV-1 confirmatory test approved by the FDA for use with oral fluid. The OraSure® device is sold predominantly in the insurance market for the screening of life

insurance applicants, in physicians offices and in the public health market.

A collection device that is substantially similar to the OraSure® device is marketed under the name Intercept®. This device and the associated oral fluid immunoassays constitute the only laboratory-based oral fluid drug test that has been cleared by the FDA. The Intercept® device is used to collect oral fluid to be tested for various drugs, such as marijuana, cocaine, opiates, amphetamines, methamphetamines, phencyclidine (PCP), benzodiazepines, barbiturates, and methadone. Intercept® is used primarily by companies to test their employees and prospective employees, in the

Table of Contents

criminal justice system for testing prison inmates, arrestees and parolees, and in drug treatment and community/family service programs.

Histofreezer®. The Histofreezer® product is an alternative to liquid nitrogen treatment for the removal of warts and other benign skin lesions by freezing. We sell our Histofreezer® product through a dealer network in more than 20 countries worldwide, with most of our revenues coming from sales in the United States to family doctors, pediatricians and podiatrists. By using our Histofreezer® product, these medical professionals can treat warts and other skin lesions for patients that would otherwise need to be referred to a dermatologist for treatment.

We are expanding our Histofreezer® marketing and sales efforts in the professional markets through the engagement of specialized sales forces which will target obstetricians, gynecologists and family physicians. In addition, in April 2003, we entered into an agreement with the maker of the Compound W® line of wart removal products to distribute Histofreezer® under the trade name Freeze Off® into the over-the-counter market in the United States.

Other Information

Our Company was formed in May 2000 under Delaware law solely for the purposes of combining two companies, STC Technologies, Inc. and Epitope, Inc., 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. Our telephone number is (610) 882-1820, and our website address is http://www.orasure.com. Information contained on our website is not incorporated into this registration statement.

Table of Contents

RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones facing our Company. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our common stock or other securities could decline due to any of these risks, and you may lose all or part of your investment.

This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us and described below or elsewhere in this prospectus.

Regulatory Risks

The Time Needed 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. For example, we are seeking FDA approval for the use of the OraQuick® rapid HIV-1 antibody test on venous whole blood samples and intend to pursue approval of claims for oral fluid and plasma samples. Approval of these claims will include the submission of clinical data and could require significant time to obtain. The submission of an application to the FDA or other regulatory authority for these or other claims 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.

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 and increases the risk that we will not succeed in introducing or selling them in the United States or other countries.

At the present time, we have received FDA clearance or approval for the OraSure® and Intercept® oral fluid collection devices, the OraQuick® rapid HIV-1 antibody test (for use with finger-stick whole blood samples only), the UP*link* drug testing system and opiates assay, the Histofreezer® portable cryosurgical system (in both the professional and over-the-counter markets), the Q.E.D.® saliva alcohol test, the OraSure® oral fluid Western blot HIV-1 confirmatory test, and various other tests.

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, the Substance Abuse and Mental Health Services Administration (SAMHSA), which is part of the U.S. Department of Health and Human Services, is in the process of drafting regulations for the use of oral fluid drug testing for federal workers. Although we believe the SAMHSA regulations, when issued in final form, will permit us to market and sell our oral fluid drug tests for use with federal workers, there is no guarantee that those regulations will do so, and our ability to sell those products in that market could be limited.

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

Table of Contents

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 European Union (EU) must bear the CE mark indicating conformance with the essential requirements of the In Vitro Diagnostic Directive (IVDD). The deadline for meeting this requirement is December 7, 2003. We will not be permitted to sell our products in the EU without a CE mark after this date, which could lead to the termination of strategic alliances and agreements for sales of those products in the EU. While we intend to CE mark certain existing and future products, and are not aware of any material reason why we will be unable to do so, there can be no assurance that compliance with all provisions of the IVDD will be demonstrated and the CE mark obtained prior to the deadline. The OraSure® and Intercept® collection devices (collection pad only) and Histofreezer® product currently bear the CE mark.

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

We can manufacture and sell many of our products, both in the United States and in some cases abroad, 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.

During 2000, the FDA issued warning letters with respect to our serum Western blot HIV-1 confirmatory test, stating that we were not in compliance with the FDA s regulations. We have responded to each of these letters and voluntarily discontinued this product. The concerns raised by the FDA also applied to the production of our oral fluid Western blot HIV-1 confirmatory test, which we still manufacture in Oregon. Although we believe that we have satisfactorily addressed the points raised by the FDA, the FDA could force us to stop manufacturing products at our Oregon facility if the FDA concludes that we remain out of compliance with applicable regulations. In addition, if the FDA were to find that we are not in compliance with applicable regulations at our manufacturing facilities in Bethlehem, Pennsylvania, we could be forced to stop manufacturing products at those locations as well. The FDA could also require us to recall products if we fail to comply with applicable regulations, which could force us to stop manufacturing such products.

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

We Have a History of Losses.

We have not achieved full-year profitability. We incurred net losses of approximately $3.3 million, $3.7 million, $12.7 million and $1.1 million, in 2002, 2001 and 2000 and for the three months ended March 31, 2003, respectively. As of March 31, 2003, the Company had an accumulated deficit of approximately $130.5 million.

Our limited combined operating history makes it difficult to forecast our future operating results. In order to achieve sustainable profitability, our revenues will have to continue to grow at a significant rate. However, our revenues have remained essentially flat during the past two years.

Our ability to achieve revenue growth, and therefore profitability, will be dependent upon a number of factors including, without limitation, the following:

Creating market acceptance for and selling increasing volumes of the OraSure® collection device, the Intercept® and UP*link* drug testing products, and the OraQuick® rapid HIV-1 antibody test;

The degree to which certain of our new products may replace sales of our existing products and the financial impact of that change, including the degree to which our OraQuick® test will replace our OraSure® collection device for HIV-1 testing or sales of the Freeze Off® wart removal product in the over-the-counter market will replace sales of our Histofreezer® product to physicians offices or other professional markets;

Achieving growth in sales of the Freeze Off® wart removal product in the over-the-counter market;

Achieving growth in international markets with our OraQuick® rapid HIV-1 antibody test and other products; and

Table of Contents

Commercially developing, and obtaining regulatory approval and creating market acceptance for, our Up-converting Phosphor Technology, (UPT), the UP*link* drugs-of-abuse rapid detection system, and other new products in a time frame consistent with our objectives.

We have not yet fully achieved these objectives and there can be no assurance that we will be able to do so. Moreover, even if we achieve our objectives and become profitable, there can be no assurance that we will be able to sustain such profitability in the future.

Our Reported Financial Results May be Adversely Affected by Changes in Accounting Principles Generally Accepted in the United States.

We prepare our financial statements in conformity with accounting principles generally accepted in the United States. These accounting principles are subject to interpretation by the Financial Accounting Standards Board (FASB), the American Institute of Certified Public Accountants, the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change.

For example, while current accounting rules allow us to exclude the expense of stock options granted to our employees from our financial statements, influential legislators and business policy groups have suggested that the rules be changed to require those options to be expensed. We rely on stock options as an important component of our employee compensation packages. As of April 22, 2003, the FASB had decided to require companies to expense the value of employee stock options and is expected to issue formal guidance on this matter later in 2003 that could become effective in 2004.

If we are required to expense stock options, we may be less likely to achieve profitability, or we may have to decrease or eliminate option grants. Decreasing or eliminating option grants may adversely impact our ability to attract and retain qualified employees.

We May Require Future Additional Capital to Fund Our Operations.

Although we have made significant progress in the past toward controlling expenses and increasing product revenue, we have historically depended, to a substantial degree, on capital raised through the sale of equity securities and bank borrowings to fund our operations.

Our future liquidity and 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 scope and results of clinical testing;

The magnitude of capital expenditures;

Changes in existing and potential relationships with business partners;

The time and cost of obtaining regulatory approvals;

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

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

The timing of the commercial launch of new products;

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

Competing technological and market developments; and

The scope and timing of strategic acquisitions.

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

Table of Contents

The Recent Economic Downturn and Terrorist Attacks May Adversely Affect Our Business.

Since the September 11, 2001 terrorist attacks, the United States economy has experienced a decline. Changes in economic conditions could adversely affect our business. For example, in a difficult economic environment, customers may be unwilling or unable to invest in new diagnostic products, may elect to reduce the amount of their purchases or may perform less drug testing because of declining employment levels. A weakening business climate could also cause longer sales cycles and slower growth, and could expose us to increased business or credit risk in dealing with customers adversely affected by economic conditions.

The terrorist attacks and subsequent governmental responses to these attacks could cause further economic instability or lead to further acts of terrorism in the United States and elsewhere. These actions could adversely affect economic conditions outside the United States and reduce demand for our products internationally. Terrorist attacks could also cause regulatory agencies, such as the FDA or agencies that perform similar functions outside the United States, to focus their resources on vaccines or other products intended to address the threat of biological or chemical warfare. This diversion of resources could delay our ability to obtain regulatory approvals required to manufacture, market or sell our products in the United States and other countries.

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 Treatment 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. Our principal competitors often 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.

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 HIV or 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 or 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, if at all, and we may have to abandon a product in which we have invested substantial amounts.

During 2002, 2001 and 2000, we incurred $8.3 million, $9.4 million and $10.4 million, respectively, in research and development expenses. During the three months ended March 31, 2003, we incurred $2.1 million in research and development expenses. We expect to continue to incur significant costs from our research and development activities.

A primary focus of our efforts has been, and is expected to continue to be, our UPT technology and the related UP*link* rapid detection system, which are still under development. However, there can be no assurance that we will succeed in our research and development efforts with respect to UPT, UP*link* or other technologies or products.

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

Table of Contents

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.

We May be Sued for Product Liabilities for Injuries Resulting From the Use of Our Diagnostic Products.

We may be held liable if any of our products, or any product which is made with the use or incorporation of any of our technologies, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. Although we have obtained product liability insurance, this insurance may not fully cover potential liabilities. As we bring new products to market, we may need to increase our product liability coverage. We have obtained the required regulatory approvals to sell our Histofreezer® portable cryosurgical system in the consumer or over-the-counter market. We believe the sale of this or other products in the over-the-counter market could increase the risk of potential product liability exposure and the required level of insurance coverage that we will need to maintain. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could affect our decision to commercialize new products.

Efforts to Consolidate or Restructure Could Adversely Affect Our Business.

We may from time to time restructure and consolidate various aspects of our operations in order to achieve cost savings and other efficiencies. For example, during 2001 we began a restructuring of our manufacturing operations which included the transfer of OraQuick® manufacturing from our Beaverton, Oregon facility to Bethlehem, Pennsylvania. In addition, we plan to close our Oregon facility and transfer all remaining manufacturing operations and research and development activities in that facility related to the oral fluid Western blot HIV-1 confirmatory test, along with our contract manufacturing operations for the OraSure® and Intercept® collection devices, to our facilities in Pennsylvania. We must obtain FDA approval to transfer certain operations to another location. This transfer and the need to obtain FDA approval could interfere with or delay our manufacturing processes and disrupt continued operations. Any delay in or disruption of operations, and in particular manufacturing operations, could result in increased costs or could delay or prevent us from selling certain products and thereby result in a loss of revenue.

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;

Table of Contents

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 to be derived from an acquisition could be affected by other factors, such as regulatory developments, general economic conditions and increased competition; and

An acquisition of a foreign business may involve additional risks, including not being able to successfully assimilate differences in foreign business practices or overcome language barriers.

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

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. For example, our OraSure® oral fluid collection device is distributed to the insurance industry through major insurance testing laboratories. Our sales depend to a substantial degree on our ability to sell products to these customers and develop new product distribution channels, and on the marketing abilities of the companies with which we collaborate.

Some of our distributors have recently consolidated, and such consolidation has had, and may continue to have, an adverse impact on the level of orders for our products. One of these laboratories, Lab*One*, Inc., acquired another large insurance laboratory customer, Osborne Group, Inc., in 2001. These customers together accounted for approximately 26%, 29% and 30% of our revenues for the years 2002, 2001, and 2000, respectively. As a result of efficiencies gained following this acquisition, Lab*One* purchased approximately $1 million less of our insurance assays in 2002 than both companies purchased in 2001.

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, Lab*One* and our other insurance testing laboratories are facing this pressure and are using lower cost insurance testing assays that they have developed internally or purchased from our competitors. This has reduced our sales of insurance assays and is expected to lower sales of these products in 2003 and beyond.

Although we will try to maintain and expand our business with our distributors, there can be no assurance that such companies will continue to purchase or distribute our products or maintain historic order volumes, or that new distribution channels will be available on satisfactory terms.

Table of Contents

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

We currently purchase certain critical components of our products from sole supply sources. For example, all of the HIV-1 antigen used to make our oral fluid Western blot HIV-1 confirmatory test is purchased from bioMerieux, Inc. (BMX), and all of the HIV antigen and nitrocellulose required to make our OraQuick® rapid HIV-1 antibody test is purchased from sole source suppliers. If these suppliers are unable or unwilling to supply the required component, we would need to find another source, and perform additional development work and obtain FDA approval for the use of the alternative component for our products. Completing that development and obtaining such FDA approval could require significant time to complete and may not occur at all. These events could either disrupt our ability to manufacture and sell certain of our products or completely prevent us from doing so. Either event would 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 screening test approved by the FDA for use with our OraSure® device. Where an oral fluid sample screens positive for HIV-1, our customers must then use our oral fluid Western blot HIV-1 confirmatory test, which has also been approved by the FDA for use with our OraSure® device, to confirm that positive indication.

BMX (bioMerieux, Inc.) manufactures and sells the only oral fluid HIV-1 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 has developed a new HIV-1 screening test, and has indicated that this new test will eventually replace its existing FDA-approved HIV-1 screening test. We are working with BMX to obtain FDA approval for use of the new screening test with our OraSure® 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.

If BMX ceases to manufacture or sell an HIV-1 screening test approved by the FDA for use with our OraSure® collection device, or if our oral fluid Western blot HIV-1 confirmatory test is not made available to our customers (because BMX either fails to supply the HIV-1 antigen required to make this product or fails to distribute this product), we would need to find alternate suppliers for these products, which would require additional development work and FDA approval. These activities would likely require significant time to complete. If our customers cannot obtain an HIV-1 screening test or Western blot HIV-1 confirmatory test that has been approved by the FDA for use in connection with our OraSure® collection device, these customers would likely stop purchasing our OraSure® device. Sales of the OraSure® device were approximately $12.7 million and $11.5 million, or 40% and 35% of our total revenues, in 2002 and 2001, respectively.

We Are Dependent Upon 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. In particular, our strategy for development and commercialization of UPT, including the UP*link* rapid detection system, and certain other products may entail entering into additional 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, 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.

Risks Relating to Intellectual Property

Our Success Depends on Our Ability to Protect Our Proprietary Technology.

The diagnostics industry places considerable importance on obtaining patent, trademark, and trade secret protection, as well as other intellectual property rights, for new technologies, products and processes. Our success

Table of Contents

depends, in part, on our ability to develop and maintain a strong intellectual property portfolio or obtain licenses to patents for products and technologies both in the United States and in other countries.

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

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

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

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

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

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

The Sales Potential for OraQuick® Will be Affected by Our Ability to Obtain Certain Licenses.

There are several factors that will affect the specific countries in which we will be able to sell our OraQuick® rapid HIV antibody test and therefore the overall sales potential of the test. One factor is whether we can arrange a sublicense or distribution agreement related to patents for detection of the HIV-2 virus. HIV-2 is a type of the HIV virus estimated to represent a small fraction of the known HIV cases worldwide. Nevertheless, HIV-2 is considered to be an important component in the testing regimen for HIV in many markets. HIV-2 patents are in force in the United States, Canada and Mexico, in most of the countries of Western Europe, and in Japan, Korea, South Africa, and Australia. Access to a license for one or more HIV-2 patents may be necessary to sell HIV-2 tests in countries where such patents are in force, or to manufacture in countries where such patents are in force and then sell into non-patent markets.

The importance of HIV-2 differs by country, and can be affected by both regulatory requirements and by competitive pressures. Because the competitive situation in each country will be affected by the availability of other testing products as well as the country s regulatory environment, we may be at a competitive disadvantage in some markets without an HIV-2 product. In particular, our ability to sell a product that does not include an HIV-2 test may be limited, or a competitor s product that includes an HIV-2 test may be preferred and have a competitive advantage over an HIV-1 only test that we sell.

Another factor that may affect the specific countries in which we will be able to sell an OraQuick® rapid HIV-1 or HIV-2 test, and therefore the overall sales potential, concerns whether we can arrange a sublicense or distribution

Table of Contents

agreement related to any patents which claim lateral flow assay methods and devices covering the OraQuick® rapid HIV antibody tests or their use. OraQuick® is a lateral flow assay device that tests for specific antibodies or other substances. The term lateral flow generally refers to a test strip through which a sample flows and which provides a test result on a portion of the strip downstream from where the sample is applied. There are numerous patents in the United States and other countries which claim lateral flow assay methods and devices. Some of these patents may broadly cover the technology used in the OraQuick® test and are in force in the United States and other countries. We may not be able to make the OraQuick® test in the United States and sell it in countries where there is no patent on the device. We have obtained licenses under several lateral flow patents, which we believe should be sufficient to permit the manufacturing and sale of the OraQuick® device as currently contemplated. However, licenses under additional patents may be required.

In the event that it is determined that a license is required and it is not possible to negotiate a license agreement under a necessary patent, we may be able to modify the OraQuick® rapid HIV antibody test such that a license would not be necessary. However, this alternative could delay or limit our ability to sell the OraQuick® rapid HIV antibody test in the United States and other markets, which would adversely affect our results of operations, cash flows and business.

We are Dependent Upon Patents, Licenses and Other Proprietary Rights From Third Parties, Including Rights to Up-Converting Phosphor Compositions, Methods and Apparatuses.

We have licensed the worldwide rights to UPT compositions, methods and apparatuses for use in diagnostic applications, which are the subject of numerous United States patents and several pending United States applications. Corresponding patents and patent applications have been granted, issued or filed in numerous foreign countries, including, for example, European countries, Japan and Canada. We cooperate with the licensor to prosecute such patent applications and protect such patent rights. If the licensors do not meet their obligations under the license agreements or do not reasonably consent to sublicenses by us, or if the license agreement is terminated, we could lose the opportunity to develop UPT.

Risks Relating to Product Marketing and Sales

A Market for Our Products May Not Develop.

Our future success will depend, in part, on the market acceptance, and the timing of such acceptance, of new products such as the Intercept® drug test, the OraQuick® rapid HIV-1 antibody test, products currently under development such as the UP*link* drugs of abuse rapid detection system and other products using the UPT technology, and other new products or technologies that may be developed or acquired and introduced in the future. To achieve market acceptance, we must make substantial marketing efforts and spend significant funds to inform potential customers and the public of the perceived benefits of these products. We currently have limited evidence on which to evaluate the market reaction to products that may be developed, and there can be no assurance that any products will meet with market acceptance and fill the market need that is perceived to exist.

If Acceptance and Adoption of Our Oral Fluid Testing in the Market Does Not Continue, Our Future Results May Suffer.

We have made significant progress in gaining acceptance of oral fluid testing for HIV in the insurance and public health markets. We have also made significant progress in gaining acceptance of oral fluid testing for drugs of abuse in the workplace and criminal justice testing markets.

However, the ultimate degree of acceptance in these markets is uncertain, and other markets may resist the adoption of oral fluid HIV testing as a replacement for other testing methods in use today. In addition, certain state laws prohibit or restrict the use of oral fluid testing for drugs of abuse in certain markets. As a result, there can be no assurance that we will be able to expand the use of our oral fluid testing products in these or other markets.

Table of Contents

Our Increasing International Presence May be Affected by Regulatory, Cultural or Other Restraints.

We intend to increase international sales of our products. Our international sales accounted for approximately $3.9 million or 12% of total revenues for 2002, approximately $5.3 million or 16% of total revenues for 2001, and approximately $4.0 million or 14% of total revenues for 2000.

A number of factors can slow or prevent international sales, or substantially increase the cost of international sales, including those set forth below:

- Regulatory requirements (including compliance with applicable customs regulations) may slow, limit, or prevent the offering of products in foreign jurisdictions;
- The unavailability of licenses to certain patents in force in a foreign country which cover our products may restrict our ability to sell into that country;
- Our inability to obtain the CE mark on our products in a timely manner may preclude or delay our ability to sell products to the European Union;
- Cultural and political differences may make it difficult to effectively market, sell and gain acceptance of products in foreign jurisdictions;
- Inexperience in international markets may slow or limit our ability to sell products in foreign countries;
- Exchange rates, currency fluctuations, tariffs and other barriers, extended payment terms and dependence on and difficulties in managing international distributors or representatives may affect our revenues even when product sales occur;
- The creditworthiness of foreign entities may be less certain and foreign accounts receivable collection may be more difficult;
- Economic conditions, the absence of available funding sources, terrorism, civil unrest and war may slow or limit our ability to sell our products in foreign countries;
- International markets often have long sales cycles, especially sales to foreign governments, quasi-governmental agencies and international public health agencies, thereby delaying or limiting our ability to sell our products; and
- We may be at a disadvantage if competitors in foreign countries sell competing products at prices at or below such competitors or our cost.

In February 2000, we entered into an agreement for the distribution of our OraQuick® rapid HIV antibody test in a number of African countries. Because of the lack of funding sources in those countries for the purchase of our product and other factors, our distributor failed to meet its minimum purchase commitments under our agreement. As a result, we were forced to write-off approximately $0.6 million of OraQuick®

inventory initially manufactured in contemplation of sales to this distributor.

In addition, we have entered into a contract for the manufacture and supply of the OraQuick® rapid HIV antibody test in Thailand. However, we do not have significant direct experience with the use of international manufacturers. Factors such as economic and political conditions and foreign regulatory requirements may slow or prevent the manufacture and distribution of our products in countries other than the United States. Interruption of the supply of our products could reduce revenues or cause us to incur significant additional expenses in finding an alternative source of supply.

Table of Contents

Risks Related to this Offering

Applicable law, our charter, our bylaws and preferred stock purchase rights may delay or prevent a change in control or the removal of our current management.

Our board has the authority to issue up to 25,000,000 shares of preferred stock and to determine the price, privileges and other terms of such shares. Our board may exercise this authority without the approval of, or notice to, our stockholders. Accordingly, the rights of the holders of our common stock may be adversely affected by the rights of the holders of any preferred stock that may be issued in the future. In addition, the issuance of preferred stock may make it more difficult for a third party to acquire a majority of our outstanding voting stock in order to effect a change in control or replace our current management.

We are also subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. The application of Section 203 could also delay or prevent a third party or a significant stockholder of ours from acquiring control of us or replacing our current management. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder, unless the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns 15% or more of a corporation s voting stock.

In May 2000, our board of directors adopted a plan that grants each holder of our common stock the right to purchase shares of our series A preferred stock. This plan is designed to help insure that all our stockholders receive fair value for their shares of common stock in the event of a proposed takeover of us, and to guard against the use of partial tender offers or other coercive tactics to gain control of us without offering fair value to the holders of our common stock.

In addition, there are provisions in our charter and bylaws, such as a staggered board and significant notice provisions for nominations of directors and proposals for consideration at a meeting of our stockholders. The stockholder rights plan and our charter and bylaws may make it more difficult for a third party to acquire a majority of our outstanding voting stock in order to effect a change in control or replace our current management.

Our stock price could continue to be volatile.

Our stock price has been volatile. For example, since July 1, 2001, the market price of our common stock has fluctuated between $15.00 and $3.33, and since July 1, 2002, the market price of our common stock has fluctuated between $8.62 and $3.33.

The following factors, among others, could have a significant impact on the market for our common stock:

- future announcements concerning us;

future announcements concerning our competitors or industry;

governmental regulation;

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

developments in patent or other proprietary rights;

litigation or public concern as to the safety of products that we or others have developed;

the relatively low trading volume for our common stock;

period to period fluctuations in our operating results;

Table of Contents

changes in estimates of our performance by securities analysts;

general market and economic conditions; and

terrorist attacks, civil unrest and war.

The issuance of additional equity securities may have a dilutive effect on our existing stockholders and could lead to a decline in the price of our common stock.

Any additional sale of equity securities may have a dilutive effect on our existing stockholders. In addition, the perceived risk associated with the possible sale of a large number of shares could cause some of our stockholders to sell their stock, thus causing the price of our stock to decline. Subsequent sales of our common stock in the open market or the private placement of our common stock or securities convertible into common stock could also have an adverse effect on the market price of the shares. If our stock price declines, it may be more difficult or we may be unable to raise additional capital.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in the Sections entitled, Who We Are and Risk Factors, and elsewhere in this prospectus, constitute forward-looking statements. These statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry s results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, those listed under the Section entitled, Risk Factors, and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terminology such as may, will, should, intend, expect, plan, anticipate, believe, estimate, predict, potential, or continue or the negative of such terms terminology.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance, or achievements. We do not assume responsibility for the accuracy and completeness of the forward-looking statements. We do not intend to update any of the forward-looking statements after the date of this prospectus to conform them to actual results, except as required by the federal securities laws.

RATIO OF EARNINGS TO FIXED CHARGES

Earnings were insufficient to cover fixed charges by approximately the following amounts for the periods ended as set forth below (in thousands):

	Three Months Ended	Fiscal Year Ended December 31,			Three Months Ended December 31,	Fiscal Year Ended September 30,	
	March 31, 2003	2002	2001	2000	1999	1999	1998
Deficiency of earnings to cover fixed charges	$ 1,087,981	$ 3,342,473	$ 3,699,000	$ 12,722,187	$ 421,287	$ 4,183,264	$ 2,374,146

Fixed charges consists of interest expense plus the portion of rent expense under operating leases deemed by us to be representative of the interest factor.

Our Company was formed in May 2000, for the purpose of combining two companies, STC Technologies, Inc. (STC) and Epitope, Inc. (Epitope). On September 29, 2000, STC and Epitope were merged into our Company. The merger was accounted for as a pooling of interests and, accordingly, all prior period financial statements of Epitope have been restated to include the results of STC. The above financial data for each of the years ended September 30, 1999 and 1998 include Epitope s previous September 30 fiscal year amounts and STC s December 31 calendar year amounts. On September 29, 2000, the Company changed its fiscal year-end from September 30 to December 31, effective with the calendar year beginning January 1, 2000. A three-month transition period from October 1, 1999 through December 31, 1999 preceded the start of the 2000 fiscal year. As a result of the merger, financial statements for the three-month period ended December 31, 1999 include amounts for Epitope and STC for the three months ended December 31, 1999. Accordingly, STC s results of operations for the three months ended December 31, 1999 are included in both the financial statements for the year ended September 30, 1999 and for the three-month transition period ended December 31, 1999.

We would have had to generate additional earnings of approximately $1,088,000 for the three-month period ended March 31, 2003 to achieve an earnings to fixed charges ratio of 1:1.

Table of Contents

USE OF PROCEEDS

Except as otherwise described in the applicable prospectus supplement, the net proceeds from the sale of the securities offered hereunder will be added to our general funds and used for general corporate purposes, which may include, but are not limited to:

- ongoing research and development activities;
- commercialization of new products;
- potential acquisitions;
- capital expenditures;
- patent license fees;
- debt service and retirement; and
- general working capital.

The amounts and timing of our actual expenditures for each purpose may vary significantly depending upon numerous factors, including the status of our research and product development efforts, regulatory approvals, competition, marketing and sales activities, the market acceptance of any products introduced by us and economic or other conditions. Pending such uses, we intend to invest the net proceeds of this offering in short-term, investment grade, interest-bearing securities.

THE SECURITIES WE MAY OFFER

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. We will also include in the prospectus supplement information, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange or market, if any, on which the securities will be listed.

We may sell from time to time, in one or more offerings:

- common stock;

preferred stock; and/or

debt securities.

In this prospectus, we will refer to the common stock, preferred stock and debt securities collectively as securities. The total dollar amount of all securities that we may issue will not exceed $75,000,000.

If we issue debt securities at a discount from their original stated principal amount, then, for purposes of calculating the total dollar amount of all securities issued under this prospectus, we will treat the initial offering price of the debt securities as the total original principal amount of the debt securities.

Table of Contents

DESCRIPTION OF COMMON STOCK AND PREFERRED STOCK

The following description of our common stock and preferred stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future common stock or preferred stock that we may offer, we will describe the particular terms of any series of these securities in more detail in the applicable prospectus supplement.

Under our certificate of incorporation, our authorized capital stock consists of 120,000,000 shares of common stock, par value $0.000001 per share, and 25,000,000 shares of preferred stock, par value $0.000001 per share. As of June 27, 2003, we had 38,470,426 shares of common stock outstanding and no shares of preferred stock outstanding. As of June 27, 2003, we had reserved for issuance 120,000 shares of series A preferred stock in connection with our stockholder rights plan (described below). As of the date of this prospectus, we have not issued any shares of our series A preferred stock.

Common Stock

Voting. For all matters submitted to a vote of stockholders, each holder of common stock is entitled to one vote for each share registered in his or her name. Subject to applicable law and any preferential rights we may grant to the holders of preferred stock, if any is outstanding, holders of our common stock will have all voting power. Our common stock does not have cumulative voting rights. As a result, subject to the voting rights of any outstanding preferred stock, of which there currently is none, persons who hold more than 50% of the outstanding common stock entitled to elect members of our board of directors can elect all of the directors who are up for election in a particular year.

Dividends. If our board of directors declares a dividend, holders of common stock will receive payments from our funds that are legally available to pay dividends. However, this dividend right is subject to any preferential dividend rights we may grant to the holders of preferred stock, if any is outstanding.

Liquidation and Dissolution. If we are liquidated or dissolve, the holders of our common stock will be entitled to share ratably in all the assets that remain after we pay our liabilities and any amounts we may owe to the holders of preferred stock, if any is outstanding.

Other Rights and Restrictions. Holders of our common stock do not have preemptive rights, and they have no right to convert their common stock into any other securities. Our common stock is not subject to redemption by us. The rights, preferences and privileges of holders of our common stock are subject to the rights of the holders of any series of preferred stock which we may designate in the future. Our certificate of incorporation and bylaws do not restrict the ability of a holder of common stock to transfer his or her shares of common stock. When we issue shares of common stock under this prospectus, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

Listing. Our common stock is listed on the Nasdaq National Market under the symbol OSUR.

Transfer Agent and Registrar. The transfer agent and registrar for our common stock is Mellon Investor Services LLC.

Preferred Stock

General. Our certificate of incorporation authorizes the issuance of up to 25,000,000 shares of preferred stock, par value $0.000001 per share. We have reserved for issuance 120,000 shares of series A preferred stock in connection with our stockholder rights plan. We may issue, from time to time in one or more series, up to 24,880,000 shares of preferred stock, the terms of which may be determined at the time of issuance by our board of directors, without further action by our stockholders, and may include voting rights, preferences as to dividends and liquidation, conversion rights,

Table of Contents

redemption rights and sinking fund provisions. The shares of each series of preferred stock shall have preferences, limitations and relative rights, including voting rights, identical with those of other shares of the same series and, except to the extent provided in the description of such series, of those of other series of preferred stock.

The issuance of any preferred stock could adversely affect the rights of the holders of common stock and, therefore, reduce the value of the common stock. The ability of our board of directors to issue preferred stock could discourage, delay or prevent a takeover or change in control.

The description of the terms of a particular series of preferred stock in the applicable prospectus supplement will not be complete. You should refer to the applicable certificate of designation for complete information regarding a series of preferred stock. The prospectus supplement will also contain a description of U.S. federal income tax consequences relating to the preferred stock, if material.

The terms of any particular series of preferred stock will be described in the prospectus supplement relating to that particular series of preferred stock, including, where applicable:

- the series designation, stated value and liquidation preference of such preferred stock and the number of shares offered;
- the offering price;
- the dividend rate or rates (or method of calculation), the date or dates from which dividends shall accrue, and whether such dividends shall be cumulative or noncumulative and, if cumulative, the dates from which dividends shall commence to cumulate;
- any redemption or sinking fund provisions;
- the amount that shares of such series shall be entitled to receive in the event of our liquidation, dissolution or winding-up;
- the terms and conditions, if any, on which shares of such series shall be exchangeable for shares of our stock of any other class or classes, or other series of the same class;
- the voting rights, if any, of shares of such series in addition to those set forth in the Section entitled, Voting Rights, below;
- the status as to reissuance or sale of shares of such series redeemed, purchased or otherwise reacquired, or surrendered to us on conversion or exchange;
- the conditions and restrictions, if any, on the payment of dividends or on the making of other distributions on, or the purchase, redemption or other acquisition by us, of our common stock or of any other class of our stock ranking junior to the shares of such series as to dividends or upon liquidation;

the conditions and restrictions, if any, on the creation of indebtedness of us, or on the issue of any additional stock ranking on a parity with or prior to the shares of such series as to dividends or upon liquidation; and

any additional dividend, liquidation, redemption, sinking or retirement fund and other rights, preferences, privileges, limitations and restrictions of such preferred stock.

If we issue shares of preferred stock under this prospectus, the shares will be fully paid and non-assessable and will not have, or be subject to, any preemptive or similar rights.

Voting Rights. The General Corporation Law of Delaware provides that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of that

Table of Contents

preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Other. Our issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of common stock or could adversely affect the rights and powers, including voting rights, of the holders of common stock. The issuance of preferred stock could have the effect of decreasing the market price of our common stock.

Certain Effects of Authorized But Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, facilitating corporate acquisitions or paying a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, if we issue preferred stock, the issuance could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation.

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law, or the DGCL, which, subject to certain exceptions and limitations, prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that such stockholder became an interested stockholder, unless:

(i) prior to such date, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

(ii) upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced (for the purposes of determining the number of shares outstanding under the DGCL, those shares owned (x) by persons who are directors and also officers and (y) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer are excluded from the calculation); or

(iii) on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

For purposes of Section 203, a business combination includes:

(i) any merger or consolidation involving the corporation and the interested stockholder;

(ii) any sale, lease, exchange, mortgage, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

Table of Contents

(iii) subject to certain exceptions, any transaction which results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

(iv) any transaction involving the corporation which has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

(v) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

For purposes of Section 203, an interested stockholder is defined as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

Selected Certificate of Incorporation and Bylaw Provisions

Our certificate of incorporation provides that the number of directors shall be as determined by the board of directors from time to time, but shall be at least three and not more than twelve. It further provides that directors may be removed only for cause, and then only by the affirmative vote of the holders of at least a majority of all outstanding voting stock entitled to vote in an election of directors. These provisions, in conjunction with the provision of the certificate of incorporation authorizing the board of directors to fill vacant directorships, will prevent stockholders from removing incumbent directors without cause and filling the resulting vacancies with their own nominees.

Our certificate of incorporation further provides that the board of directors will be divided into three classes, with each class containing as nearly as possible one-third of the total number of directors and the members of each class serving for staggered three-year terms. At each annual meeting of our stockholders, the number of directors equal to the number of the class whose term expires at the time of such meeting will be elected to hold office until the third succeeding annual meeting of stockholders. This provision could make it more difficult for stockholders to take control of the board of directors.

Our certificate of incorporation provides that stockholders may act only at an annual or special meeting of stockholders and may not act by written consent unless such consent is unanimous. Special meetings of the stockholders can be called only by our Chairman of the Board, Chief Executive Officer, President, or board of directors pursuant to a resolution approved by a majority of the whole board of directors. This provision will prevent stockholders from removing board members by calling a special meeting of stockholders without the consent of the Chairman of the Board, the Chief Executive Officer, the President or the board of directors.

Our bylaws contain provisions (i) requiring that advance notice be delivered to us of any business to be brought by a stockholder before any meeting of stockholders and (ii) establishing procedures to be followed by stockholders in nominating persons for election to the board of directors. Generally, such advance notice provisions provide that written notice must be given to us by a stockholder, with respect to director nominations or stockholder proposals, not less than 90 nor more than 120 days prior to the meeting (except that if less than 100 days notice or prior public disclosure of the date of the meeting is given or made to stockholders, then notice by the stockholder, to be timely, must be received within 10 days of the date on which notice of the date of the meeting was mailed or such public disclosure was made, whichever first occurs). Such notice must set forth specific information regarding such stockholder and such business or director nominee, as described in the bylaws.

Our certificate of incorporation authorizes the board of directors to take into account (in addition to any other considerations which the board of directors may lawfully take into account) in determining whether to take or to refrain from taking corporate action on any possible acquisition proposals, including proposing any related matter to our stockholders, the long-term as well as short-term interests of our company and its stockholders, including the possibility that these may be best served by the continued independence of our company, customers, employees and other constituencies and any subsidiaries, as well as the effect upon communities in which we do business. In considering the

Table of Contents

foregoing and other pertinent factors, the board of directors is not required, in considering our best interests, to regard any particular corporate interest or the interest of any particular group affected by such action as a controlling interest.

Certain provisions of the certificate of incorporation and bylaws, including those described above, may only be amended by stockholders upon the affirmative vote of the holders of at least two-thirds of the outstanding voting capital stock entitled to vote on such amendment.

The preceding provisions could have the effect of discouraging, delaying or making more difficult certain attempts to acquire us or to remove incumbent directors even if a majority of our stockholders believe the attempt to be in their or our best interests. The foregoing summaries are qualified in their entirety by reference to our certificate of incorporation and bylaws, copies of which are incorporated by reference into the registration statement of which this prospectus is a part.

Stockholder Rights Plan

In May 2000, our board of directors adopted a stockholder rights plan. Pursuant to the rights plan, we distributed a dividend of one right to purchase shares of our capital stock under certain circumstances specified in the rights plan, for each outstanding share of common stock. We refer to these purchase rights as the Rights. The Rights trade with the common stock and will detach and become exercisable only if, in a transaction not approved by our board of directors, ten business days elapse after either a person (together with that person s affiliates or associates) acquires 15% or more of the outstanding shares of our common stock, or announces a tender offer the completion of which would result in ownership by a person (together with such person s affiliates or associates) of 15% or more of those shares.

If the Rights detach and become exercisable as a result of the commencement of a tender offer, unless subsequently redeemed, each Right then would entitle its holder to purchase one one-thousandth of a share of the series A preferred stock for an exercise price specified in the rights plan (which is intended to equal the estimated value of our common stock at the end of the ten-year life of the Rights). If we were to be involved in a merger or other business combination transaction after the Rights become exercisable, each Right would entitle its holder to purchase, for the Right s exercise price, a number of the acquiring or surviving company s shares of common stock having a market value equal to twice the exercise price. If, in a transaction not approved by our board of directors, a person (together with such person s affiliates or associates) acquires 15% or more of the outstanding shares of our common stock, each Right would entitle its holder (other than the acquiring person and its affiliates and associates, all of whose Rights become automatically void) to purchase, for the Right s exercise price, a number of shares of our common stock having a market value equal to twice the exercise price. At any time after a person (together with such person s affiliates or associates) acquires at least 15%, but not more than 50%, of the outstanding shares of our common stock, our board of directors can elect to exchange one share of common stock for each Right (other than Rights held by such acquiring person and its affiliates and associates). We would be entitled to redeem the Rights at $.01 per Right at any time until ten business days following a public announcement that a person (together with such person s affiliates or associates) has acquired beneficial ownership of 15% or more of the outstanding shares of common stock. Following such an announcement, or, subject to certain exceptions specified in the rights plan, the acquisition of beneficial ownership of 15% or more of the outstanding shares of common stock by the acquirer (together with such person s affiliates or associates), the Rights acquired by such person or persons would be null and void. Prior to the date upon which the Rights detach, the terms of the rights plan could be amended by our board of directors without the consent of the holders of the Rights. The Rights expire on May 6, 2010, unless earlier redeemed by us.

The rights plan may deter takeover bids for our Company. To the extent an acquirer would be discouraged by the rights plan from acquiring an equity position in us, stockholders may be deprived from receiving a premium for their shares. The issuance of additional shares of common stock prior to the time the Rights become exercisable would result in an increase in the number of Rights outstanding.

We anticipate that the series A preferred stock, if issued, would rank junior to all other series of preferred stock as to the payment of dividends and the distribution of assets in liquidation, unless the terms of any such other series provide otherwise. Each share of series A preferred stock would have a quarterly dividend rate per share equal to 1,000 times the per share amount of any dividend (other than a dividend payable in shares of common stock or a subdivision of the common stock) declared from time to time on the common stock, subject to certain adjustments. The holders of series

Table of Contents

A preferred stock would be entitled to receive a preferred liquidation payment per share of $1,000 (plus accrued and unpaid dividends) or, if greater, an amount equal to 1,000 times the payment to be made per share of common stock. Generally, the holder of each share of series A preferred stock would vote together with the common stock (and any other series of preferred stock entitled to vote on such matter) on any matter as to which the common stock is entitled to vote, including the election of directors. The holder of each share of series A preferred stock would be entitled to 1,000 votes, or one vote for each one one-thousandth of a share. In the event of any merger, consolidation, combination or other transaction in which shares of common stock are exchanged for or changed into other stock or securities, cash and/or property, the holder of each share of series A preferred stock would be entitled to receive 1,000 times the aggregate amount of stock, securities, cash and/or property into which or for which each share of common stock is changed or exchanged.

The foregoing dividend, voting and liquidation rights of the series A preferred stock would be protected against dilution in the event that additional shares of common stock are issued pursuant to a stock split or stock dividend. Because of the nature of the series A preferred stock s dividend, voting, liquidation and other rights, the value of the one one-thousandth of a share of series A preferred stock purchasable with each Right is intended to approximate the value of one share of common stock.

Stock Option Plan

As of June 27, 2003, a total of 4,472,419 options to purchase shares of our common stock have been granted and remain outstanding and unexercised under our stock option plan.

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we may offer, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement.

The debt securities will be our direct unsecured general obligations and may include debentures, notes, bonds and/or other evidences of indebtedness. The debt securities will be either senior debt securities or subordinated debt securities. The debt securities will be issued under one or more separate indentures. Senior debt securities will be issued under a senior indenture, and subordinated debt securities will be issued under a subordinated indenture. We use the term indentures to refer to both the senior indenture and the subordinated indenture. We have filed forms of the indentures as exhibits to the registration statement which includes this prospectus.

The indentures will be qualified under the Trust Indenture Act of 1939. We use the term debenture trustee to refer to either the senior trustee or the subordinated trustee, as applicable.

The following summaries of material provisions of the debt securities and indentures are subject to, and qualified in their entirety by reference to, all the provisions of the indenture and any relevant indenture supplement applicable to a particular series of debt securities. Except as we might otherwise indicate, the terms of the senior indenture and subordinated indenture are identical.

23

Table of Contents

General

We will describe in each prospectus supplement the following terms relating to a series of debt securities:

- the title;
- the principal amount being offered, and if a series, the total authorized amount and the total amount outstanding;
- any limit on the amount that may be issued;
- whether or not we will issue the series of debt securities in global form, the terms and who the depository will be;
- the maturity date;
- the annual interest rate, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- whether and under what circumstances, if any, we will pay additional amounts on any debt securities held by a person who is not a United States person for tax purposes, and whether we can redeem the debt securities if we have to pay such additional amounts;
- the place where payments will be payable;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;
- the date, if any, after which, and the price at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;
- the date, if any, on which, and the price at which, we are obligated, pursuant to any mandatory sinking fund provisions or otherwise, to redeem, or at the holder s option to purchase, the series of debt securities;
- whether the indenture will restrict our ability to pay dividends, or will require us to maintain any asset ratios or reserves;
- whether we will be restricted from incurring any additional indebtedness or issuing additional securities;
- a discussion on any material or special United States federal income tax considerations applicable to the debt securities;

information describing any book-entry features;

the denominations in which we will issue the series of debt securities, if other than denominations of $1,000 and any integral multiple thereof;

material changes in the amount of outstanding debt that is secured, and/or senior debt ranking equally with the senior debt that may be issued under the senior indenture and senior to the subordinated debt that may be issued under the subordinated indenture;

any provisions for payment of additional amounts for taxes and any provision for redemption, if we must pay such additional amount with respect to any debt security;

Table of Contents

whether the debt securities are to be offered at a price such that they will be deemed to be offered at an original issue discount as defined in paragraph (a) of Section 1273 of the Internal Revenue Code; and

any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities including any additional events of default or covenants provided with respect to the debt securities, and any terms which may be required by us or advisable under applicable laws or regulations.

Conversion or Exchange Rights

We will set forth in the prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for common stock or other securities of ours. We will include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of common stock or other securities of ours that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

The indentures do not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of all or substantially all of our assets. However, any successor to or acquirer of such assets must assume all of our obligations under the indentures or the debt securities, as appropriate.

Redemption

The indentures contain a provision which allow us to redeem all or a portion of the debt securities on and after the dates specified in the applicable prospectus supplement and in accordance with the terms established for such debt securities as specified in the applicable prospectus supplement. We are required to send a notice to all debt securities holders no less than 30 days and no more than 90 days prior to the redemption date which shall specify:

the redemption date;

the redemption price; and

the particular debt securities to be redeemed if such redemption is not for the entire debt security.

If less than all of the debt securities of a series are to be redeemed, we must give the debenture trustee at least 45 days notice in advance of the redemption date as to the aggregate principal amount of debt securities of the series to be redeemed. Upon receipt of the notice, the debenture trustee shall select, by lot or in such other manner as it shall deem appropriate and fair in its discretion, the debt securities to be redeemed and shall thereafter promptly notify us in writing of the numbers of the debt securities to be redeemed, in whole or in part. In any event, the debenture trustee s determination shall provide for the selection of a portion or portions (equal to one thousand U.S. dollars ($1,000) or any

integral multiple thereof) of the principal amount of such debt securities of a denomination larger than $1,000.

Events Of Default Under The Indenture

The following are events of default under the indentures with respect to any series of debt securities that we may issue:

if we fail to pay interest when due and our failure continues for 90 days and the time for payment has not been extended or deferred;

Table of Contents

- if we fail to pay the principal, or premium, if any, when due and the time for payment has not been extended or delayed;

- if we fail to observe or perform any other covenant or agreement contained in the debt securities or the indentures, other than a covenant or agreement specifically relating to another series of debt securities, and our failure continues for 90 days after we receive notice from the debenture trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and

- if specified events of bankruptcy, insolvency or reorganization occur as to us.

If an event of default with respect to debt securities of any series occurs and is continuing, the debenture trustee or the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the debenture trustee if notice is given by such holders, may declare the unpaid principal of all debt securities of that series due and payable immediately.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indentures, if an event of default under an indenture shall occur and be continuing, the debenture trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the debenture trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the debenture trustee, or exercising any trust or power conferred on the debenture trustee, with respect to the debt securities of that series, provided that:

- the direction so given by the holder is not in conflict with any law or the applicable indenture; and

- subject to its duties under the Trust Indenture Act of 1939, the debenture trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders of debt securities of any other series.

A holder of the debt securities of any series will only have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

- the holder has given written notice to the debenture trustee of a continuing event of default with respect to that series;

- the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity, to the debenture trustee to institute the proceeding as trustee; and

- the debenture trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions, within 90 days after the notice, request and offer.

26

Table of Contents

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the debenture trustee regarding our compliance with specified covenants in the indentures.

Modification of Indenture; Waiver

We and the debenture trustee may change an indenture without the consent of any holders with respect to specific matters, including:

- to fix any ambiguity, defect or inconsistency in the indenture;
- to comply with the provisions described above under the Section entitled, Consolidation, Merger or Sale;
- to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act of 1939;
- to evidence and provide for the acceptance of appointment by a successor trustee;
- to provide for uncertificated debt securities and to make all appropriate changes for such purpose;
- to add to our covenants such new covenants, restrictions, conditions or provisions for the protection of the holders, or to surrender any right or power conferred on us under the indenture; and
- to change anything that does not materially adversely affect the interests of any holder of debt securities of any series.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the debenture trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, we and the debenture trustee may only make the following changes with the consent of each holder of any outstanding debt securities affected:

- extending the fixed maturity of the series of debt securities;
- reducing the principal amount, reducing the rate of or extending the time for payment of interest, or any premium payable upon the redemption of any debt securities; or

reducing the percentage of debt securities, the holders of which are required to consent to any amendment.

Discharge

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for obligations to:

register the transfer or exchange of debt securities of the series;

replace stolen, lost or mutilated debt securities of the series;

maintain paying agencies;

Table of Contents

hold monies for payment in trust;

compensate and indemnify the trustee; and

appoint any successor trustee.

In order to exercise our rights to be discharged, we must deposit with the trustee money or government obligations sufficient to pay all the principal of, premium, if any, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we otherwise specify in the applicable prospectus supplement, in denominations of $1,000 and any integral multiple thereof. The indentures provide that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company or another depository named by us and identified in a prospectus supplement with respect to that series. See Section entitled, Legal Ownership of Securities, for a further description of the terms relating to any global or book-entry securities.

At the option of the holder, subject to the terms of the indentures and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indentures and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will make no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If we elect to redeem the debt securities of any series, we will not be required to:

issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or

register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Table of Contents

Information Concerning the Debenture Trustee

The debenture trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the debenture trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the debenture trustee is under no obligation to exercise any of the powers given it by the indentures at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registere