TRANSGENOMIC INC
Form 10-K
March 14, 2012
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K
(Mark One)

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

For the fiscal year ended December 31, 2011
OR

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

For the transition period from to
Commission File Number 000-30975

TRANSGENOMIC, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	91-1789357
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification Number)
12325 Emmet Street Omaha, NE 68164	68164
(Address of Principal Executive Offices)	(Zip Code)

(402) 452-5400
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange On Which Registered
None	N/A

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $.01 per share
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes No X

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.
Yes No X

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes X No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes X No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form10-K

1

Table of Contents

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of “accelerated filer”, “large accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer ¨ Accelerated Filer ý Non-Accelerated Filer ¨ Smaller Reporting Company ¨

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2).

Yes No X

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based on the last reported closing price per share of Common Stock as reported on the OTC Bulletin Board on the last business day of the registrant’s most recently completed second quarter was approximately $86.2 million.

At March 13, 2012, the registrant had 71,625,725 shares of Common Stock outstanding.

Table of Contents

TRANSGENOMIC, INC.
Index to Form 10-K for the Fiscal Year Ended December 31, 2011

This Annual Report on Form 10-K references the following registered trademarks which are the property of Transgenomic, Inc.: DNASEP® Cartridges, WAVE® System, WAVEMAKER® Software, TRANSGENOMIC® and the Globe Logo®; MutationDiscovery.com® Website, OLIGOSEP® Cartridges for Systems and Reagents,

OPTIMASE® Polymerase, RNASEP® Cartridges, WAVE OPTIMIZED® reagents, WAVE® MD Systems, MitoScreen™ Kits, ProtocolWriter™ Software, Navigator™ Software, THE POWER OF DISCOVERY® for Lab Reagents and Educational Programs, SURVEYOR® Nuclease, and FAMILION®. All other trademarks or trade names referred to in this Annual Report on Form 10-K are the property of their respective owners.

Table of Contents

PART I

FORWARD-LOOKING STATEMENTS

This report, including Management's Discussion & Analysis, contains forward-looking statements. These statements are based on management's current views, assumptions or beliefs of future events and financial performance and are subject to uncertainty and changes in circumstances. Readers of this report should understand that these statements are not guarantees of performance or results. Many factors could affect our actual financial results and cause them to vary materially from the expectations contained in the forward-looking statements. These factors include, among other things: our expected revenue, income (loss), receivables, operating expenses, supplier pricing, availability and prices of raw materials, Medicare/Medicaid/Insurance reimbursements, product pricing, foreign currency exchange rates, sources of funding operations and acquisitions, our ability to raise funds, sufficiency of available liquidity, future interest costs, future economic circumstances, business strategy, industry conditions and key trends, our ability to execute our operating plans, the success of our cost savings initiatives, competitive environment and related market conditions, expected financial and other benefits from our organizational restructuring activities, actions of governments and regulatory factors affecting our business and other risks as described in our reports filed with the Securities and Exchange Commission (the "SEC"). In some cases these statements are identifiable through the use of words such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “project,” “target,” “can,” “could,” “may,” “shou and similar expressions.

You are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements we make are not guarantees of future performance and are subject to various assumptions, risks and other factors that could cause actual results to differ materially from those suggested by these forward-looking statements. Actual results may differ materially from those suggested by the forward-looking statements that we make for a number of reasons including those described in Item 1A, “Risk Factors,” and other factors identified by cautionary language used elsewhere in this report.

We expressly disclaim any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

The following discussion should be read together with our financial statements and related notes contained in this report. Results for the year ended December 31, 2011 are not necessarily indicative of results that may be attained in the future.

Item 1. Our Business

Transgenomic, Inc. is a global biotechnology company advancing personalized medicine in the detection and treatment of cancer and inherited diseases through its proprietary molecular technologies and world-class clinical and research services. We have three complementary business segments.

- Clinical Laboratories. Our clinical laboratories specialize in genetic testing for cardiology, neurology, mitochondrial disorders, and oncology. Located in New Haven, Connecticut and Omaha, Nebraska the molecular clinical reference laboratories are certified under the Clinical Laboratory Improvement Amendment (CLIA) as high complexity labs and our Omaha facility is also accredited by the College of American Pathologists (CAP).
- Pharmacogenomics Services. Our Contract Research Organization located in Omaha, Nebraska provides pharmacogenomics research services supporting Phase II and Phase III clinical trials conducted by our pharmaceutical customers. This lab specializes in pharmacogenomic, biomarker and mutation discovery research serving the pharmaceutical and biomedical industries worldwide for disease research, drug and diagnostic development and clinical trial support.
- Diagnostic Tools. Our proprietary product is the WAVE® System which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. There is a worldwide installed base of over 1,500 WAVE Systems as of December 31, 2011. We also distribute bioinstruments produced by other manufacturers (“OEM Equipment”) through our sales and distribution network. Service contracts to maintain installed systems are sold and supported by our technical support personnel. The installed WAVE base and some OEM Equipment platforms

generate a demand for consumables that are required for the continued operation of the bioinstruments. We develop, manufacture and sell these consumable products. In addition, we manufacture and sell consumable products that can be used on multiple, independent platforms. These products include SURVEYOR® Nuclease and a range of chromatography columns.

Table of Contents

Business Strategy

Our primary goal is to provide products and services to biomedical researchers, physicians, medical institutions, and diagnostic and pharmaceutical companies that are tied to advancements in the field of genomics and, increasingly, personalized medicine. Advances in genomics have fueled our efforts to understand individual differences in disease susceptibility, disease progression, and response to therapy.

The markets in which we compete require a wide variety of technologies, products, and capabilities. The combination of technological complexity and rapid change within our markets makes it difficult for a single company to develop all of the technological solutions that it desires to offer within its family of products and services. We work to broaden the range of products and services we deliver to customers in target markets through acquisitions, investments, and alliances. We employ the following strategies to address the need for new or enhanced products and services:

- Developing new technologies and products internally
- Acquire all or parts of other companies
- Entering into joint-development efforts with other companies
- Reselling other companies' products

Our strategy is to leverage the synergies of our three divisions, capitalizing on discoveries in our R&D and Pharmacogenomic Services labs to create “kits” or assays to distribute through our Tools division, as well as tests to conduct in our Clinical Laboratories.

We will continue to develop new technologies, such as our ICECOLD-PCR, and capitalize on our expertise and intellectual properties to develop new ground-breaking tests, such as our PGxPredict®:CLOPIDOGREL Panel. We also continue to cultivate new and expanded relationships with industry leaders across the globe, such as A. Menarini in our Tools business, and a list of medical research facilities working with our two laboratory divisions.

We continue to evaluate a range of acquisition targets, including smaller single-test labs as well as larger private and public entities, as well as divisions of entities. We acquired the Familion business in December, 2010, and quickly integrated it into our existing business, and believe we are skilled at such acquisition integrations.

Products

Our highly specialized genetics service and expertise are delivered by our Pharmacogenomic Services Laboratory in Omaha, NE and in our Clinical Laboratory Improvement Act (CLIA)-certified Clinical Laboratories in Omaha and New Haven, CT. Our Pharmacogenomics Lab supports pharmaceutical companies in their clinical trials, primarily phase II and phase III trials. Our Clinical Laboratories division support medical professionals in the diagnosis and treatment of patients, primarily in the specialties of Cardiology, Neurology and Oncology with a range of tests within each medical specialty.

In cardiology, our FAMILION® family of tests focuses on detecting mutations that can cause cardiac channelopathies, cardiomyopathies and other rare, potentially lethal heart conditions. The specific diseases include Long QT Syndrome (LQTS), Familial Atrial Fibrillation (AF), Hypertrophic Cardiomyopathy (HCM), and Dilated Cardiomyopathy (DCM) . By reducing uncertainty and finding the specific genetic causes of cardiac channelopathies and cardiomyopathies, the FAMILION tests can:

- Help diagnose a patient's disease
- Guide treatment options
- Determine whether family members are at risk

Also in cardiology, our PGxPredict®:CLOPIDOGREL Panel seeks to identify the approximately 50% of patients with a genetic deficiency that prevents them from receiving the expected pharmacological benefit from clopidogrel (Plavix®). Information from the PGxPredict®:CLOPIDOGREL Panel can be used by the health care provider to ensure the most appropriate anti-platelet therapy is being used in an effort to reduce adverse cardiac events.

In Neurology, we have a focus on mitochondrial disorders and epilepsy and epilepsy-like diseases. We employ a wide variety of technologies, including proprietary technologies such as the WAVE, and industry standards such as Sanger sequencing. In 2011 we introduced the NuclearMitome test, which is based on next-generation sequencing, currently run in a partner lab at Seattle Children's Hospital.

Our oncology tests are focused heavily on genetic mutations commonly associated with the major cancer types - Lung, Colorectal, Breast, and Prostate. We primarily test for mutations in the K-RAS, N-RAS, BRAF, and PIK3CA

genes, all associated with the most common cancers. We also offer tests for hereditary cancer-predisposing syndromes.

Our lab expertise is leveraged into our Diagnostic Tools division, which focuses on assembly and delivery of highly sensitive mutation detection equipment, primarily our WAVE, WAVEmce, and Hanabi instruments, as well as the

Table of Contents

bioconsumables used in these instruments for molecular testing and cytogenetics. Transgenomic equipment systems offer discovery and detection of genetic variation at close to 100% sensitivity, making them among the most sensitive and accurate technologies for detection of known and unknown mutations and single nucleotide polymorphisms (SNPs). These equipment systems are used throughout the world to screen for a large variety of diseases. More than 350 human genes have been screened entirely or partly by Direct High Pressure Liquid Chromatography (DHPLC), the underlying technology used by our equipment systems. A multitude of other applications are being used with WAVE Systems in such diverse areas as plant genomics, microbial analysis, and drug sensitivity.

We continue to leverage the synergies of the three divisions, capitalizing on discoveries in our R&D and Pharmacogenomic Services labs to create “kits” or test assays to distribute through our Tools division, as well as tests to conduct in our Clinical Laboratories.

Sales and Marketing

Our Sales and Support team consists of regionally based sales people, service engineers and applications scientists to support our sales and marketing activities worldwide. We have sold our products to customers in over 50 countries. We use a direct sales and support staff for sales in the U.S. and Europe. For the rest of the world, we sell our products through dealers and distributors within local markets. We have over 35 dealers and distributors.

Customers

Physicians requesting genetic tests for their patients are our primary source of laboratory services. Fees for laboratory testing services rendered for these physicians are billed either to the physician, the patient or the patient’s third-party payer such as an insurance company, Medicare or Medicaid. Billings are typically on a fee-for-service basis. The patient or third-party payer is billed at our patient fee schedule. Commercial insurance providers are billed at contracted rates or other generally accepted market reimbursement rates. Revenues received from Medicare and Medicaid billings are based on government established fee schedules and reimbursement rules.

Our customers include a number of large, established pharmaceutical, biotech and commercial companies as well as leading academic and medical institutions. In addition, our customers also include a number of large, established pharmaceutical, biotech and commercial companies both in the U.S. and abroad. No customer accounted for more than 10% of our consolidated net sales for the years ended December 31, 2011, 2010 or 2009. Information regarding the revenues attributable to U.S. and international markets is set forth in Note P to the footnotes to our consolidated financial statements.

Research and Development

We continue to invest in research and development in order to remain competitive and to take advantage of new business opportunities as they arise. We maintain a program of research and development with respect to instruments and services, engaging existing and new technologies to create scientific and medical applications that will add value to patient care as well as significant commercial value. Major areas of focus include (i) development of SURVEYOR® Nuclease based oncology mutation detection kits utilizing multiple instrument platforms for aid in therapeutic treatment decisions for cancers such as colorectal, melanoma, non small cell lung; (ii) a new discovery in high sensitivity DNA mutation detection for Sanger Sequencing; (iii) development of ICE COLD-PCR applications for ultra-high sensitivity mutation detection in any tissue samples (fresh, frozen, FNA, FFPE, etc.) and body fluids (plasma, serum, ascites); (iv) a “toolbox” of mitochondrial DNA assays to assess damage, copy number, deletion and mutation for applications ranging from toxicology to diabetes to aging; and (v) development of a biomarker for FC Gamma receptor to aid in the selection of therapeutic options for monoclonal antibody cancer drugs. For the years ended December 31, 2011, 2010 and 2009, our research and development expenses were $2.2 million, $2.3 million and $3.2 million, respectively.

Manufacturing

We manufacture bioconsumable products including our separation columns, liquid reagents, and enzymes. The major components of our WAVE Systems are manufactured for us by a third party. We integrate our hardware and software with these third party manufactured components. Our manufacturing facilities for WAVE Systems and bioconsumables are located in Omaha, Nebraska and San Jose, California.

Intellectual Property

To establish and protect our proprietary technologies and products, we rely on a combination of patent, copyright, trademark and trade-secret laws, license agreements' contractual provisions and confidentiality agreements. Our WAVE Systems and related consumables are protected by patents and in-licensed technologies that expire in various periods beginning in 2012 through 2030. As part of the FAMILION Acquisition, we acquired exclusive rights to the FAMILION family of

Table of Contents

genetic tests for inherited disease, including the patents protecting this technology. As we expand our product offerings, we also extend our patent development efforts to protect such product offerings. Established competitors, as well as companies that purchase and enforce patents and other intellectual property, may already have patents covering similar products. There is no assurance that we will be able to obtain patents covering our products, or that we will be able to obtain licenses from such companies on favorable terms or at all. However, while patents are an important element of our success, our business as a whole is not significantly dependent on any one patent.

We will continue to file patent applications, seek new licenses, take advantage of available copyright and trademark protections and implement appropriate trade-secret protocols to protect our intellectual property. Despite these precautions, there can be no assurance that misappropriation of our products and proprietary technologies will not occur.

In addition to own products, we distribute or act as a sales agent for OEM Equipment developed by third parties. Our rights to those third-party products and the associated intellectual property rights are limited by the terms of the contractual agreement between us and the respective third-party.

Although we believe that our developed and licensed intellectual property rights do not infringe upon the proprietary rights of third parties, there can be no assurance that third parties will not assert infringement claims against us. Further, there can be no assurance that intellectual property protection will be available for our products in all foreign countries.

Like many companies in the biotechnology and other high-tech industries, third parties have in the past and may in the future assert claims or initiate litigation related to patent, copyright, trademark or other intellectual property rights to business processes, technologies and related standards that are relevant to us and our customers. These assertions have increased over time as a result of the general increase in patent claims assertions, particularly in the United States. Third parties may also claim that their intellectual property rights are being infringed by our customers' use of a business process method that utilizes products in conjunction with other products, which could result in indemnification claims against us by our customers. Any claim against us, with or without merit, could be time-consuming, result in costly litigation, cause product delivery delays, require us to enter into royalty or licensing agreements or pay amounts in settlement, or require us to develop alternative non-infringing technology. We could also be required to defend or indemnify our customers against such claims. A successful claim by a third-party of intellectual property infringement by us or one of our customers could compel us to enter into costly royalty or license agreements, pay significant damages or even stop selling certain products and incur additional costs to develop alternative non-infringing technology.

Government Regulation

We are subject to a variety of federal, state and municipal environmental and safety laws based on our use of hazardous materials in both manufacturing and research and development operations. We believe that we are in material compliance with applicable environmental laws and regulations. If we cause contamination to the environment, intentionally or unintentionally, we could be responsible for damages related to the clean-up of such contamination or individual injury caused by such contamination. We cannot predict how changes in laws and regulations will impact how we conduct our business operations in the future or whether the costs of compliance will increase in the future.

Regulation by governmental authorities in the United States and other countries is not expected to be a significant factor in the manufacturing, labeling, distribution and marketing of our products and systems

Competition

The markets in which we operate are highly competitive and characterized by rapidly changing technological advances. A number of our competitors possess greater resources than us and may be able to develop and offer a greater breadth of products and/or services, coupled with significant marketing and distribution capabilities. We compete principally on the basis of uniquely enabling scientific technical advantages in specific but significant market segments.

Our Laboratory Services division faces competition from a number of companies offering contract DNA sequencing and other genomic analysis services, including Genzyme, SeqWright and others. In addition, several clinical diagnostics service providers, such as Labcorp, Quest, GeneDx and Baylor College of Medicine, also offer related laboratory services. Finally, additional competition arises from academic core laboratory facilities. Competition for our WAVE System arises primarily from DNA sequencing and genotyping technologies. Competitors in these areas include Applied Biosystems, Qiagen, Roche, Sequenom, and others. Competition for some of our non-WAVE consumable products comes from numerous well-diversified life sciences reagents providers, including, among others, Invitrogen, Qiagen, Roche, Stratagene, and Promega.

Table of Contents

Employees

As of December 31, 2011 and 2010, we had employees focused in the following areas of operation:

	December 31, 2011	2010
Manufacturing and Laboratory	68	62
Sales, Marketing and Administration	92	88
Research and Development	9	12
	169	162

Our employees were employed in the following geographical locations:

	December 31, 2011	2010
United States	148	136
Europe (other than the United Kingdom)	10	15
United Kingdom	11	10
Canada	—	1
	169	162

General Information

We were incorporated in Delaware on March 6, 1997. Our principal office is located at 12325 Emmet Street, Omaha, Nebraska 68164 (telephone: 402-452-5400). This facility houses our administrative staff and laboratories. We maintain manufacturing facilities in Omaha, Nebraska and San Jose, California. We maintain research and development offices in Omaha, Nebraska. We maintain laboratories in Omaha, Nebraska and New Haven, Connecticut that have been certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA").

Our Internet website is located at http://www.transgenomic.com. The information on our website is not a part of this annual report. We make available free of charge on our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Unite States Securities and Exchange Commission ("SEC"). Our SEC reports can be accessed through the investor relations section of our Internet website.

The public may also read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The SEC's Internet website is located at http://www.sec.gov.

Executive Officers of the Registrant

Craig J. Tuttle. Mr. Tuttle, age 59, has served as our President and Chief Executive Officer since 2006. From 2004 to 2005, Mr. Tuttle was President and Chief Operating Officer of Duke Scientific. From 1999 to 2003, Mr. Tuttle served as President and Chief Executive Officer of Applied Biotech, Inc. The Board selected Mr. Tuttle to serve as a director because he is the Company's Chief Executive Officer. He has expansive knowledge and experience in the biotech industry, as well as relationships with chief executives and other senior management at biotechnology companies and leading research institutions.

Chad M. Richards. Mr. Richards, age 42, joined the Company in October 2007 as Senior Vice President, Sales and Marketing and was promoted to Chief Commercial Officer in January 2011. Before joining the Company,

Mr. Richards was the National Sales Director for Anatomic Pathology with Quest Diagnostics. During his career with Quest Diagnostics, Mr. Richards held a variety of sales management roles in both their physician and hospital business segments. Before joining Quest Diagnostics, Mr. Richards held different marketing and sales management roles with Roche Diagnostics Ventana Medical Systems Division, one of the world's leading developers and manufacturers of immunohistochemistry and in-situ hybridization instruments and

Table of Contents

reagent systems. Before embarking on a career in diagnostics, Mr. Richards served in the United States Marine Corps.

Brett L. Frevert. Mr. Frevert, age 49, was appointed as our Chief Financial Officer by the Board of Directors on June 28, 2010. Mr. Frevert serves as Chief Financial Officer pursuant to the terms a letter agreement with CFO Systems, LLC ("CFO Systems") and Brett L. Frevert. Under the letter agreement CFO Systems provides financial and consulting services to us. Since 2004 Mr. Frevert has been Managing Director of CFO Systems, which he founded. During that time he has served as CFO of several Midwestern companies, including SEC registrants and private companies. Prior to founding CFO Systems, Mr. Frevert was Chief Financial Officer of a regional real estate firm and also served as Interim Chief Financial Officer of First Data Europe. Mr. Frevert began his career with Deloitte & Touche, serving primarily SEC-registered clients in the food and insurance industries.

Item 1A. Risk Factors

We have a history of operating losses and may incur losses in the future.

We have experienced annual losses from continuing operations since inception of our operations. Our operating loss for the years ended December 31, 2011, 2010 and 2009 were $3.0 million, $3.6 million and $1.9 million, respectively. These historical losses have been due principally to the high levels of research and development expenses and sales and marketing expenses that we have incurred in order to develop and market our products, the fixed nature of our manufacturing costs, restructuring charges, impairment charges and merger and acquisition costs.

We might enter into new acquisitions that are difficult to integrate, disrupt our business, dilute stockholder value or divert management attention.

Our success will depend in part on our ability to continually enhance and broaden our product offerings in response to changing technologies, customer demands and competitive pressures. We expect to seek to acquire businesses, technologies or products that will complement or expand our existing business, including acquisitions that could be material in size and scope. Any acquisition we might make in the future might not provide us with the benefits we anticipated upon entering into the transaction. Any future acquisitions involve various risks, including:

- Difficulties in integrating the operations, technologies, products and personnel of the acquired entities;
- The risk of diverting management's attention from normal daily operations of the business;
- Potential difficulties in completing projects associated with in-process research and development;
- Risks of entering markets in which we have no or limited direct prior experience and where competitors in such markets have stronger market positions;
- Initial dependence on unfamiliar supply chains or relatively small supply partners;
- Unexpected expenses resulting from the acquisition;
- Potential unknown liabilities associated with acquired businesses;
- Insufficient revenues to offset increased expenses associated with the acquisition; and
- The potential loss of key employees of the acquired entities.

An acquisition could result in the incurrence of debt, restructuring charges or large one-time write-offs. Acquisitions also could result in goodwill and other intangible assets that are subject to impairment tests, which might result in future impairment charges. Furthermore, if we finance acquisitions by issuing convertible debt or equity securities, our existing stockholders may be diluted.

From time to time, we might enter into negotiations for acquisitions that are not ultimately consummated. Those negotiations could result in diversion of management time and potentially significant out-of-pocket costs. If we fail to evaluate and execute acquisitions accurately, we could fail to achieve our anticipated level of growth and our business and operating results could be adversely affected.

Continued weakness in U.S. or global economic conditions could have an adverse effect on our businesses.

The economies of the United States and other regions of the world in which we do business have experienced significant weakness, which, in the case of the U.S., has resulted in significant unemployment and slower growth in economic activity. A continued decline in economic conditions may adversely affect demand for our services and products, thus reducing our revenue. These conditions could also impair the ability of those with whom we do

business to satisfy their obligations to us.

Sales have been variable.

Testing volumes in our Clinical Laboratory are dependent on patient visits to doctors' offices and other providers of

Table of Contents

health care and tends to fluctuate on a seasonal basis. Testing volume generally declines during the year-end holiday periods, other major holidays and the summer.

Our Pharmacogenomics Services depends on project-based work that changes from quarter to quarter. Therefore, comparison of the results of successive quarters may not accurately reflect trends or results for the full year.

Changes in payer mix could have a material adverse impact on our net sales and profitability.

Testing services are billed to physicians, patients, Medicare, Medicaid and insurance companies. Tests may be billed to different payers depending on a particular patient's medical insurance coverage. Increases in the percentage of services billed to government payors could have an adverse impact on our net sales.

Governmental payers and health care plans have taken steps to control costs.

Medicare, Medicaid and private insurers have increased their efforts to control the costs of health care services, including clinical testing services. They may reduce fee schedules or limit/exclude coverage for types of tests that we perform. Medicaid reimbursement varies by state and is subject to administrative and billing requirements and budget pressures. We expect efforts to reduce reimbursements, impose more stringent cost controls and reduce utilization of testing services will continue. These efforts, including changes in law or regulations, may have a material adverse impact on our business.

Our Laboratory requires ongoing CLIA certification.

CLIA extended federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally approved accreditation agency. CLIA requires that all clinical laboratories meet quality assurance, quality control and personnel standards. Laboratories must also undergo proficiency testing and are subject to inspections.

The sanctions for failure to comply with CLIA requirements include suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, cancellation or suspension of the laboratory's approval to receive Medicare and/or Medicaid reimbursement, as well as significant fines and/or criminal penalties. The loss or suspension of a CLIA certification, imposition of a fine or other penalties, or future changes in the CLIA law or regulations (or interpretation of the law or regulations) could have a material adverse effect on us.

We believe that we are in compliance with all applicable laboratory requirements, but no assurances can be given that our laboratories will pass all future certification inspections.

Failure to comply with HIPAA could be costly.

The Health Insurance Portability and Accountability Act (HIPAA) and associated regulations protect the privacy and security of certain patient health information and establish standards for electronic health care transactions in the United States. These privacy regulations establish federal standards regarding the uses and disclosures of protected health information. Our Molecular Labs are subject to HIPAA and its associated regulations. If we fail to comply with these laws and regulations we could suffer civil and criminal penalties, fines, exclusion from participation in governmental health care programs and the loss of various licenses, certificates and authorizations necessary to operate our Laboratory Services business. We could also incur liabilities from third party claims.

Our business could be adversely impacted by health care reform.

Government attention to the health care industry in the United States is significant and may increase. The Patient Protection and Affordable Care Act passed by Congress and signed into law by the President in March 2010 could adversely impact our business. While the ultimate impact of the legislation on the health care industry is unknown, it is likely to be extensive and could result in significant change.

We may be subject to client lawsuits.

Providers of clinical testing services may be subject to lawsuits alleging negligence or other legal claims. Potential suits could involve claims for substantial damages. Litigation could also have an adverse impact on our client base and reputation. We maintain liability insurance coverage for certain claims that could result from providing or failing to provide clinical testing services, including inaccurate testing results and other exposures. Our insurance coverage limits our maximum recovery on individual claims and, therefore, there is no assurance that such coverage will be adequate.

Market demand is outside of our control.

There are many factors that affect the market demand for our products and services that we cannot control. Demand

10

Table of Contents

for our WAVE System is affected by the needs and budgetary resources of research institutions, universities, hospitals and others who use the WAVE System for genetic-variation research. The WAVE System represents a significant expenditure by these types of customers and often requires a long sales cycle. Similarly, the sales cycle for the OEM Equipment that we sell can be lengthy.

The sale of our products and business operations in international markets subjects us to additional risks.

During the past several years, international sales have represented a significant portion of our total net sales. As a result, a major portion of our net sales are subject to risks associated with international sales and operations. These risks include:

- payment cycles in foreign markets are typically longer than in the U.S., and capital spending budgets for research agencies can vary over time with foreign governments;
- changes in foreign currency exchange rates can make our products more costly in local currencies since our foreign sales are typically paid for in British Pounds or the Euro;
- the potential for changes in U.S. and foreign laws or regulations that result in additional import or export restrictions, higher tariffs or other taxes, more burdensome licensing requirements or similar impediments to our ability to sell products and services profitably in these markets; and
- the fluctuation of foreign currency to the US Dollar and the Euro to the British Pound can cause our net sales and expenses to increase or decrease, which adds risk to our financial statements.

Our WAVE System includes hardware components and instrumentation manufactured by a single supplier and if we are no longer able to obtain these components and instrumentation our ability to manufacture our products could be impaired.

We rely on a single supplier, Hitachi High Technologies America, to provide the basic instrument modules used in our WAVE Systems. While other suppliers of instrumentation are available, we believe that our arrangement with Hitachi offers strategic advantages. We have successfully converted the latest model of WAVE Systems to utilize Hitachi's newest instrument line. If we were required to seek alternative sources of supply, it could be time consuming and may require significant and costly modification of our WAVE System. Also, if we were unable to obtain instruments from Hitachi in sufficient quantities or in a timely manner, our ability to manufacture our products could be impaired, which could limit our future net sales.

The current economy may cause suppliers of products to not be able to perform.

We rely on various suppliers for products and materials needed to produce our products. In the event that they would be unable to deliver those items due to product shortage or business closure, we may be unable to deliver our products to our customers timely or may need to increase our prices. The current economy poses additional risk of our suppliers' ability to continue their businesses as usual.

Our markets are very competitive.

Many of our competitors have greater resources than we do and may enjoy other competitive advantages. This may allow them to more effectively market their products to our customers or potential customers, to develop products that make our products obsolete or to produce and sell products less expensively than us. As a result of these competitive factors, demand for and pricing of our products and services could be negatively affected.

Our patents may not protect us from others using our technology which could harm our business and competitive position.

Patent law relating to the scope of claims in the technology fields in which we operate is still evolving. The degree of future protection for our proprietary rights is uncertain. Furthermore, we cannot be certain that others will not independently develop similar or alternative products or technology, duplicate any of our products, or, if patents are issued to us, design around the patented products developed by us. Our patents or licenses could be challenged by litigation and, if the outcome of such litigation were adverse to us, our competitors could be free to use our technology. We may not be able to obtain additional patents for our technology, or if we are able to do so, patents may not provide us with adequate protection or be commercially beneficial. In addition, we could incur substantial costs in

litigation if we are required to defend ourselves in patent suits brought by third parties or if we initiate such suits.

We cannot be certain that other measures taken to protect our intellectual property will be effective.

We rely upon trade secrets, copyright and trademark laws, non-disclosure agreements and other contractual provisions for some of our confidential and proprietary information that is not subject matter for which patent protection is being sought. Such measures, however, may not provide adequate protection for our trade secrets or other proprietary information. If such measures do not protect our rights, third parties could use our technology and our ability to compete in the market would be

Table of Contents

reduced.

We are dependent upon licensed technologies and may need to obtain additional licenses in the future to offer our products and remain competitive.

We have licensed key components of our technologies from third parties. If these agreements were to terminate prematurely due to our breach of the terms of these licenses or we otherwise fail to maintain our rights to such technology, we may lose the right to manufacture or sell a substantial portion of our products. In addition, we may need to obtain licenses to additional technologies in the future in order to keep our products competitive. If we fail to license or otherwise acquire necessary technologies, we may not be able to develop new products that we need to remain competitive.

The protection of intellectual property in foreign countries is uncertain.

A significant percentage of our sales are to customers located outside the U.S. Patent and other intellectual property laws of some foreign countries may not protect our intellectual property rights to the same extent as U.S. laws. We may need to bring proceedings to defend our patent rights or to determine the validity of our competitors' foreign patents. These proceedings could result in substantial cost and diversion of our efforts. Finally, some of our patent protection in the U.S. is not available to us in foreign countries due to the laws of those countries.

Our products could infringe on the intellectual property rights of others.

There are a significant number of U.S. and foreign patents and patent applications submitted for technologies in, or related to, our area of business. As a result, any application or exploitation of our technology by us could infringe patents or proprietary rights of others and any licenses that we might need as a result of such infringement might not be available to us on commercially reasonable terms, if at all. This may lead others to assert patent infringement or other intellectual property claims against us.

Our failure to comply with any applicable government regulations or otherwise respond to claims relating to improper handling, storage or disposal of hazardous chemicals that we use may adversely affect our results of operations.

Our research and development and manufacturing activities involve the controlled use of hazardous materials and chemicals. We are subject to federal, state, local and international laws and regulations governing the use, storage, handling and disposal of hazardous materials and waste products. If we fail to comply with applicable laws or regulations, we could be required to pay penalties or be held liable for any damages that result and this liability could exceed our financial resources. We cannot assure you that accidental contamination or injury will not occur. Any such accident could damage our research and manufacturing facilities and operations, resulting in delays and increased costs.

Our common stock is deemed to be "penny stock" which may make it more difficult for investors to sell their shares due to suitability requirements.

Our common stock is classified as a "penny stock" under the rules of the SEC. The SEC has adopted Rule 3a51-1 that establishes the definition of a "penny stock" for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, Rule 15g-9 requires that:

- a broker or dealer approve a person's account for transactions in penny stocks; and
- the broker or dealer receives from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person; and
- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which is in highlight form:

- sets forth the basis on which the broker or dealer made the suitability determination; and
- that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Table of Contents

Generally, brokers may be less willing to execute transactions in securities subject to “penny stock” rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

We may issue a substantial amount of our common stock to holders of options and warrants and this could reduce the market price for our stock.

At December 31, 2011, we had obligations to issue 17,648,273 shares of common stock upon exercise of outstanding stock options, warrants or conversion rights. The issuance of these additional shares of common stock may be dilutive to our current shareholders and could negatively impact the market price of our common stock.

Our common stock is thinly traded and a large percentage of our shares are held by a small group of unrelated, institutional owners.

At December 31, 2011, we had 49,625,725 shares of common stock outstanding. The sale of a significant number of shares into the public market has the potential to cause significant downward pressure on the price of our common stock. This is particularly the case if the shares being placed into the market exceed the market’s ability to absorb the stock. This presents an opportunity for short sellers to contribute to the further decline of our stock price. If there are significant short sales of our stock, the price decline that would result from this activity will cause the share price to decline more so, which, in turn, may cause long holders of the stock to sell their shares thereby contributing to sales of stock in the market.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease facilities throughout the world under non-cancellable leases with various terms. The following table summarizes certain information regarding our leased facilities. Annual rent amounts presented in the table are reflected in thousands.

Location	Function	Square Footage	2012 Scheduled Rent	Lease Term Expires
Omaha, Nebraska	WAVE and Consumable Manufacturing	25,000	$139	July 2016
San Jose, California	Consumable Manufacturing	9,110	$57	February 2016
Glasgow, Scotland	Multi Functional (1)	5,059	$36	March 2017
Omaha, Nebraska	Multi Functional (1)	18,265	$204	July 2022
New Haven, Connecticut	Laboratory	22,459	$472	March 2018

(1) Multi Functional facilities include functions related to manufacturing, services, sales and marketing, research and development and/or administration.

We believe that these facilities are adequate to meet our current and planned needs. We believe that if additional space is needed in the future, we could find alternate space at competitive market rates without substantial increase in cost.

Item 3. Legal Proceedings.

We are subject to a number of claims of various amounts which arise out of the normal course of our business. In our opinion, the disposition of pending claims will not have a material adverse effect on our financial position, results of operations or cash flows.

Table of Contents

Item 4. Mine Safety Disclosures

Not applicable.

Table of Contents

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information. Share price information for our common stock is available on the OTC Bulletin Board under the symbol TBIO.OB. The following table sets forth the high and low closing prices for our common stock during each of the quarters of 2011 and 2010. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	High	Low
Year Ended December 31, 2011		
First Quarter	$0.90	$0.61
Second Quarter	$1.75	$0.82
Third Quarter	$1.77	$1.00
Fourth Quarter	$1.44	$1.07
Year Ended December 31, 2010		
First Quarter	$0.88	$0.61
Second Quarter	$0.86	$0.49
Third Quarter	$0.59	$0.33
Fourth Quarter	$0.71	$0.32

Company Stock Price Performance Graph. The following graph compares five-year cumulative total returns of the Company, the NASDAQ Composite Index and the NASDAQ Biotechnology Stock Index. The graph assumes $100 was invested in the common stock of Transgenomic, Inc. and each index as of December 31, 2006 and that all dividends were re-invested.

The information contained in this Stock Performance Graph section shall not be deemed to be "soliciting material" or "filed" or incorporated by reference in future filings with the SEC, or subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference into a document filed under

Table of Contents

the Securities Act of 1933 (the "Securities Act") or the Securities Exchange Act of 1934.

Holders. At December 31, 2011, there are 49,625,725 shares of our common stock outstanding and approximately 2,800 holders of record.

Dividends. We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. Dividends on our common stock will be paid only if and when declared by our Board of Directors. The Board's ability to declare a dividend is subject to limits imposed by Delaware corporate law. In determining whether to declare dividends, the Board may consider our financial condition, results of operations, working capital requirements, future prospects and other relevant factors. The holders of our Series A Convertible Preferred Stock (the "Series A Preferred Stock") are entitled to receive quarterly dividends.

Sale of Unregistered Securities. On December 29, 2010, the Company issued 2,586,205 shares of Series A Preferred Stock pursuant to applicable exemptions from the registration requirements of the Securities Act of 1933. The issuance of such Series A Preferred Stock was in connection with the FAMILION Acquisition. Please refer to the Series A Convertible Preferred Stock Purchase Agreement among the Company and Third Security Senior Staff 2008 LLC, Third Security Staff 2010 LLC and Third Security Incentive 2010, LLC ("Third Security Investors") dated December 29, 2010.

On November 8, 2011, the Company entered into an Amendment Agreement with the Third Security Investors, which are the holders of all of the outstanding shares of the Company's Series A Preferred Stock. Pursuant to the Amendment Agreement, the Third Security Investors and the Company agreed to amend the Certificate of Designation to eliminate certain features of the Series A Preferred Stock relating to (i) an anti-dilution adjustment to the conversion rate upon which the Series A Preferred Stock is convertible into the Company's common stock and (ii) an optional redemption of the Series A Preferred Stock by the Third Security Investors (the "Certificate Amendment"); subject to the requisite stockholder approval of the Certificate Amendment at the Company's next annual meeting of its stockholders. Pursuant to the Amendment Agreement, the Third Security Investors agreed to vote the Series A Preferred Stock and their common stock in favor of the Certificate Amendment and agreed to waive their rights to the features of the Series A Preferred Stock being eliminated by the Certificate Amendment. In exchange for the Third Security Investors entering into the Amendment Agreement, the Company agreed to issue to the holders an aggregate of 245,903 shares of common stock having a market value of $0.3 million.

On December 30, 2011, the Company entered into a Convertible Promissory Note Purchase Agreement (the "Note Purchase Agreement") with the Third Security Investors in the aggregate amount of $3.0 million. Under the Note Purchase Agreement, the Company sold to the Third Security Investors convertible notes that mature on March 31, 2012. The Note Purchase Agreement and notes provide for conversion of any amount remaining due to the Third Security Investors under the notes into equity securities of the Company of the same class(es) or series and at the same price as the equity securities of the Company sold in the Company's first sale or issuance of its equity securities after December 30, 2011, in the aggregate amount of at least $3.0 million. The notes and the equity securities into which the notes are convertible have not been registered under the Securities Act and applicable state securities laws, but have been offered and sold in the United States pursuant to applicable exemptions from registration requirements under the Securities Act and applicable state securities laws.

On February 2, 2012, the Company entered into a Securities Purchase Agreement with certain institutional and other accredited investors pursuant to which the Company: (i) sold to the investors an aggregate of 19,000,000 shares of the Company's common stock at a price per share of $1.00 for aggregate gross proceeds of approximately $19.0 million; and (ii) issued to the investors warrants to purchase up to an aggregate of 9,500,000 shares of common stock with an exercise price of $1.25 per share. The warrants may be exercised, in whole or in part, at any time from February 7, 2012 until February 7, 2017 and contain both cash and "cashless exercise" features. The warrants also impose penalties on the Company for failure to deliver the shares of common stock issuable upon exercise. The Securities Purchase Agreement also requires the filing by the Company of a registration statement with the SEC covering all shares issued and issuable under such Securities Purchase Agreement and imposes significant penalties for the failure to file such

registration statement by March 23, 2012. The Company currently intends to use the net proceeds from the offering for general corporate and working capital purposes, primarily to accelerate development of several of the company's key initiatives. The common stock and warrants were issued pursuant to applicable exemptions from registration requirements under the Securities Act and applicable securities law.

As part of the offering and, in connection with the conversion of certain convertible promissory notes in the aggregate amount of $3.0 million issued by the Company on December 30, 2011 to the Third Security Investors, the Third Security Investors collectively received 3,000,000 shares of common stock and warrants to purchase up to 1,500,000 shares of common stock upon the same terms as the investors.

Information with respect to the securities of the Company as described above sold by the Company during the period covered by this Annual Report and thereafter through the date of the filing of this Annual Report with the SEC that were not

Table of Contents

registered under the Securities Act has previously been provided in the Company's Current Reports on Form 8-K filed with the SEC on January 6, 2012, February 3, 2012 and February 7, 2012.

Issuer Purchase of Equity Securities. The Company made no purchases of its common stock during the year ended December 31, 2011. Therefore, tabular disclosure is not presented.

Item 6. Selected Consolidated Financial Data.

The selected consolidated balance sheet data as of December 31, 2011 and 2010 and the selected consolidated statements of operations data for each year ended December 31, 2011, 2010 and 2009 have been derived from our audited consolidated financial statements that are included elsewhere in this Annual Report on Form 10-K. The selected consolidated balance sheet data as of December 31, 2009, 2008 and 2007 and the selected consolidated statements of operations data for each year ended December 31, 2008 and 2007 have been derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K. Dollar amounts, except per share data, are presented in thousands.

This data should be read together with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations", and the consolidated financial statements and related notes included elsewhere in this Annual Report. The financial information below is not necessarily indicative of the results of future operations. Future results could differ materially from historical results due to may factors, including those discussed in Item 1A in the section entitled "Risk Factors."

	Year Ended December 31,				
	2011	2010	2009	2008	2007
Statement of Operations Data:					
Net sales	$31,971	$20,048	$22,023	$23,993	$23,176
Cost of good sold	13,534	10,284	10,418	10,345	10,483
Gross profit	18,437	9,764	11,605	13,648	12,693
Selling, general and administrative	19,150	10,933	10,319	10,795	11,466
Research and development	2,218	2,305	3,182	2,465	3,033
Restructuring charges [1]	41	138	—	118	1,516
Impairment charges [2]	—	—	—	638	—
Operating expenses	21,409	13,376	13,501	14,016	16,015
Other income (expense) [3]	(6,765)	628	18	86	1,391
Loss before income taxes	(9,737)	(2,984)	(1,878)	(282)	(1,931)
Income tax expense	45	150	42	213	243
Loss from continuing operations	(9,782)	(3,134)	(1,920)	(495)	(2,174)
Gain from discontinued operations, net of tax [4]	—	—	—	—	1,374
Net loss	$(9,782)	$(3,134)	$(1,920)	$(495)	$(800)
Preferred stock dividends and accretion [5]	(1,010)	—	—	—	—
Net loss available to common stockholders	$(10,792)	$(3,134)	$(1,920)	$(495)	$(800)
Basic and diluted loss per share:					
From continuing operations	$(0.22)	$(0.06)	$(0.04)	$(0.01)	$(0.05)
From discontinued operations	—	—	—	—	0.03
	$(0.22)	$(0.06)	$(0.04)	$(0.01)	$(0.02)
Basic and diluted weighted average shares outstanding	49,362	49,244	49,190	49,190	49,190
	As of December 31,				
	2011	2010	2009	2008	2007
Balance Sheet Data:					
Working capital	$870	$6,781	$10,351	$11,350	$11,316
Total assets	33,562	32,027	16,004	17,556	19,090
Total liabilities and mezzanine equity	22,514	23,527	4,342	4,351	4,988
Total stockholders' equity [6]	11,048	8,500	11,662	13,205	14,102

(1) Restructuring plans were implemented in 2010, 2008 and 2007 to reduce and align our expenses with current business prospects. The plans included employee terminations, office closures, termination of collaborations and write-offs of abandoned intellectual property. As a result, restructuring charges were recorded and are included in operating expenses.

Table of Contents

Refer to Note D to the accompanying consolidated financial statements.

(2) Impairment charges in 2008 relate to the impairment of goodwill.

(3) Other income (expense) for all years presented primarily includes interest expense, interest income and in 2011, expense associated with the "Series A Preferred Stock" and warrants to purchase shares of Series A Preferred Stock (the "Series A Warrants") of $6.1 million, which is due to the change in fair value of the preferred stock conversion feature. The expense associated with the change in value of the preferred stock conversion feature is a non-cash item. Other income in 2011 and 2010 includes $0.2 million and $0.6 million net of consulting fees, respectively, awarded in a federal grant under the Qualifying Therapeutic Discovery Project Program related to 2009 projects. Other income in 2007 includes $0.9 million from the sale of an investment security and $0.2 million in insurance proceeds related to equipment destroyed in a fire at our Cramlington, England facility.

(4) Discontinued Operations include a reclassification of $1.3 million for an adjustment to other comprehensive income related to the closure of the Nucleic Acids segment. In the fourth quarter of 2005, we implemented a plan to exit the Nucleic Acids operating segment which was primarily engaged in the manufacture of phosphoramadites and the raw materials to produce phosphoramadites which are used to produce synthetic DNA. The Nucleic Acids operating segment consisted primarily of a manufacturing facility in Glasgow, Scotland.

(5) For 2011, includes accrued dividends on Series A Preferred Stock of $0.6 million and Series A Preferred Stock accretion of $0.4 million.

(6) Reference Footnote Q. "Subsequent Events" to our accompanying consolidated financial statements for a pro forma analysis of our total stockholders' equity as of December 31, 2011 as the result of a private placement offering performed in February 2012 by the Company.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This Management Discussion and Analysis contains forward-looking statements that involve risks and uncertainties. Please see the section entitled "Forward-Looking Statements" at the beginning of Item 1 and the section entitled "Risk Factors" under Item 1A for important information to consider when evaluating such statements.

You are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements we make are not guarantees of future performance and are subject to various assumptions, risks and other factors that could cause actual results to differ materially from those suggested by these forward-looking statements.

We expressly disclaim any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Transgenomic, Inc. is a global biotechnology company advancing personalized medicine in the detection and treatment of cancer and inherited diseases through its proprietary molecular technologies and world-class clinical and research services. We have three complementary business segments.

- Clinical Laboratories. Our clinical laboratories specialize in genetic testing for cardiology, neurology, mitochondrial disorders, and oncology. Located in New Haven, Connecticut and Omaha, Nebraska the molecular clinical reference laboratories are certified under the Clinical Laboratory Improvement Amendment (CLIA) as high complexity labs and our Omaha facility is also accredited by the College of American Pathologists (CAP).
- Pharmacogenomics Services. Our Contract Research Organization located in Omaha, Nebraska provides pharmacogenomics research services supporting Phase II and Phase III clinical trials conducted by our pharmaceutical customers. This lab specializes in pharmacogenomic, biomarker and mutation discovery research serving the

pharmaceutical and biomedical industries world-wide for disease research, drug and diagnostic development and clinical trial support.

- Diagnostic Tools. Our proprietary product is the WAVE® System which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. There is a worldwide installed base of over 1,500 WAVE Systems as of December 31, 2011. We also distribute bioinstruments produced by other manufacturers

Table of Contents

("OEM Equipment") through our sales and distribution network. Service contracts to maintain installed systems are sold and supported by our technical support personnel. The installed WAVE base and some OEM Equipment platforms generate a demand for bioconsumables that are required for the continued operation of the bioinstruments. We develop, manufacture and sell these bioconsumable products. In addition, we manufacture and sell consumable products that can be used on multiple, independent platforms. These products include SURVEYOR® Nuclease and a range of chromatography columns.

The following discussion should be read together with our financial statements and related notes contained in this report. Results for the year ended December 31, 2011 are not necessarily indicative of results that may be attained in the future.

Executive Summary

2011 Results

2011 vs. 2010 Dollars in Thousands

	Years Ended		Change		
	2011	2010	$	%	
Net sales	$31,971	$20,048	$11,923	59	%
Gross profit	18,437	9,764	8,673	89	%
Preferred stock and warrant expense	6,066	—	(6,066)	nm	
Net loss	(9,782)	(3,134)	(6,648)	212	%

Net sales for 2011 increased by $11.9 million or 59% compared to 2010. These results include revenues received from the FAMILION acquisition in our Clinical Laboratories segment. During 2011, net sales from Clinical Laboratories increased by $12.4 million compared to 2010. The Clinical Laboratories increase is a result of the revenue of $11.1 million related to the FAMILION acquisition. Net sales from Pharmacogenomics Services increased by $0.9 million for 2011 compared to 2010. Net sales in Diagnostic Tools were down 9% or $1.4 million for 2011 compared to 2010. Our gross profit margin increased from 49% for 2010 to 58% for 2011. Clinical Laboratories gross margin increased from 41% in 2010 to 59% for 2011. Loss from operations was $3.0 million for 2011 compared to $3.6 million for 2010.

During 2011, the Company recorded non-cash expense of $6.1 million associated with the Series A Preferred Stock and Series A Warrants. Such expense is due to the change in fair value of the preferred stock conversion feature.

2012 Outlook

We anticipate continued growth in 2012 in all three of our business units, Clinical Labs, Pharmacogenomic Services and Diagnostic Tools, as we commercialize new assay technologies and tests we have developed internally or in-licensed, and as we expand into other markets and regions worldwide. The foundation of these efforts was a successful 2011, driven by top line growth and the continued benefit of our FAMILION acquisition. Revenues increased by 59% to $32 million for the year ended December 31, 2011.

Our FAMILION franchise, which we acquired in December 2010, includes eleven tests for inherited cardiac disorders. We continue to believe that there is significant opportunity to expand this business based on increased use of existing tests and the launch of new products into the marketplace. In May, the Heart Rhythm Society issued new diagnostic guidelines supporting the use of some of our key cardiac tests. In November 2011, we launched two new genetic tests at the annual American Heart Association meeting. These include our PGxPredict:CLOPIDOGREL Panel, a uniquely comprehensive test to predict a patient's response to clopidogrel (Plavix®), the most widely prescribed antiplatelet drug used to reduce the risks of death, stroke and heart attack, and a test for familial atrial fibrillation.

The clopidogrel response test, in particular, is a significant opportunity for Transgenomic, as it is the only test which analyzes the genes CYP2C19 and ABCB1 to help predict a patient's ability to absorb and metabolize clopidogrel. Clopidogrel is taken in an inactive form, known as a prodrug, and must be absorbed through the intestine and then

metabolized by the liver to form the active drug in a process controlled by these genes. Patients with dysfunctional or lower functioning ABCB1 or CYP2C19 are at heightened risk for cardiovascular events than patients with normal protein function due to poorer availability of the active drug.

Table of Contents

The risk associated with dysfunctional or lower functioning CYP2C19 prompted the FDA in 2010 to add a black box warning to the clopidogrel label.

In March of 2012, Transgenomic announced the publication of a new study by researchers at Vanderbilt University in the journal “Clinical Pharmacology and Therapeutics.” This large, independent study, the third such study examining CYP2C19 and ABCB1, demonstrated the importance of both genes in determining which patients would benefit from treatment with clopidogrel and which should pursue alternative treatment. ABCB1 is proprietary to Transgenomic, protected by an issued patent in Europe and pending patent in the US. There are approximately 6 million new patients prescribed Plavix each year, of which about 47% will not fully benefit from their therapy because of genetic variations in either CYP2C19 or ABCB1. This highlights a need for broad-based testing, and represents a potential multi-billion dollar opportunity for Transgenomic's Clinical Laboratories division.

In June 2011, we launched our Nuclear Mitome Test, a 400-gene screen of the nuclear genes linked to mitochondrial function that provides useful clinical information in understanding the underlying genetic causes of this spectrum of diseases. This test has been well-received by mitochondrial experts and physicians already and is assisting them to better diagnose this serious and difficult to discern set of disorders.

In our Pharmacogenomics Services Unit, we continue to perform cancer pathway gene mutation analysis and other associated genomics service testing for a number of pharmaceutical companies: both for pre-clinical drug discovery projects and phase II and III clinical trials. Although we may experience variability in quarter-to-quarter revenues based on the timing of projects or when specimens may arrive, we continue to experience growth in this area of the business. We can now analyze a patient's blood serum rather than a tumor to detect DNA mutations, using our ultra-sensitive DNA mutation detection technology, termed “ICE COLD-PCR”. This is a significant achievement, and we believe it should lead to faster growth of our pharmacogenomics research services as pharmaceutical companies adopt this novel approach for both drug and disease research.

In addition to ICE COLD-PCR, which offers sensitivity improvements as much as 1,000 times higher than routine DNA testing technology, we have recently discovered a technique to further improve mutation detection sensitivity of standard Sanger sequencing. We have termed this new discovery “BLOCker-Sequencing” and we are combining this new discovery with our ICE COLD-PCR program to bring what we believe to be the most accurate and sensitive mutation detection technology available in the market today.

Results of Continuing Operations

Net Sales.

Net sales consisted of the following:

2011 vs. 2010	Dollars in Thousands			
	Years Ended		Change	
	2011	2010	$	%