

TRANSGENOMIC INC  
Form 10-K  
March 14, 2013

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

FORM 10-K  
(Mark One)

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

For the fiscal year ended December 31, 2012

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

(State or Other Jurisdiction of  
Incorporation or Organization)

91-1789357

(IRS Employer  
Identification Number)

12325 Emmet Street

Omaha, NE

(Address of Principal Executive Offices)

(402) 452-5400

(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class

None

Name of Each Exchange On Which Registered

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

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

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  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  No

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K

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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  Non-Accelerated Filer  Smaller Reporting Company   
(Do not check if a smaller reporting company)

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

Yes  No

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 \$64.4 million.

At March 13, 2013, the registrant had 88,225,725 shares of common stock outstanding.

TRANSGENOMIC, INC.

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This Annual Report on Form 10-K references the following registered trademarks which are the property of Transgenomic, Inc.: Transgenomic, WAVE, WAVEMAKER, MutationDiscovery.com, OPTIMASE, DNASEP, OLIGOSEP, RNASEP, WAVE OPTIMIZED, SURVEYOR, FAMILION and ScoliScore™. The following are

trademarks which are the property of Transgenomic, Inc.: Advancing Personalized Medicine, the helix logo, ProtocolWriter and Navigator. All other trademarks or trade names referred to in this Annual Report on Form 10-K are the property of their respective owners.

## PART I

### FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual 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," "should," "will," "would" or the negative of such terms and other 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 Annual 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 Annual Report. Results for the year ended December 31, 2012 are not necessarily indicative of results that may be attained in the future.

#### Item 1. Our Business

Transgenomic, Inc. ("we", "us", "our Company" or "Transgenomic") 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. Our operations are organized and reviewed by management along its product lines and presented in the following 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. 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.

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Segment information related to revenues, a performance measure of profit, capital expenditures, and total assets is contained in Footnote 14 "Operating Segment and Geographic Information" to our accompanying consolidated financial statements.

#### 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;
- Acquiring all or parts of other companies;
- Entering into joint-development efforts with other companies; and
- Reselling other companies' products.

Our strategy is to leverage the synergies of our three divisions, capitalizing on discoveries in our Research and Development ("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 C-GAAP 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 several 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 we acquired the ScolioScore™ assay technology in September 2012, and we have integrated both into our existing business. We believe that we are skilled at such acquisition integrations.

#### Products

Our highly specialized genetics service and expertise are delivered by our Pharmacogenomic Services Laboratory in Omaha, Nebraska and in our Clinical Laboratory Improvement Act (CLIA)-certified Clinical Laboratories in Omaha and New Haven, Connecticut. Our Pharmacogenomics Lab supports pharmaceutical companies in their clinical trials, primarily Phase II and Phase III trials. Our Clinical Laboratories division supports medical professionals in the diagnosis and treatment of patients, primarily in the specialties of Cardiology and Neurology 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; and
- Determine whether family members are at risk.

Also in cardiology, our C-GAAP 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 C-GAAP 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, and which is currently run in a partner lab.

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ScoliScore™ is the first clinically validated and commercially available saliva-based multi-gene test that provides a highly accurate assessment of the likelihood of spinal curve progression for individuals diagnosed with Adolescent Idiopathic Scoliosis (AIS), or an abnormal lateral curve of the spine. The ScoliScore™ Test identifies patients that will not progress to a severe curvature of the spine and reduces those patients' need for repeated doctor visits, physical examinations and, most importantly, years of exposure to radiation from frequent X-Rays.

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, WAVE MCE and Hanabi instruments, as well as the 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 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, 2012, 2011 or 2010. Information regarding the revenues attributable to U.S. and international markets is set forth in Note 14 "Operating Segment and Geographic Information" to our accompanying 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 and non-small cell lung; (ii) development of a new strategy for mutation detection and sequence confirmation using microcapillary electrophoresis; (iii) development of ICE COLD-PCR applications for ultra-high sensitivity mutation detection in any tissue samples (fresh, frozen, FNA, FFPE, etc.) or body fluids (plasma, serum, ascites); (iv) the use of commercially available assays and the development of custom assays for detection of somatic mutations in cancer samples using Next Generation

Sequencing; 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, 2012, 2011 and 2010, our research and development expenses were \$2.5 million, \$2.2 million and \$2.3 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 in 2010, we acquired exclusive rights to the FAMILION family of 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 our 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 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, among others, 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.

#### Employees

As of December 31, 2012 and 2011, we had employees focused in the following areas of operation:

	December 31,	
	2012	2011
Manufacturing and Laboratory	86	68
Sales, Marketing and Administration	105	92
Research and Development	11	9
	202	169

Our employees were employed in the following geographical locations:

	December 31,	
	2012	2011
United States	181	148
Europe (other than the United Kingdom)	10	10
United Kingdom	11	11
	202	169

#### 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 New Haven facility also houses certain administrative and financial operations.

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 amended (the "Exchange Act"), as soon as reasonably practicable after we electronically file such material with, or furnish it to, the United 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 60, 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, a specialty chemical and diagnostic company which he sold to Fisher Healthcare. From 1999 to 2003, Mr. Tuttle served as Vice President of Business Development for Apogent Technologies, a \$1.0 billion healthcare company that was acquired by Fisher Healthcare and subsequently became ThermoFisher, and President and Chief Executive Officer of Applied Biotech, Inc., an Apogent Technologies company. Prior to that, Mr. Tuttle was President and General manager of Seradyn, Inc. a diagnostic and genomic products company within the Apogent Technologies group of companies. Mr. Tuttle has also held senior management positions at Boehringer Mannheim, Bayer Diagnostics and Difco Laboratories. He began his career at Syva Company, a subsidiary of Syntex Pharmaceuticals and Cetus Corporation where he led the development of the first thermocycler system for automating PCR. Mr. Tuttle holds a B.S. in Biochemistry from UCLA, an M.S. in Biochemistry from the University of Colorado and an M.B.A. in Business and Marketing from St. Mary's College.

Mark P Colonnese. Mr. Colonnese, age 57, was appointed as our Executive Vice President and Chief Financial Officer by the Board in September 2012. Mr. Colonnese has nearly 30 years of experience in leading business growth and financial strategies for life sciences companies. He most recently served as Executive Vice President, Commercial Operations and Chief Financial Officer at Salutria Pharmaceuticals, LLC, a privately-held, development-stage pharmaceutical company from April 2009 to August 2012. Prior to that, Mr. Colonnese served as an executive in a number of capacities at AtheroGenics, Inc., a development-stage pharmaceutical company, from January 1999 to April 2009, including Executive Vice President, Commercial Operations and Chief Financial Officer from May 2006 to April 2009, as Senior Vice President of Finance and Administration and Chief Financial Officer since 2002, and as Vice President of Finance and Administration and Chief Financial Officer since 1999. Prior to joining AtheroGenics, Mr. Colonnese served as Senior Vice President and Chief Financial Officer at Medaphis Corporation and has also held executive positions at Applied Analytical Industries, Inc. and Schering-Plough Corporation. Mr. Colonnese is a Certified Public Accountant.

Chad M. Richards. Mr. Richards, age 43, joined our Company in October 2007 as Senior Vice President, Sales and Marketing and was promoted to Chief Commercial Officer in January 2011. Before joining our 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 reagent systems. Before embarking on a career in diagnostics, Mr. Richards served in the United States Marine Corps.

### 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, 2012, 2011 and 2010 was \$9.5 million, \$3.0 million and \$3.6 million, respectively. These historical losses have been due principally to the 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 significant 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.

Our future capital needs are uncertain and we may need to raise additional funds in the future.

Our future capital needs are uncertain and we may need to raise additional funds in the future through debt or equity offerings. Our future capital requirements will depend on many factors, including, but not limited to:

revenue generated by sales of our products;

expenses incurred in manufacturing and selling our products;

costs of developing new products or technologies;

costs associated with capital expenditures;

the number and timing of acquisitions and other strategic transactions; or

working capital requirements related to growing new acquisitions or existing business.

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 segment are dependent on patient visits to doctors' offices and other providers of health care and tend to fluctuate. Testing volume generally declines during the year-end holiday periods, other major holidays and the summer.

Our Pharmacogenomics Services segment 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.

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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 payers could have an adverse impact on our net sales.

We may experience temporary disruptions and delays in processing tissue samples at our facilities.

We may experience delays in processing biological samples caused by software and other errors. In early 2012, our laboratory information management system ("LIMS") installed in our New Haven, Connecticut laboratory testing facility experienced a software failure that resulted in reduced sample processing capacity. Although we have reviewed and improved our internal procedures to secure proper function of the LIMS and we believe that the full sample processing capacity has been restored, there are no assurances that we will not experience future temporary delays or disruptions in processing samples at our New Haven, Connecticut facility or at our other facilities. Any delay in processing samples could have an adverse effect on our business, financial condition and results of operations.

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 certain portions of the legislation have already gone into effect, the ultimate impact of the legislation on the health care industry is still unknown, and the overall impact on our business is likely to be extensive and could result in significant changes to our business and our customers' businesses.

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 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 U.S. 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 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.

We may need additional capital to finance our growth or to compete, which may cause dilution to existing stockholders or limit our flexibility in conducting our business activities.

We currently anticipate that existing cash and cash equivalents and cash flow from operations will be sufficient to meet our anticipated needs for working capital, operating expenses and capital expenditures for at least the next twelve months. However, we may need to raise additional capital in the future to fund expansion, respond to competitive pressures or acquire complementary businesses, technologies or services. Such additional financing may not be available on terms acceptable to us or at all. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution, and to the extent we engage in additional debt financing, if available, we may become subject to additional restrictive covenants that could limit our flexibility in conducting future business activities. If additional financing is not available or not available on acceptable terms, we may not be able to fund our expansion, promote our brands, take advantage of acquisition opportunities, develop or enhance services or respond to competitive pressures.

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 under the Exchange Act, which provides that the definition of a “penny stock” for the purposes relevant to us, is 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 15c-9 under the Exchange Act 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 must, among other things:

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

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.

SEC rules also require disclosure 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, 2012, we had obligations to issue 29,660,038 shares of common stock upon exercise of outstanding stock options, warrants or conversion rights. In January 2013, we completed a private placement, pursuant to which we issued warrants to purchase up to an aggregate of 8,300,000 shares of common stock and shares of our common stock. 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, 2012, we had 71,645,725 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. In addition, the large concentration of our shares held by a small group of stockholders could result in increased volatility in our stock price due to the limited number of shares available 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	2013 Scheduled Rent	Lease Term Expires
Omaha, Nebraska	WAVE and Consumable Manufacturing	25,000	\$141	July 2016
San Jose, California	Consumable Manufacturing	9,110	\$58	February 2016
Glasgow, Scotland	Multi Functional <sup>(1)</sup>	5,059	\$37	May 2017
Omaha, Nebraska	Multi Functional <sup>(1)</sup>	18,265	\$208	July 2022
Omaha, Nebraska	Multi Functional <sup>(1)</sup>	4,410	\$38	May 2017
New Haven, Connecticut	Multi Functional <sup>(1)</sup>	22,459	\$432	June 2018

<sup>(1)</sup> 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 a 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.

## Item 4. Mine Safety Disclosures

Not applicable.

## 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 2012 and 2011. 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, 2012		
First Quarter	\$ 1.35	\$ 1.15
Second Quarter	\$ 1.13	\$ 0.78
Third Quarter	\$ 1.06	\$ 0.75
Fourth Quarter	\$ 0.97	\$ 0.54
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

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, 2007 and that all dividends were re-invested. The comparisons shown in the graph are based upon historical data and we caution that the stock price performance shown in the graph is neither indicative of, nor intended to forecast, the potential future performance of our stock.

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 Exchange Act,

except to the extent that we specifically incorporate it by reference into a document filed under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act.

Holders. At December 31, 2012, there were 71,645,725 shares of our common stock outstanding and approximately 3,200 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.

Series A Preferred Shares and Series A Preferred Warrants: On December 29, 2010, we entered into a Series A Convertible Preferred Stock Purchase Agreement (the "Series A Purchase Agreement") with Third Security Senior Staff 2008 LLC, Third Security Staff 2010 LLC, and Third Security Incentive 2010 LLC (collectively, the "Third Security Investors"), pursuant to which we: (i) sold to the Third Security Investors an aggregate of 2,586,205 shares of our Series A Convertible Preferred Stock (the "Series A Preferred") at a price per share of \$2.32 for aggregate gross proceeds of approximately \$6,000,000; and (ii) issued to the Third Security Investors warrants (the "Series A Warrants") to purchase up to an aggregate of 1,293,102 shares of Series A Preferred with an exercise price of \$2.32 per share (collectively, the "2010 Financing"). The Series A Preferred and Series A Warrants were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act and Rule 506 promulgated thereunder. The agreements executed in connection with the 2010 Financing contained representations to support our reasonable belief that the Third Security Investors had access to information concerning our operations and financial condition, the Third Security Investors acquired the securities for their own account and not with a view to the distribution thereof in the absence of an effective registration statement or an applicable exemption from registration, and that the Third Security Investors are sophisticated within the meaning of Section 4(2) of the Securities Act and are "accredited investors" (as defined by Rule 501 under the Securities Act). The Series A Warrants may be exercised at any time from December 29, 2010 until December 28, 2015 and contain a "cashless exercise" feature. The shares of Series A Preferred issuable pursuant to the Series A Purchase Agreement and upon exercise of the Series A Warrants are initially convertible into shares of common stock at a rate of 4-for-1, which conversion rate is subject to further adjustment as set forth in the Certificate of Designation. We used the net proceeds from the 2010 Financing to acquire certain assets of Clinical Data, Inc. ("Clinical Data") and PGx Health, LLC, a wholly-owned subsidiary of Clinical Data.

In connection with the 2010 Financing, we also entered into a registration rights agreement with the Third Security Investors (the "2010 Registration Rights Agreement"). Pursuant to the terms of the 2010 Registration Rights Agreement, we have granted the Third Security Investors certain demand, "piggyback" and S-3 registration rights covering the resale of the shares of Common Stock underlying the Series A Preferred issued pursuant to the Series A Purchase Agreement and issuable upon exercise of the Series A Warrants and all shares of Common Stock issuable upon any dividend or other distribution with respect thereto.

On November 8, 2011, we entered into an Amendment Agreement with the Third Security Investors, which are the holders of all of the outstanding shares of our Series A Preferred. Pursuant to the Amendment Agreement, the Third Security Investors and we agreed to amend the Certificate of Designation to eliminate certain features of the Series A Preferred relating to (i) an anti-dilution adjustment to the conversion rate upon which the Series A Preferred is convertible into our common stock, and (ii) an optional redemption of the Series A Preferred by the Third Security Investors (the "Certificate Amendment"); subject to the requisite stockholder approval of the Certificate Amendment at the next annual meeting of our stockholders. Pursuant to the Amendment Agreement, the Third Security Investors agreed to vote the Series A Preferred and their common stock in favor of the Certificate Amendment and agreed to waive their rights to the features of the Series A Preferred being eliminated by the Certificate Amendment. In

exchange for the Third Security Investors entering into the Amendment Agreement, we agreed to issue to the holders an aggregate of \$0.3 million market value of common stock or 245,903 shares of common stock. Our stockholders approved the Certificate Amendment at the 2012 Annual Meeting of Stockholders held on May 23, 2012, and we filed the Certificate Amendment with the Delaware Secretary of State on May 25, 2012.

Convertible Promissory Notes: On December 30, 2011, we 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. Affiliates of the investors currently own all the outstanding shares of our Series A Preferred. Under the Note Purchase Agreement, we sold to each of the Third Security Investors a convertible note which had a March 31, 2012 maturity date. The Note Purchase Agreement and notes provided for conversion of any amount remaining due to the Third Security Investors under the notes into our equity securities of the same class(es) or series and at the same price as the equity securities sold in our first sale or issuance of our 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 were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act and Rule 506 promulgated thereunder. The Note Purchase Agreement contained representations to support our reasonable belief that the Third Security Investors had access to information concerning our operations and financial condition, the Third Security Investors acquired the securities for their own account and not with a view to the distribution thereof in the absence of an effective registration statement or an applicable exemption from registration, and that the Third Security Investors are sophisticated within the meaning of Section 4(2) of the Securities Act and are “accredited investors” (as defined by Rule 501 under the Securities Act). The Securities Purchase Agreement also required us to file a registration statement with the SEC covering all shares issued and issuable under such Securities Purchase Agreement and imposed significant penalties for the failure to file such registration statement by March 23, 2012. We used the net proceeds from the offering for general corporate and working capital purposes, primarily to accelerate development of several of our key initiatives. The common stock and warrants were issued pursuant to applicable exemptions from registration requirements under the Securities Act and applicable securities law.

**2012 Private Placement and Note Conversion:** On February 2, 2012, we entered into a Securities Purchase Agreement with certain institutional and other accredited investors pursuant to which we: (i) sold to the investors an aggregate of 19,000,000 shares of our common stock (the “2012 Financing Shares”) 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 “2012 Financing Warrants”). The 2012 Financing 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 2012 Financing Warrants also impose penalties on us for failure to deliver the shares of common stock issuable upon exercise. These warrants also contain certain anti-dilution provisions that provide for an adjustment to the exercise price and number of shares issuable upon exercise of the warrant in the event that we engage in certain issuances of shares of our common stock at a price lower than the exercise price of the warrant. We used the net proceeds from the offering for general corporate and working capital purposes, primarily to accelerate development of several of our key initiatives.

As part of the offering, in connection with the conversion of the convertible promissory notes in the aggregate amount of \$3.0 million issued by us on December 30, 2011 to the Third Security Investors, the Third Security Investors collectively received 3,000,000 shares of common stock (the “Third Security Common Shares”) and warrants to purchase up to 1,500,000 shares of common stock (the “Third Security Warrants”) upon the same terms as the investors. We offered and sold the 2012 Financing Shares, 2012 Financing Warrants, Third Security Common Shares and Third Security Warrants to “accredited investors” as such term is defined in the Securities Act and in reliance on the exemption from registration afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws. Each investor represented that it was an “accredited investor,” as defined in Regulation D, and acquired the 2012 Financing Shares, 2012 Financing Warrants, Third Security Common Shares, Third Security Warrants and shares of common stock issuable upon exercise of the 2012 Financing Warrants and Third Security Warrants for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof.

In connection with the offering, we also entered into a registration rights agreement with the investors and the Third Security Investors (the “2012 Registration Rights Agreement”). The 2012 Registration Rights Agreement required us to file a registration statement with the SEC within forty-five (45) days of the closing date of the offering for the resale by the investors and the Third Security Investors of all of the 2012 Financing Shares, the shares of common stock issuable upon exercise of the 2012 Financing Warrants, the Third Security Common Shares, the shares of Common Stock issuable upon exercise of the Third Security Warrants and all shares of common stock issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect thereto. Pursuant to and as required by the 2012 Registration Rights Agreement, on March 21, 2012, we filed a registration statement on Form S-1 registering for resale the 2012 Financing Shares, the shares of common stock issuable upon exercise of the 2012 Financing Warrants, the Third Security Common Shares, the shares of common stock issuable upon exercise of the

Third Security Warrants and all shares of common stock issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect thereto. The registration statement was declared effective by the SEC on April 4, 2012.

Craig-Hallum Capital Group LLC served as the sole placement agent for the offering. In consideration for services rendered as the placement agent in the offering, we agreed to (i) pay to the placement agent cash commissions equal to \$1,330,000, or 7.0% of the gross proceeds received in the offering, (ii) issue to the placement agent a five-year warrant to purchase up to 380,000 shares of our common stock (representing 2% of the 2012 Financing Shares sold in the offering) with an exercise price of \$1.25 per share and other terms that are the same as the terms of the 2012 Financing Warrants and the Third Security Warrants issued in connection with the offering; and (iii) reimburse the placement agent for reasonable out-of-pocket expenses, including fees paid to the placement agent's legal counsel, incurred in connection with the offering, which reimbursable expenses shall not exceed \$125,000. The calculation of the placement agent's fees did not include the Third Security Common Shares and Third



Security Warrants issued to the Third Security Investors in connection with the conversion of the convertible promissory notes described above.

2013 Private Placement: On January 24, 2013, we entered into a Securities Purchase Agreement with certain institutional and other accredited investors pursuant to which we: (i) sold to the investors an aggregate of 16,600,000 shares of common stock at a price per share of \$0.50 for aggregate gross proceeds of approximately \$8.3 million; and (ii) issued to the investors warrants to purchase up to an aggregate of 8,300,000 shares of common stock with an exercise price of \$0.75 per share. The warrants may be exercised, in whole or in part, at any time from January 30, 2013 until January 30, 2018 and contain both cash and “cashless exercise” features. The warrants also impose penalties on us for failure to deliver the shares of common stock issuable upon exercise. We currently intend to use the net proceeds from the offering for general corporate and working capital purposes, primarily to accelerate development of several of our key initiatives. The common stock and warrants were offered and sold in transactions exempt from registration under the Securities Act, in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder. Each investor represented that it was an “accredited investor,” as defined in Regulation D, and acquired the common stock, warrants and shares issuable upon exercise of the warrants for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof.

The above common stock transaction required the repricing and issuance of additional common stock warrants to the warrant holders of the February 2012 common stock sale. The exercise price decreased from \$1.25 per share to \$1.08 per share and the number of shares issuable upon exercise of the warrant increased from 11,380,000 to 13,171,268. In connection with the offering, we also entered into a Registration Rights Agreement with the investors. The Registration Rights Agreement requires us to file a registration statement with the Securities and Exchange Commission within forty-five (45) days of the closing date of the offering for the resale by the investors of all of the common shares, the shares of common stock issuable upon exercise of the warrants, and all shares of common stock issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect thereto. The initial registration statement must be declared effective by the SEC within ninety (90) days of the closing date of the offering subject to certain adjustments. Upon the occurrence of certain events, including, but not limited to, that the initial Registration Statement is not filed prior to the filing date, we will be required to pay liquidated damages to each of the investors upon the date of the event and then monthly thereafter until the earlier of the date that: (i) the event is cured, or (ii) the registrable shares are eligible for resale under Rule 144 without manner of sale or volume limitations. In no event shall the aggregate amount of liquidated damages payable to each of the investors exceed in the aggregate 10% of the aggregate purchase price paid by such investor for the registrable securities. Pursuant to this Registration Statement and as required by the Registration Rights Agreement, we are registering the resale of the common shares, the shares of common stock issuable upon exercise of the warrants and all shares of common stock issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect thereto.

Lazard Capital Markets LLC served as the lead placement agent for the offering, and Craig-Hallum Capital Group LLC acted as co-placement agent. In consideration for services rendered as the placement agents in the offering, we agreed to (i) pay to the placement agents cash commissions equal 7% of the gross proceeds received in the offering, and (ii) reimburse the placement agent for reasonable out-of-pocket expenses, including fees paid to the placement agents' legal counsel, incurred in connection with the offering, which reimbursable expenses shall not exceed \$25,000. Information with respect to the securities as described above sold by us 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 registered under the Securities Act has previously been provided in our Current Reports on Form 8-K filed with the SEC on January 6, 2012, February 3, 2012, February 7, 2012, January 25, 2013 and January 30, 2013.

Issuer Purchases of Equity Securities. We made no purchases of our common stock during the year ended December 31, 2012. Therefore, tabular disclosure is not presented.



## Item 6. Selected Consolidated Financial Data.

The selected consolidated balance sheet data as of December 31, 2012 and 2011 and the selected consolidated statements of operations data for each year ended December 31, 2012, 2011 and 2010 have been derived from our audited consolidated financial statements that are included elsewhere in this Annual Report. The selected consolidated balance sheet data as of December 31, 2010, 2009 and 2008 and the selected consolidated statements of operations data for each year ended December 31, 2009 and 2008 have been derived from our audited consolidated financial statements that are not included in this Annual Report. 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 many factors, including those discussed in Item 1A in the section entitled "Risk Factors."

	Year Ended December 31,				
	2012	2011	2010	2009	2008
Statement of Operations Data:					
Net sales	\$31,480	\$31,971	\$20,048	\$22,023	\$23,993
Cost of goods sold	16,470	13,534	10,284	10,418	10,345
Gross profit	15,010	18,437	9,764	11,605	13,648
Selling, general and administrative	22,023	19,150	10,933	10,319	10,795
Research and development	2,491	2,218	2,305	3,182	2,465
Restructuring charges <sup>(1)</sup>	—	41	138	—	118
Impairment charges <sup>(2)</sup>	—	—	—	—	638
Operating expenses	24,514	21,409	13,376	13,501	14,016
Other income (expense) <sup>(3)</sup>	1,323	(6,765)	628	18	86
Loss before income taxes	(8,181)	(9,737)	(2,984)	(1,878)	(282)
Income tax expense	146	45	150	42	213
Net Loss	\$(8,327)	\$(9,782)	\$(3,134)	\$(1,920)	\$(495)
Preferred stock dividends and accretion <sup>(4)</sup>	(660)	(1,010)	—	—	—
Net loss available to common stockholders	\$(8,987)	\$(10,792)	\$(3,134)	\$(1,920)	\$(495)
Basic and diluted loss per share	\$(0.13)	\$(0.22)	\$(0.06)	\$(0.04)	\$(0.01)
Basic and diluted weighted average shares outstanding	69,417	49,362	49,244	49,190	49,190
	As of December 31,				
	2012	2011	2010	2009	2008
Balance Sheet Data:					
Working capital	\$2,189	\$870	\$6,781	\$10,351	\$11,350
Total assets	38,791	33,562	32,027	16,004	17,556
Total liabilities and mezzanine equity	18,517	22,514	23,527	4,342	4,351
Total stockholders' equity <sup>(5)</sup>	20,274	11,048	8,500	11,662	13,205

Restructuring plans were implemented in 2011, 2010 and 2008 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.

(2) Impairment charges in 2008 relate to the impairment of goodwill related to our Tools segment.

(3)

Other income in 2012 includes \$2.2 million associated with the change in fair value of the common stock warrants. The income related to the change in fair value of the common stock warrants is a non-cash item. Other expense for 2011 includes 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.

(4) 2012 includes accrued dividends on Series A Preferred Stock of \$0.7 million. 2011 includes accrued dividends on Series A Preferred Stock of \$0.6 million and Series A Preferred Stock accretion of \$0.4 million.

Please see Footnote 17. "Subsequent Events" to our accompanying consolidated financial statements for a pro forma analysis of our total stockholders' equity as of December 31, 2012 as the result of the private placement offering we completed in January 2013.

#### 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. ("we", "us", "our Company" or "Transgenomic") 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. Our operations are organized and reviewed by management along its product lines and presented in the following 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. 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.

The following discussion should be read together with our financial statements and related notes contained in this Annual Report. Results for the year ended December 31, 2012 are not necessarily indicative of results that may be attained in the future.



## Executive Summary

## 2012 Results

2012 vs. 2011

Dollars in Thousands

	Year Ended December 31,		Change		
	2012	2011	\$	%	
Net sales	\$31,480	\$31,971	\$(491	) (2	)%
Gross profit	15,010	18,437	(3,427	) (19	)%
Preferred Stock and Common Stock Warrant income (expense)	2,200	(6,066	) 8,266	(136	)%
Net loss available to common stockholders	(8,987	) (10,792	) 1,805	(17	)%

Overall net sales for 2012 were consistent with net sales in 2011. During 2012, net sales from Clinical Laboratories increased by \$1.4 million compared to 2011. Net sales from Pharmacogenomics Services decreased by \$0.4 million for 2012 compared to 2011. Net sales in Diagnostic Tools were down 11%, or \$1.5 million, for 2012 compared to 2011. Our gross profit margin decreased from 58% for 2011 to 48% for 2012. Clinical Laboratories gross margin decreased from 59% in 2011 to 49% for 2012. Loss from operations was \$9.5 million for 2012 compared to \$3.0 million for 2011.

During 2012, we recorded non-cash revenue of \$2.2 million associated with our common stock warrants due to the change in the fair value of the common stock warrants. During 2011, we recorded non-cash expense of \$6.1 million associated with our Series A Preferred Stock and Series A Warrants. Such expense is due to the change in fair value of the preferred stock warrants and conversion feature. Due to a change in terms we are no longer required to fair value the preferred stock warrants and conversion feature, therefore no income or expense was recorded in 2012 related to the preferred stock warrants and conversion feature.

## 2013 Outlook and 2012 Overview

We are advancing personalized medicine in cardiology, oncology, and inherited diseases through our proprietary molecular technologies and world-class clinical research services. Today, we are a global leader in cardiac genetic testing with a family of innovative products, including the C-GAAP test. We anticipate growth in all three of our business units, Clinical Laboratories, Pharmacogenomic Services, and Diagnostic Tools, as we commercialize new technologies and tests we have developed internally, in-licensed, or acquired, and as we expand into other markets and regions worldwide.

In the Clinical Labs business, we continue to provide increased sales and marketing support behind our proprietary C-GAAP (Clopidogrel Genetic Absorption Activation Panel) test. In July 2012, we successfully secured Medicare coverage for C-GAAP, which is a simple but comprehensive saliva test that accurately predicts a patient's response to Plavix® (clopidogrel). This innovative test analyzes markers in two important genes to identify patients who are at a genetically increased risk of major adverse cardiovascular events due to diminished effectiveness of Plavix®. As a result of this coverage, the 48 million Americans currently covered by Medicare will have access to this important genetic test.

Clopidogrel is the most widely prescribed antiplatelet drug used to reduce the risks of death, stroke and heart attack in heart disease patients. Patients with dysfunctional CYP2C19 and ABCB1 genes treated with clopidogrel exhibit a 50% increase in major adverse cardiovascular event rates than do patients with normal CYP2C19 and ABCB1 genetic function. Our C-GAAP is the only assay on the market that includes both genes in the test.

We also announced in September 2012, the acquisition of global rights to the ScoliScore™ Adolescent Idiopathic Scoliosis (AIS) Prognostic Test from Axial Biotech. This acquisition provides us with the ScoliScore™ assay technology and intellectual property, an established revenue and customer base, and access to a testing market estimated at 400,000 patients in the United States alone. ScoliScore™ is the first clinically validated and commercially available saliva-based multi-gene test that provides a highly accurate assessment of the likelihood of spinal curve progression for individuals diagnosed with AIS, or an abnormal lateral curve of the spine. ScoliScore™ has the ability to

identify patients that will not progress to a severe curvature of the spine and reduces those patients' need for repeated doctor visits, and more importantly, years of exposure to radiation from frequent X-Rays which significantly increases these patients' risk for cancer. The health economic benefits of the Scoliscore™ test are considerable for patients, physicians, and payers, when taking into account the time and expense associated with repeated



radiography and the costs related to treating AIS. ScolioScore™ is representative of the kind of value-added, proprietary genetic test on which we are built.

We continue to expand the global reach of our cardiology platform through the growth of our FAMILION franchise, which currently includes thirteen tests designed to detect for the vast number of genetic mutations that can cause cardiac disorders. The comprehensive nature of our FAMILION genetic tests demonstrates our commitment to setting the standard for cardiac genetic testing today.

In July 2012, we announced a new commercial collaboration with the Medical College of Wisconsin Laboratories, a world-renowned institution with a robust presence in genomics and genetic testing. In addition to traditional sequencing services, MCW is the first lab to offer our proprietary NuclearMitome Test which employs next-generation sequencing technology to identify mutations in 448 genes and, to date, represents the most comprehensive genetic test available for mitochondrial disorders. Mitochondrial disorders are notoriously difficult to diagnose because they affect multiple organ systems, including the liver, the brain and nervous system, kidneys, and cardiovascular system. This collaboration allows us to rapidly expand the commercial use of this innovative test in addition to building out our offerings in whole genome and exome testing.

In our Pharmacogenomics Services business, 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.

In mid-2012, we launched the REVEAL Kit, a breakthrough technology that utilizes ICE COLD-PCR mutation detection technology, and enables unmatched sensitivity and complete DNA mutation detection using the standard sequencing equipment already installed in laboratories around the world. The extremely high sensitivity of ICE COLD-PCR enables detection of mutations from virtually any sample type including tissue biopsies, blood, and circulating tumor cells (CTCs). The broad use of this innovative technology has the potential to revolutionize cancer screening, diagnosis, monitoring, and therapy selection since it has the ability to perform safer, less invasive, and more frequent assessments of a cancer and its mutations, all through a simple blood draw.

The breakthrough ICE COLD-PCR technology, exclusively licensed by us for DNA sequencing analysis, was developed in collaboration with the Dana-Farber Cancer Institute and is supported by multiple validation studies confirming reproducible mutation detection up to 1,000 to 10,000 times more sensitive than traditional sequencing and PCR techniques. The technology is also being evaluated in an ongoing study with The University of Texas MD Anderson Cancer Center to characterize tumor-derived DNA in blood and DNA isolated from circulating tumor cells (CTCs) from patients with a variety of cancers to choose therapies shown to target specific mutations.

We have entered into a number of collaborations with key opinion leaders at leading cancer institutions to validate our ultra-sensitive ICE COLD-PCR technology and expand the evidence base for its clinical utility. Several prospective trials have begun and samples from patients with lung cancer will be collected to detect rare mutations in blood or in biopsy samples that are associated with disease recurrence, progression, or emergence of resistance to targeted drugs. Collaborating clinicians have also been able to supply blood samples from patients with cancers such as melanoma, pancreatic cancer, and colorectal cancer to see if mutations found in DNA circulating in the serum or derived from circulating tumor cells match those from the patients' primary tumors. The presence of certain mutations in the blood or other samples may indicate recurrence of disease prior to clinical signs, and help direct clinicians to initiate the best possible therapies, or change therapies if mutations associated with drug resistance are detected. We have also initiated a program of beta site testing to validate the performance of our REVEAL ICE COLD-PCR kits prior to full commercialization.

In June 2012, we announced that the U.S. Patent and Trademark Office issued patent number US 8,137,919 titled "Method of Determining the Sensitivity of Cancer Cells to EGFR Inhibitors including Cetuximab, Panitumumab and Erlotinib." The patent inventors demonstrated that key mutations in the gene PIK3CA are powerful predictors for the efficacy of EGFR-targeted cancer therapies. The addition of this patent allows us to effectively apply high sensitivity mutation detection technologies, such as SURVEYOR® Scan, REVEAL ICE COLD-PCR and BLOcker™-Sequencing, to PIK3CA assays in order to be able to detect genetic variations in very low mutant load samples and is a valuable addition to our genetic biomarker intellectual property portfolio.

In the Diagnostic Tools business, we experienced an increase in the number of units sold as compared to a year ago albeit at lower, distributor prices. Our instrument sales translate into incremental revenue from consumables and service contract sales, providing compounded and repeating revenue. We believe that our collaboration with A. Menarini Diagnostics, our European distribution partner, offers the potential for revenue growth over the next several years.

We also achieved CE IVD Mark registration in Europe for the diagnostic use of our proprietary WAVE MCE System and SURVEYOR® Scan KRAS Kit. This kit contains a simple, yet highly sensitive test to identify mutations in the KRAS gene,

which are key determinants of the effectiveness of modern cancer drugs. Gaining the CE IVD Mark expands the market reach significantly by allowing product sales in the European Union.

In September 2012, we announced the appointment of Mark P. Colonnese as our Executive Vice President and Chief Financial Officer. Mr. Colonnese has nearly 30 years of experience in leading business growth and financial strategies for life sciences companies.

#### Results of Continuing Operations

##### Net Sales.

Net sales consisted of the following:

2012 vs. 2011	Dollars in Thousands				
	Year Ended December 31,		Change		
	2012	2011	\$	%	
Clinical Laboratories	\$17,453	\$16,038	\$1,415	9	%
Pharmacogenomic Services	1,876	2,280	(404)	(18)	%
Diagnostic Tools	12,151	13,653	(1,502)	(11)	%
Total net sales	\$31,480	\$31,971	\$(491)	(2)	%

Clinical Laboratories net sales increased \$1.4 million during the year ended December 31, 2012, compared to 2011. Revenue increased in 2012 compared to 2011 due to higher test volumes, and a modest shift towards higher priced tests driven by sales of our recently launched NuclearMitome, C-GAAP and ScoliScore™ tests.

Pharmacogenomic Services had net sales of \$1.9 million during the year ended December 31, 2012, a decrease of \$0.4 million compared to 2011. The decrease is due to the reduced volume of genetic testing performed in connection with various clinical trials by our pharmaceutical company clients. Pharmacogenomic Services net sales trends are more volatile than our other segments due to the nature of patient enrollment patterns and timing of clinical trials. While the revenue generated from genetic testing related to clinical trials can be significant, it is usually earned over the duration of the trial. Therefore, each period for Pharmacogenomics Services should be considered on a stand-alone basis and is not indicative of future net sales.

Diagnostic Tools net sales decreased \$1.5 million, or 11%, during the year ended December 31, 2012, as compared to 2011. We sold more instruments in 2012 than in 2011, but there was a shift in sales to our distributor at lower distributor prices resulting in lower gross margins as well. We sold thirty-one WAVE Systems in 2012 compared to thirteen in 2011. Demand for WAVE Systems has been affected by significant competitive challenges from traditional (i.e., sequencing) and evolving technologies. We sold ten OEM Equipment instruments in the year ended December 31, 2012 compared to fourteen in the same period in 2011. Bioconsumables net sales were down \$0.7 million, during the year ended December 31, 2012 compared to 2011 due to lower volume in our European market.

2011 vs. 2010	Dollars in Thousands				
	Year Ended December 31,		Change		
	2011	2010	\$	%	
Clinical Laboratories	\$16,038	\$3,606	\$12,432	345	%
Pharmacogenomic Services	2,280	1,373	907	66	%
Diagnostic Tools	13,653	15,069	(1,416)	(9)	%
Total net sales	\$31,971	\$20,048	\$11,923	59	%

Clinical Laboratories net sales increased \$12.4 million during the year ended December 31, 2011, compared to 2010. Of this increase in revenue, \$11.1 million is due to revenue from the FAMILION family of genetic tests, which we acquired on December 29, 2010. In addition, our revenue increased by \$1.3 million in our neurology family of tests due to the mix of tests performed and the average revenue per test.

Pharmacogenomic Services had net sales of \$2.3 million during the year ended December 31, 2011, which increased \$0.9 million compared to 2010. The increase is due to the completion of a significant project with a pharmaceutical company client. Pharmacogenomics Services net sales have peaks due to the nature of project-related services performed on behalf of our clients. Each period for Pharmacogenomics Services should be considered on a stand-alone basis and is not indicative of future net sales.

Diagnostic Tools net sales decreased \$1.4 million, or 9%, during the year ended December 31, 2011, as compared to 2010. The decrease was due to fewer instruments sold in the year ended December 31, 2011. We sold thirteen WAVE instruments in 2011 compared to twenty-five WAVE instruments in 2010. Demand for WAVE Systems has been affected by significant competitive challenges from traditional (i.e. sequencing) and evolving technologies. Lower WAVE System sales are offset by slightly higher OEM Equipment sales in 2011. We sold fourteen OEM Equipment instruments in the year ended December 31, 2011 compared to ten in the same period in 2010. Bioconsumables net sales were down \$0.6 million, during the year ended December 31, 2011 compared to 2010 due to lower volume in Europe.

#### Costs of Goods Sold.

Costs of goods sold include material costs for the products that we sell and substantially all other costs associated with our manufacturing facilities (primarily personnel costs, rent and depreciation) as well as the wholesale price we pay manufacturers of OEM Equipment that we distribute. It also includes direct costs (primarily personnel costs, rent, supplies and depreciation) associated with our Clinical Laboratories and Pharmacogenomics Services operations.

#### Gross Profit.

Gross profit and gross margins for each of our business segments were as follows:

2012 vs. 2011	Dollars in Thousands			
	Year Ended December 31,		Margin %	
	2012	2011	2012	2011
Clinical Laboratories	\$8,487	\$9,478	49	% 59
Pharmacogenomic Services	829	1,050	44	% 46
Diagnostic Tools	5,694	7,909	47	% 58
Gross profit	\$15,010	\$18,437	48	% 58

Gross profit was \$15.0 million, or 48%, of total net sales during the year ended December 31, 2012, compared to \$18.4 million, or 58%, during the same period of 2011. During the year ended December 31, 2012, the gross margin for Clinical Laboratories was 49%, as compared to 59%, in the same period of 2011. The change in the Clinical Laboratories gross margin for the year ended December 31, 2012 is attributable to a change in the mix of tests performed and higher operating supplies, wages and software costs as we increased capacity in our laboratories in anticipation of higher volume from our newly launched tests. Pharmacogenomics Services gross margin decreased to 44% for the year ended December 31, 2012 compared to 46% in the same period of 2011. Pharmacogenomics Services have a relatively fixed-cost base so any increase or decrease in revenue directly impacts gross margins. Diagnostic Tools gross margin decreased to 47% in the year ended December 31, 2012 from 58% in the same period of 2011 due to a shift to sales to our distributor at lower distributor prices resulting in lower gross margins.

2011 vs. 2010

Dollars in Thousands

	Year Ended December 31,		Margin %		
	2011	2010	2011	2010	
Clinical Laboratories	\$9,478	\$1,481	59	% 41	%
Pharmacogenomic Services	1,050	(43	) 46	% (3	)%
Diagnostic Tools	7,909	8,326	58	% 55	%
Gross profit	\$18,437	\$9,764	58	% 49	%

Gross profit during the year ended December 31, 2011 was \$18.4 million, or 58%, of total net sales during the year ended December 31, 2011, compared to \$9.8 million, or 49%, during the same period of 2010. During the year ended December 31, 2011, the gross margin for Clinical Laboratories was \$9.5 million, or 59%, as compared to \$1.5 million, or 41% in the same period of 2010. Results for the year ended December 31, 2011 includes gross profit from sales of the FAMILION family of genetic tests, which we acquired on December 29, 2010. During the year ended December 31, 2011, the gross margin for Pharmacogenomic Services was \$1.1 million, or 46%, as compared to a loss of less than \$0.1 million, or (3)%, in the same period of 2010. Pharmacogenomic Services have a relatively fixed cost base so any increase or decrease in revenue directly impacts gross margin. Diagnostic Tools gross margin increased to 58% in the year ended December 31, 2011 from 55% in the same period of 2010 due to the change in the mix of types of instruments sold.

Operating expenses.

The following table summarizes operating expenses further described below for the years ended December 31, 2012, 2011 and 2010:

	Dollars in Thousands		
	Year Ended December 31,		
	2012	2011	2010
Selling, general and administrative	\$22,023	\$19,150	\$10,933
Research and development	2,491	2,218	2,305
Restructuring charges	—	41	138
Total	\$24,514	\$21,409	\$13,376

Selling, General and Administrative Expenses.

Selling, general and administrative expenses consist primarily of personnel costs, marketing, travel costs, professional fees, and facility costs. In addition, the effect of foreign currency revaluation is included here. Our selling, general and administrative costs increased to \$22.0 million during the year ended December 31, 2012 compared \$19.2 million for the same period in 2011. The increase in selling, general and administrative costs included \$1.2 million in additional employee related expenses which were incurred to increase the size of our sales force to support the launch of both C-GAAP and ScoliScore™, and higher marketing materials expenses. In addition, our bad debt provision of was \$0.7 million higher during the year ended December 31, 2012 due to a higher level of past due receivables compared to 2011.

Our selling, general and administrative costs increased to \$19.2 million, from \$10.9 million, during the year ended December 31, 2011 compared to 2010. The increase in our selling, general and administrative costs is due primarily to \$4.9 million in expenses related to the FAMILION family of genetic tests, which we acquired on December 29, 2010, \$1.0 million in expense related to the vesting of the employee stock option grants, \$1.2 million in amortization of the acquired intangibles and bad debt expense of \$1.7 million. Losses from foreign currency revaluation for the year ended December 31, 2011 were less than \$0.1 million compared to losses of \$0.3 million for the same period in 2010.

Research and Development Expenses.

Research and development expenses include primarily personnel costs, legal fees, outside services, collaboration expenses, supplies, and facility costs and are expensed in the period in which they are incurred. During the year ended December 31, 2012 and 2011 these costs totaled \$2.5 million and \$2.2 million, respectively. Research and development expenses totaled 8% and 7% of net sales during the years ended December 31, 2012 and 2011,

respectively. The increase is due primarily to activities related

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to our programs validating the use of ICE COLD-PCR and expanding our portfolio of tests and the platforms on which they are performed.

During the years ended December 31, 2011 and 2010 research and development costs totaled \$2.2 million and \$2.3 million, respectively. Research and development expenses totaled 7% and 11% of net sales during the years ended December 31, 2011 and 2010, respectively. The decrease is due primarily to the consolidation of our research and development activities in Omaha, Nebraska, the benefit of which is partially offset by legal costs to defend a patent. Other Income (Expense).

The following table summarizes other income (expense) for the years ended December 31, 2012, 2011 and 2010:  
Dollars in Thousands

	Year Ended December 31,		
	2012	2011	2010
Interest expense	\$ (888)	) \$ (958)	) \$ (4)
Preferred stock and warrants expenses	—	(6,066)	) —
Income from change in fair value of warrants	2,200	—	—
Other, net	11	259	632
Total other income (expense), net	\$ 1,323	) \$ (6,765)	) \$ 628

Other income for the year ended December 31, 2012 totaled \$1.3 million. Other income includes the income associated with the change in fair value of the common stock warrants, partially offset by interest expense. The income associated with the common stock warrants is a non-cash item.

Other expense for the year ended December 31, 2011 totaled \$6.8 million. Other expense includes interest expense as well as the expense associated with the Series A Preferred Stock and Series A Warrants, which is due to the change in fair value of the preferred stock conversion feature and the consideration given to the owners of the Series A Convertible Preferred Stock in exchange for the Series A Preferred Stock Certificate Amendment. The expenses associated with the Series A Preferred Stock are non-cash items. Other, net includes an award of a federal grant under the Qualifying Therapeutic Discovery Project of \$0.2 million, net of consulting fees.

Income Tax Expense.

Income tax expense recorded during the years ended December 31, 2012, 2011 and 2010 related to income taxes in states, foreign countries and other local jurisdictions and totaled \$0.1 million, less than \$0.1 million, and \$0.2 million, respectively. The effective tax rate for the year ended December 31, 2012 is negative 1.8%, which is primarily the result of valuation allowances against net operating losses for the United States, partially adjusted by permanent differences related to inter-company foreign currency exchange of our subsidiary outside the United States. The effective tax rate for the years ended December 31, 2011 and 2010 were negative 0.5% and negative 5%, respectively. A net deferred tax liability was recorded during 2012 and 2011 relating to the UK income taxes of less than \$0.1 million. We will continue to assess the recoverability of deferred tax assets and the related valuation allowance. To the extent we begin to generate taxable income in future periods and determine that such valuation allowance is no longer required, the tax benefit of the remaining deferred tax assets will be recognized at such time. Our net operating loss carry-forwards of \$109.3 million will expire at various dates from 2018 through 2032, if not utilized. We also had state income tax loss carry-forwards of \$46.0 million at December 31, 2012. These carry-forwards will also expire at various dates from 2018 to 2032 if not utilized.

Liquidity and Capital Resources

Our working capital positions at December 31, 2012 and 2011 were as follows (in thousands):

	December 31,		
	2012	2011	Change
Current assets (including cash and cash equivalents of \$4,497 and \$4,946 respectively)	\$ 18,717	\$ 17,198	\$ 1,519
Current liabilities	16,528	16,328	(200)
Working capital	\$ 2,189	\$ 870	\$ 1,319





On January 24, 2013 we entered into definitive agreements with institutional and other accredited investors to raise approximately \$8.3 million (before offering costs and selling agent commissions) in a private placement. The funding occurred in January 2013. Pursuant to the terms of the private placement, we issued an aggregate of 16,600,000 shares of our common stock at a price per share of \$0.50 as well as five-year warrants to purchase up to an aggregate of 8,300,000 shares of common stock with an exercise price of \$0.75 per share.

Please see the section entitled "Contractual Obligations and Other Commitments" that follows shortly in this document and Footnote 5 "Debt" to our accompanying consolidated financial statements for additional information regarding our outstanding debt and debt servicing obligations.

At December 31, 2012, we had cash and cash equivalents of \$4.5 million and in January 2013 we received approximately \$8.3 million in gross proceeds in connection with the private placement. We believe that existing sources of liquidity as of December 31, 2012 along with the net proceeds of the January 2013 private placement, are sufficient to meet expected cash needs. Accordingly, we believe we have sufficient liquidity to continue our operations for at least the next 12 months.

#### Analysis of Cash Flows

The following table presents a summary of our cash flows:

	(amounts in thousands)		
	2012	2011	2010
Net cash provided by (used in):			
Operating activities	\$(10,204 )	\$220	\$(1,718 )
Investing activities	(4,878 )	(508 )	(6,226 )
Financing activities	14,604	1,726	5,761
Effect of exchange rates on cash	29	54	(5 )
Net increase (decrease) in cash and cash equivalents	\$(449 )	\$1,492	\$(2,188 )

Net Change in Cash and Cash Equivalents. Cash and cash equivalents decreased by \$0.4 million during 2012, increased by \$1.5 million during 2011 and decreased by \$2.2 million during 2010.

Cash Flows Provided By (Used In) Operating Activities. We used cash for operating activities of \$10.2 million and \$1.7 million during 2012 and 2010, respectively. We provided cash from operating activities of \$0.2 million during 2011. During 2012, the cash flows used in operating activities include an increase of accounts receivable of \$2.9 million related to the provision for higher levels of past due receivables and an increase in inventories of \$1.4 million to purchase additional OEM instruments in anticipation of future sales. During 2012, we recorded non-cash income totaling \$2.2 million associated with the fair valuation of the common stock warrants. During 2011, we recorded non-cash expense totaling \$6.1 million associated with the fair valuation of the Series A Preferred Stock and Series A Warrants. We recorded non-cash, stock-based compensation expense of \$0.7 million, \$1.0 million and less than \$0.1 million during 2012, 2011 and 2010, respectively. We recorded depreciation and amortization expense totaling \$2.3 million, \$2.1 million and \$0.7 million during 2012, 2011 and 2010, respectively.

Cash Flows Used In Investing Activities. During 2012, we acquired the intangible assets of Scoliscore™ for \$4.4 million, \$3.6 million of which we paid in 2012. During 2010, we acquired the FAMILION family of genetic tests for consideration that included \$6.0 million in cash. We recorded purchases of property and equipment totaling \$0.9 million, \$0.2 million and \$0.2 million during 2012, 2011 and 2010, respectively.

Cash Flows Provided By Financing Activities. During 2012, we recorded net proceeds from a private placement with institutional and accredited investors of \$17.5 million. During 2011, we recorded proceeds from short term notes payable totaling \$3.0 million. During 2010, we raised \$6.0 million in the issuance Series A Preferred Stock and Series A Warrants, which was used in the financing of the acquisition of FAMILION. We recorded principal payments on notes payable totaling \$2.6 million, and \$0.9 million during 2012 and 2011, respectively. We did not have debt in 2010.

## Contractual Obligations and Other Commitments

At December 31, 2012, our contractual obligations and other commitments were as follows:

	(Amounts in thousands)						Total
	2013	2014	2015	2016	2017	After 2017	
Long term debt <sup>(1)</sup>	6,171	—	—	—	—	—	6,171
Interest <sup>(1)</sup>	461	—	—	—	—	—	461
Capital lease obligations <sup>(2)</sup>	377	170	43	3	1	—	594
Operating lease obligations <sup>(3)</sup>	1,126	1,079	980	875	763	1,348	6,171
Purchase obligations <sup>(4)</sup>	1,957	—	—	—	—	—	1,957
	\$10,092	\$1,249	\$1,023	\$878	\$764	\$1,348	\$15,354

(1) See Footnote 5 - "Debt" to our accompanying consolidated financial statements.

(2) See Footnote 6 - "Capital Leases" to our accompanying consolidated financial statements.

(3) These amounts represent non-cancellable operating leases for equipment, vehicles and operating facilities

(4) These amounts represent purchase commitments, including all open purchase orders

## Off Balance Sheet Arrangements

At December 31, 2012 and 2011, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

## Critical Accounting Policies

Accounting policies used in the preparation of the consolidated financial statements may involve the use of management judgments and estimates. Certain of our accounting policies are considered critical as they are both important to the portrayal of our financial statements and they require significant or complex judgments on the part of management. The preparation of consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of net sales and expenses during the reported period. In addition, estimates and assumptions associated with the determination of the fair value of certain assets and related impairments require considerable judgment by management. Our judgments and estimates are based on experience and assumptions that we believe are reasonable under the circumstances. Further, we evaluate our judgments and estimates from time to time as circumstances change. Actual financial results based on judgment or estimates may vary under different assumptions or circumstances. The following are certain critical accounting policies that may involve the use of judgment or estimates.

## Allowance for Doubtful Accounts and Contractual Allowances.

While payment terms are generally 30 days, we have also provided extended payment terms of up to 90 days in certain cases. We operate globally and some of the international payment terms can be greater than 90 days. Accounts receivable are carried at original invoice amount and shown net of allowance for doubtful accounts and contractual allowances. The estimate made for doubtful accounts is based on a review of all outstanding amounts on a quarterly basis. We determine the allowance for doubtful accounts and contractual allowances by regularly evaluating individual customer receivables and considering a customer's financial condition, credit history and current economic conditions. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded as income when received.

Inventories.

Inventories are stated at the lower of cost or market net of allowance for obsolete inventory. Cost is computed using standard costs for finished goods and average or latest actual cost for raw materials and work in process, which approximates the first-in, first-out (FIFO) method. We write down slow-moving and obsolete inventory by the difference between the value of the inventory and our estimate of the reduced value based on potential future uses, the likelihood that overstocked inventory will be sold and

the expected selling prices of the inventory. If our ability to realize value on slow-moving or obsolete inventory is less favorable than assumed, additional write-downs of the inventory may be required.

#### Property and Equipment.

Property and equipment are carried at cost. Depreciation is computed by the straight-line method over the estimated useful lives of the related assets.

#### Goodwill.

Goodwill is the excess of the purchase price over fair value of assets acquired and is not amortized. Goodwill is tested for impairment annually. We perform this impairment analysis during the fourth quarter of each year or when a significant event occurs that may impact goodwill. Impairment occurs when the carrying value is determined to be not recoverable thereby causing the carrying value of the goodwill to exceed its fair value. If impaired, the asset's carrying value is reduced to its fair value. No impairment existed at December 31, 2012 and 2011.

#### Intangibles.

Intangibles include intellectual property, patents and acquired products.

1. Intellectual Property. Initial costs paid to license intellectual property from independent third parties are capitalized and amortized using the straight-line method over the license period. Ongoing royalties related to such licenses are expensed as incurred.

2. Patents. We capitalize legal costs, filing fees and other expenses associated with obtaining patents on new discoveries and amortize these costs using the straight-line method over the shorter of the legal life of the patent or its economic life beginning on the date the patent is issued.

3. Acquired Products. As a part of the FAMILION acquisition and acquisition of certain intangible assets from Axial, we acquired technology, in process technology, trademarks/tradenames, customer relationships, covenants not to compete and third party relationships. These costs will be amortized pursuant to the straight-line method over their estimated economic life of seven to eight years. See Footnote 4 "Intangibles and Other Assets" to our accompanying consolidated financial statements.

We review our amortizable long lived assets for impairment whenever events indicate that the carrying amount of the asset may not be recoverable. An impairment loss would be recorded if the sum of the future undiscounted cash flows is less than the carrying amount of the asset. The amount of the loss would be determined by comparing the fair market value of the asset to the carrying amount of the asset. No loss has been recorded during the years ended December 31, 2012, 2011 or 2010.

#### Common Stock Warrants.

Our issued and outstanding warrants to purchase common stock do not qualify to be treated as equity, and accordingly, are recorded as a liability ("Common Stock Warrant Liability"). The Common Stock Warrant Liability was initially recorded at fair value using a Monte Carlo simulation model. We are required to present these instruments at fair value at each reporting date and any changes in fair values are recorded as an adjustment to earnings. The Common Stock Warrant Liability is considered a level three financial instrument. See Footnote 12 "Fair Value" to our accompanying consolidated financial statements.

#### Preferred Stock.

Prior to the 2011 modification, the Series A Preferred Stock met the definition of mandatorily redeemable stock as it was preferred capital stock which was redeemable at the option of the holder and therefore was reported outside of equity. The Series A Preferred Stock was accreted to its redemption value. Prior to the 2011 modification, the Series A Warrants did not qualify to be treated as equity and, accordingly, were recorded as a liability. A preferred stock conversion feature was embedded within the Series A Preferred Stock that met the definition of a derivative. The Series A Preferred Stock, Series A Warrants liability and Series A Preferred Stock conversion feature were all recorded separately and were initially recorded at fair value using the Black-Scholes model. We were required to

record these instruments at fair value at each reporting date and changes were recorded as an adjustment to earnings. The Series A Warrant liability and Series A Preferred Stock conversion feature were considered level three financial instruments.

We entered into a transaction with the holders of the Series A Preferred Stock (the "Series A Holders"), pursuant to an Agreement Regarding Preferred Stock (the "Amendment Agreement"), in which the Series A Holders agreed to (i) waive their rights to enforce the anti-dilution and redemption features of the Series A Preferred Stock and (ii) at the next annual shareholder meeting, vote to amend the Certificate of Designation for the Series A Preferred Stock to remove the anti-dilution and redemption features of the Series A Preferred Stock. In exchange, we issued shares of common stock to the Series A Holders having an aggregate market value of \$0.3 million. Our stockholders approved the amendments to the Certificate of Designation for the

Series A Preferred Stock at the 2012 Annual Meeting of Stockholders held on May 23, 2012, and we filed it with the Delaware Secretary of State on May 25, 2012.

As a result of the Amendment Agreement, the value of the Series A Preferred Stock and Series A Warrant, including the Series A Preferred Stock conversion feature and Series A Warrant liability, were reclassified into shareholders equity as of the date of the Amendment Agreement.

#### Stock Based Compensation.

All stock options awarded to date have exercise prices equal to the market price of our common stock on the date of grant and have ten-year contractual terms. Unvested options as of December 31, 2012 had vesting periods of one or three years from date of grant. None of the stock options outstanding at December 31, 2012 are subject to performance or market-based vesting conditions.

We measure and recognize compensation expense for all stock-based awards made to employees and directors, including stock options. Compensation expense is based on the calculated fair value of the awards as measured at the grant date and is expensed ratably over the service period of the awards (generally the vesting period).

#### Income Taxes.

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities at each balance sheet date using tax rates expected to be in effect in the year the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent that it is more likely than not that they will not be realized. Our liability for uncertain certain tax positions was \$0.3 million and \$0.2 million as of December 31, 2012 and 2011, respectively. We recorded less than \$0.1 million of additional uncertain tax positions during the current year. We had no material interest or penalties during fiscal 2012 or fiscal 2011, and we do not anticipate any such items during the next twelve months. Our policy is to record interest and penalties directly related to income taxes as income tax expense in the Consolidated Statements of Operations.

#### Net Sales Recognition.

Revenue is realized and earned when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;
- The seller's price to the buyer is fixed or determinable; and
- Collectability is reasonably assured.

Net sales from our Clinical Laboratories are recognized on an individual test basis and take place when the test report is completed, reviewed and sent to the client less the reserve for insurance, Medicare and Medicaid contractual adjustments. There are no deferred net sales associated with our Clinical Laboratories. Adjustments to the allowances, based on actual receipts from third party payers, are recorded upon settlement.

In our Pharmacogenomics Services, we perform services on a project by project basis. When we receive payment in advance, we recognize revenue when we deliver the service. These projects typically do not extend beyond one year. Net sales of Diagnostic Tools products are recognized in accordance with the terms of the sales arrangement. Such recognition is based on receipt of an unconditional customer order and transfer of title and risk of ownership to the customer, typically upon shipment of the product under a purchase order. Our sales terms do not provide for the right of return unless the product is damaged or defective. Net sales from certain services associated with the analytical instruments, to be performed subsequent to shipment of the products, is deferred and recognized when the services are provided. Such services, mainly limited to installation and training services that are not essential to the functionality of the instruments, typically are performed in a timely manner subsequent to shipment of the instrument. We also enter into various service contracts that cover installed instruments. These contracts cover specific time periods and net sales associated with these contracts are deferred and recognized ratably over the service period.

Taxes collected from customers and remitted to government agencies for specific net sales producing transactions are recorded net with no effect on the income statement.

Research and Development.

Research and development and various collaboration costs are charged to expense when incurred.

#### Translation of Foreign Currency.

Our foreign subsidiary uses the local currency of the country in which it is located as its functional currency. Its assets and liabilities are translated into U.S. dollars at the exchange rates in effect at the balance sheet date. Revenues and expenses are translated at the average rates during the period.

#### Comprehensive Income.

Accumulated other comprehensive income at December 31, 2012, 2011 and 2010 consisted of foreign currency translation adjustments, net of applicable tax of zero. We deem our foreign investments to be permanent in nature and do not provide for taxes on currency translation adjustments arising from converting investments in a foreign currency to U.S. dollars. During 2011, we reclassified \$1.3 million from accumulated other comprehensive income (loss) to accumulated deficit with no effect on total stockholders' equity or net loss.

#### Loss Per Share.

Basic earnings per share is calculated based on the weighted-average number of common shares outstanding during each period. Diluted earnings per share include shares issuable upon exercise of outstanding stock options, warrants or conversion rights that have exercise or conversion prices below the market value of our common stock.

#### Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board "FASB" issued Accounting Standards Update No. 2011-04, "Fair Value Measurement" ("ASU 2011-04"). ASU 2011-04 amends ASC 820 to achieve common fair value measurement and disclosure requirements in U.S. Generally Accepted Accounting Principles (GAAP) and International Financial Reporting Standards (IFRS). The amended guidance requires information disclosure regarding transfers between Level 1 and Level 2 of the fair value hierarchy, information disclosure regarding sensitivity of a fair value measurement categorized within Level 3 of the fair value hierarchy to changes in unobservable inputs and any interrelationships between those unobservable inputs, and the categorization by level of the fair value hierarchy for items that are not measured at fair value. The amended guidance was effective for financial periods beginning after December 15, 2011. ASU 2011-04 did not have a material effect on our consolidated financial position or results of operations.

In June 2011, the FASB issued guidance on the presentation of comprehensive income. The new guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. Instead, an entity will be required to present either a continuous statement of net income and other comprehensive income or in two separate but consecutive statements of net income and other comprehensive income. The new guidance is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2011 and will have presentation changes only. We elected to report other comprehensive income and its components in a separate statement of comprehensive income for the year ended December 31, 2012.

In July 2011, the FASB issued guidance on the presentation of net patient service revenue. The new guidance requires a change in presentation of the statement of operations by reclassifying the provision for bad debts associated with patient service revenue from an operating expense to a deduction from patient service revenue (net of contractual allowances and discounts). Additionally, enhanced disclosure about policies for recognizing revenue and assessing bad debts are required. Disclosures of patient service revenue (net of contractual allowances and discounts) as well as qualitative and quantitative information about changes in the allowance for doubtful accounts will be required. The new guidance is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2011. Our adoption of this guidance did not have a material impact on our consolidated financial statements.

In September 2011, the FASB issued guidance on intangibles including goodwill and other intangibles. The new guidance will allow an entity to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. The new guidance is effective for fiscal years beginning after December 15, 2011. We adopted this guidance in the fourth quarter of 2012.

In February 2013, the FASB issued Accounting Standards Update No. 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income, to improve the transparency



of reporting reclassifications out of accumulated other comprehensive income. The amendments in the Update do not change the current requirements for reporting net income or other comprehensive income in financial statements. The new amendments will require an organization to present (either on the face of the statement where net income is presented or in the notes) the effects on the line items of net income of significant amounts reclassified out of accumulated other comprehensive income if the item reclassified is required under U.S. GAAP to be reclassified to net income in its entirety in the same reporting period. Additionally, for other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income in the same reporting period, an

entity is required to cross-reference other disclosures required under U.S. GAAP to provide additional detail about those amounts. For public companies, the amendments are effective for reporting periods beginning after December 15, 2012. We do not expect that the adoption of this guidance will have a material impact on our consolidated financial statements.

#### Impact of Inflation

We do not believe that inflation has had a material effect on our current business, financial condition or results of operations. If our costs were to become subject to significant inflationary pressures, for example, if the cost of our materials or the cost of shipping our products to customers were to incur substantial increases as a result of the rapid rise in the cost of oil, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition and results of operations.

#### Item 7A. Quantitative and Qualitative Disclosure about Market Risk.

**Foreign Currency Translation Risk.** Sales of products in foreign countries are mainly completed in either British Pounds Sterling or the Euro. Additionally, the British Pound Sterling is the functional currency of our wholly owned subsidiary, Transgenomic Limited. Results of operations and the balance sheet are translated from the functional currency of the subsidiary to our reporting currency of the U.S. dollar. Results of operations for our foreign subsidiary is translated using the average exchange rate during the period. Assets and liabilities are translated at the exchange rate in effect at the balance sheet date. In addition, we have revaluation risk which occurs when the transaction is consummated in a currency other than the British Pound Sterling. This transaction must be revalued within the Transgenomic Limited ledger, whose functional currency is the British Pound Sterling. The majority of the transactions on this ledger are in Euros. As a result we are subject to exchange rate risk. Additionally, we do not currently engage in foreign currency hedging activities nor use derivative financial instruments for trading or speculative purposes.

Based on our overall foreign currency exchange rate exposures at December 31, 2012, we believe that a 10% change in foreign currency exchange rates would not be expected to have a material effect on our future operating results or cash flows, depending on which foreign currency exchange rates change and depending on the directional change (either a strengthening or weakening against the U.S. Dollar). If our foreign operations grow, our exposure to foreign currency exchange rate risk may become more significant.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders  
Transgenomic, Inc.

We have audited the accompanying consolidated balance sheets of Transgenomic, Inc. and Subsidiary (the Company) as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. We also have audited the Company's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (a) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (b) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (c) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Transgenomic, Inc. and Subsidiary as of December 31, 2012 and 2011, and the results of their

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operations and their cash flows for each of the years in the three-year period ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, Transgenomic, Inc. and Subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ McGladrey LLP

Omaha, Nebraska  
March 14, 2013

TRANSGENOMIC, INC. AND SUBSIDIARY  
CONSOLIDATED BALANCE SHEETS

December 31, 2012 and 2011

(Dollars in thousands except per share data)

	2012	2011
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$4,497	\$4,946
Accounts receivable (net of allowances for doubtful accounts of \$2,171 and \$1,088, respectively)	8,081	7,573
Inventories (net of allowances for obsolescence of \$616 and \$511, respectively)	5,092	3,859
Other current assets	1,047	820
Total current assets	18,717	17,198
<b>PROPERTY AND EQUIPMENT:</b>		
Equipment	10,682	10,143
Furniture, fixtures & leasehold improvements	3,848	3,682
	14,530	13,825
Less: accumulated depreciation	(12,340)	(11,969)
	2,190	1,856
<b>OTHER ASSETS:</b>		
Goodwill	6,918	6,440
Intangibles (net of accumulated amortization of \$2,805 and \$1,437, respectively)	10,764	7,966
Other assets	202	102
	\$38,791	\$33,562
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$2,052	\$2,609
Accrued compensation	1,121	1,133
Short term debt	—	3,082
Current maturities of long term debt	6,171	3,703
Accrued expenses	3,686	2,782
Deferred revenue	1,171	1,377
Other current liabilities	1,067	1,042
Accrued preferred stock dividend	1,260	600
Total current liabilities	16,528	16,328
<b>LONG TERM LIABILITIES:</b>		
Long term debt less current maturities	—	4,937
Common stock warrant liability	900	—
Other long-term liabilities	1,089	1,249
Total liabilities	18,517	22,514
<b>STOCKHOLDERS' EQUITY:</b>		
Series A preferred stock, \$.01 par value, 15,000,000 shares authorized, 2,586,205 shares issued and outstanding, respectively	26	26
Common stock, \$.01 par value, 150,000,000 and 100,000,000 shares authorized, respectively 71,645,725 and 49,625,725 shares issued and outstanding, respectively	721	501
Additional paid-in capital	170,881	152,987
Accumulated other comprehensive income	435	336
Accumulated deficit	(151,789)	(142,802)

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Total stockholders' equity	20,274	11,048
	\$38,791	\$33,562

See notes to consolidated financial statements.

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TRANSGENOMIC, INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF OPERATIONS

Years Ended December 31, 2012, 2011 and 2010

(Dollars in thousands except per share data)

	2012	2011	2010
NET SALES	\$31,480	\$31,971	\$20,048
COST OF GOODS SOLD	16,470	13,534	10,284
Gross profit	15,010	18,437	9,764
OPERATING EXPENSES:			
Selling, general and administrative	22,023	19,150	10,933
Research and development	2,491	2,218	2,305
Restructuring charges	—	41	138
	24,514	21,409	13,376
LOSS FROM OPERATIONS	(9,504	) (2,972	) (3,612
OTHER INCOME (EXPENSE):			
Interest income (expense), net	(888	) (958	) (4
Expense on preferred stock	—	(6,066	) —
Warrant revaluation	2,200	—	—
Other, net	11	259	632
	1,323	(6,765	) 628
LOSS BEFORE INCOME TAXES	(8,181	) (9,737	) (2,984
INCOME TAX EXPENSE	146	45	150
NET LOSS	\$(8,327	) \$(9,782	) \$(3,134
PREFERRED STOCK DIVIDENDS AND ACCRETION	(660	) (1,010	) —
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS	\$(8,987	) \$(10,792	) \$(3,134
BASIC AND DILUTED LOSS PER COMMON SHARE	\$(0.13	) \$(0.22	) \$(0.06
BASIC AND DILUTED WEIGHTED AVERAGE SHARES OF COMMON STOCK OUTSTANDING	69,417,419	49,361,632	49,243,839

See notes to consolidated financial statements.

TRANSGENOMIC, INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS  
 Years Ended December 31, 2012, 2011 and 2010  
 (Dollars in thousands)

	2012	2011	2010	
Net Loss	\$(8,327	) \$(9,782	) \$(3,134	)
Other Comprehensive Loss; foreign currency translation adjustment, net of tax	99	54	(56	)
Comprehensive Loss	\$(8,228	) \$(9,728	) \$(3,190	)

See notes to consolidated financial statements.



TRANSGENOMIC, INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
Years Ended December 31, 2012, 2011 and 2010  
(Dollars in thousands except share data)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Outstanding Shares	Par Value	Outstanding Shares	Par Value				
Balance, December 31, 2009	—	—	49,189,672	\$497	\$139,703	\$ (130,183 )	\$ 1,645	\$11,662
Net loss	—	—	—	\$—	\$—	\$ (3,134 )	—	\$(3,134 )
Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	(56 )	(56 )
Non-cash stock-based compensation	—	—	—	—	(14 )	—	—	(14 )
Issuance of shares of stock	—	—	100,000	1	41	—	—	42
Balance, December 31, 2010	—	—	49,289,672	\$498	\$139,730	\$ (133,317 )	\$ 1,589	\$8,500
Net loss	—	—	—	—	—	(9,782 )	—	(9,782 )
Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	54	54
Non-cash stock-based compensation	—	—	—	—	1,010	—	—	1,010
Issuance of shares of common stock	—	—	90,150	1	23	—	—	24
Preferred stock accretion	—	—	—	—	—	(410 )	—	(410 )
Amendment of preferred stock agreement	2,586,205	26	245,903	2	12,224	—	—	12,252
Reclassification of other comprehensive income (loss)	—	—	—	—	—	1,307	(1,307 )	—
Dividends on preferred stock	—	—	—	—	—	(600 )	—	(600 )
Balance, December 31, 2011	2,586,205	\$26	49,625,725	\$501	\$152,987	\$ (142,802 )	\$ 336	\$11,048
Net loss	—	—	—	—	\$—	(8,327 )	—	(8,327 )
Foreign currency translation	—	—	—	—	—	—	99	99

adjustment, net of tax								
Non-cash stock-based compensation	—	—	—	—	731	—	—	731
Issuance of shares of common stock	—	—	20,000	—	10	—	—	10
Private Placement, net	—		22,000,000	220	17,153			17,373
Dividends on preferred stock	—	—	—	—	—	(660)	) —	(660 )
Balance, December 31, 2012	2,586,205	\$26	71,645,725	\$721	\$170,881	\$ (151,789 )	\$ 435	\$20,274

See notes to consolidated financial statements.

TRANSGENOMIC, INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
Years Ended December 31, 2012, 2011 and 2010  
(Dollars in thousands)

	2012	2011	2010
<b>CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES:</b>			
Net loss	\$(8,327 )	\$(9,782 )	\$(3,134 )
Adjustments to reconcile net loss to net cash flows provided by (used in) operating activities:			
Depreciation and amortization	2,278	2,101	708
Non-cash, stock based compensation	731	1,010	(14 )
Provision for losses on doubtful accounts	2,468	1,738	28
Provision for losses on inventory obsolescence	129	48	100
Preferred stock revaluation	—	6,066	—
Warrant revaluation	(2,200 )	—	—
Loss on sale of fixed assets	23	—	—
Long term deferred income taxes	(25 )	(133 )	26
Changes in operating assets and liabilities, net of acquisitions:			
Accounts receivable	(2,913 )	(2,212 )	44
Inventories	(1,373 )	(620 )	(3 )
Prepaid expenses and other current assets	(209 )	243	95
Accounts payable	(576 )	1,028	364
Accrued liabilities	96	332	92
Other long term liabilities	(306 )	401	(24 )
Net cash flows provided by (used in) operating activities	(10,204 )	220	(1,718 )
<b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>			
Acquisitions	(3,551 )	—	(6,000 )
Purchase of property and equipment	(882 )	(231 )	(192 )
Purchase of short term investments	(8,994 )	—	—
Proceeds from the sale of short term investments	8,994	—	—
Change in other assets	(445 )	(277 )	(34 )
Net cash flows used in investing activities	(4,878 )	(508 )	(6,226 )
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:</b>			
Issuance of preferred stock and related warrants, net	—	—	5,791
Proceeds from note payable	—	3,000	—
Principal payments on capital lease obligations	(328 )	(391 )	(72 )
Issuance of common stock and related warrants, net	17,483	24	42
Principal payments on note payable	(2,551 )	(907 )	—
Net cash flows provided by financing activities	14,604	1,726	5,761
<b>EFFECT OF FOREIGN CURRENCY EXCHANGE RATE CHANGES ON CASH</b>	<b>29</b>	<b>54</b>	<b>(5 )</b>
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(449 )</b>	<b>1,492</b>	<b>(2,188 )</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>4,946</b>	<b>3,454</b>	<b>5,642</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$4,497</b>	<b>\$4,946</b>	<b>\$3,454</b>
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>			
Cash paid during the period for:			
Interest	\$964	\$732	\$7
Income taxes, net	123	108	29
<b>SUPPLEMENTAL DISCLOSURE OF NON-CASH INFORMATION</b>			

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Acquisition of equipment through capital leases	\$175	\$756	\$394
Dividends accrued on preferred stock	660	600	—

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Note payable converted to Equity	3,000	—	—
Acquisition of intangibles	849	—	—
Common stock issued for elimination of derivatives on preferred stock	—	300	—
Goodwill purchase price adjustment	—	165	—
See notes to consolidated financial statements.			

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TRANSGENOMIC, INC. AND SUBSIDIARY  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
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## 1. BUSINESS DESCRIPTION

### Business Description.

Transgenomic, Inc. ("we", "us", "our Company" or "Transgenomic") 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. Our operations are organized and reviewed by management along its product lines and presented in the following 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. 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.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### Principles of Consolidation.

The consolidated financial statements include the accounts of Transgenomic, Inc. and its wholly owned subsidiary. All inter-company balances and transactions have been eliminated in consolidation.

### Risks and Uncertainties.

Certain risks and uncertainties are inherent in our day-to-day operations and to the process of preparing our financial statements. The more significant of those risks are presented below and throughout the notes to the financial statements.

### Use of Estimates.

The preparation of consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of net sales and expenses during the reporting period. In addition, estimates and assumptions associated with the determination of the fair value of certain assets and related impairments require considerable judgment by management. Actual results could differ from the estimates and assumptions used in preparing these consolidated financial statements.

### Reclassifications.

Certain prior year amounts have been reclassified in order to conform to the current year presentation.

Fair Value.

Unless otherwise specified, book value approximates fair market value. The Company's Level 1 financial instruments include cash and cash equivalents. The Company's Level 2 financial instruments include accounts receivable, accounts payable, other current liabilities and other long-term liabilities. The Company's Level 3 financial instruments include the common stock warrant liability, preferred stock warrant liability and conversion feature, and debt. The Company is also unable to estimate the

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fair value of the debt due to the lack of comparable available credit facilities. The common stock warrant liability and Series A Preferred Stock warrant liability and conversion feature are recorded at fair value. See Footnote 12 Fair Value.

Cash and Cash Equivalents.

Cash and cash equivalents include cash and investments with original maturities at the date of acquisition of three months or less. Such investments presently consist of temporary overnight investments

Concentrations of Cash.

From time to time, we may maintain a cash position with financial institutions in amounts that exceed federally insured limits. We have not experienced any losses on such accounts as of December 31, 2012.

Accounts Receivable.

The following is a summary of activity for the allowance for doubtful accounts during the years ended December 31, 2012, 2011 and 2010:

	Dollars in Thousands			
	Beginning Balance	Provision	Write Offs	Ending Balance
Year ended December 31, 2012	\$1,088	\$2,468	\$(1,385)	) \$2,171
Year ended December 31, 2011	\$334	\$1,738	\$(984)	) \$1,088
Year ended December 31, 2010	\$310	\$28	\$(4)	) \$334

While payment terms are generally 30 days, we have also provided extended payment terms in certain cases. We operate globally and some of the international payment terms can be greater than 90 days. Accounts receivable are carried at original invoice amount and shown net of allowance for doubtful accounts and contractual allowances. The estimate made for doubtful accounts is based on a review of all outstanding amounts on a quarterly basis. We determine the allowance for doubtful accounts and contractual allowances by regularly evaluating individual customer receivables and considering a customer's financial condition, credit history and current economic conditions. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

Inventories.

Inventories are stated at the lower of cost or market net of allowance for obsolete inventory. Cost is computed using standard costs for finished goods and average or latest actual cost for raw materials and work in process, which approximates the first-in, first-out (FIFO) method. We write down slow-moving and obsolete inventory by the difference between the value of the inventory and our estimate of the reduced value based on potential future uses, the likelihood that overstocked inventory will be sold and the expected selling prices of the inventory. If our ability to realize value on slow-moving or obsolete inventory is less favorable than assumed, additional write-downs of the inventory may be required.

The following is a summary of activity for the allowance for obsolete inventory during the year ended December 31, 2012, 2011 and 2010:

	Dollars in Thousands			
	Beginning Balance	Provision	Write Offs	Ending Balance
Year ended December 31, 2012	\$511	\$129	\$(24)	) \$616
Year ended December 31, 2011	\$518	\$48	\$(55)	) \$511



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Year ended December 31, 2010                      \$507                      \$100                      \$(89                      ) \$518

We determine the allowance for obsolescence by evaluating inventory quarterly for items deemed to be slow moving or obsolete.

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Property and Equipment.

Property and equipment are carried at cost. Depreciation is computed by the straight-line method over the estimated useful lives of the related assets as follows:

Leasehold improvements	1 to 10 years
Furniture and fixtures	3 to 7 years
Production equipment	3 to 7 years
Computer equipment	3 to 7 years
Research and development equipment	2 to 7 years

Depreciation expense related to property and equipment during the years ended December 31, 2012, 2011 and 2010 was \$0.8 million, \$0.6 million and \$0.4 million, respectively. Included in depreciation for the years ended December 31, 2012, 2011 and 2010 was \$0.3 million, \$0.2 million and less than \$0.1 million, respectively, related to equipment acquired under capital leases.

Goodwill.

Goodwill is the excess of the purchase price over fair value of assets acquired and is not amortized. Goodwill is tested for impairment annually. We perform this impairment analysis during the fourth quarter of each year or when a significant event occurs that may impact goodwill. Impairment occurs when the carrying value is determined to be not recoverable thereby causing the carrying value of the goodwill to exceed its fair value. If impaired, the asset's carrying value is reduced to its fair value. No impairment existed at December 31, 2012 and 2011.

Intangibles.

Intangibles include intellectual property, patents and acquired products.

1. Intellectual Property. Initial costs paid to license intellectual property from independent third parties are capitalized and amortized using the straight-line method over the license period. Ongoing royalties related to such licenses are expensed as incurred.

2. Patents. We capitalize legal costs, filing fees and other expenses associated with obtaining patents on new discoveries and amortize these costs using the straight-line method over the shorter of the legal life of the patent or its economic life beginning on the date the patent is issued.

3. Acquired Products. As a part of the FAMILION acquisition and acquisition of certain intangible assets from Axial we acquired technology, in process technology, trademarks/tradenames, customer relationships, covenants not to compete and third party relationships. These costs will be amortized using the straight-line method over their estimated economic life of seven to eight years. See Footnote 4 Intangibles and Other Assets.

We review our amortizable long lived assets for impairment whenever events indicate that the carrying amount of the asset may not be recoverable. An impairment loss would be recorded if the sum of the future undiscounted cash flows is less than the carrying amount of the asset. The amount of the loss would be determined by comparing the fair market value of the asset to the carrying amount of the asset. No loss has been recorded during the years ended December 31, 2012 or 2011.

Common Stock Warrants.

Our issued and outstanding warrants to purchase common stock do not qualify to be treated as equity, and accordingly, are recorded as a liability ("Common Stock Warrant Liability"). The Common Stock Warrant Liability was initially recorded at fair value using a Monte Carlo simulation model. We are required to present these instruments at fair value at each reporting date and any changes in fair values are recorded as an adjustment to earnings. The Common Stock Warrant Liability is considered a level three financial instrument. See Footnote 12 -Fair Value.

Preferred Stock. Prior to the 2011 modification, the Series A Preferred Stock met the definition of mandatorily redeemable stock as it was preferred capital stock which was redeemable at the option of the holder and therefore was reported outside of equity. The Series A Preferred Stock was accreted to its redemption value. Prior to the 2011

modification, the Series A Warrants did not qualify to be treated as equity, and accordingly, was recorded as a liability. A preferred stock conversion feature

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was embedded within the Series A Preferred Stock that met the definition of a derivative. The Series A Preferred Stock, Series A Warrants liability and Series A Preferred Stock conversion feature were all recorded separately and were initially recorded at fair value using the Black-Scholes model. We were required to record these instruments at fair value at each reporting date and changes were recorded as an adjustment to earnings. The Series A Warrant liability and Series A Preferred Stock conversion feature were considered level three financial instruments.

In November 2011, we entered into a transaction with the holders of the Series A Preferred Stock (the "Series A Holders"), pursuant to an Agreement Regarding Preferred Stock (the "Amendment Agreement"), in which the Series A Holders agreed to (i) waive their rights to enforce the anti-dilution and redemption features of the Series A Preferred Stock and (ii) at the next annual shareholder meeting, vote to amend the Certificate of Designation for the Series A Preferred Stock to remove the anti-dilution and redemption features of the Series A Preferred Stock. In exchange, the Company issued shares of common stock to the Series A Holders having an aggregate market value of \$0.3 million. As a result of the Amendment Agreement, the value of the Series A Preferred Stock and Series A Warrant, including the Series A Preferred Stock conversion feature and Series A Warrant liability, were reclassified into shareholders equity as of the date of the Amendment Agreement.

#### Stock Based Compensation.

All stock options awarded to date have exercise prices equal to the market price of our common stock on the date of grant and have ten-year contractual terms. Unvested options as of December 31, 2012 had vesting periods of one or three years from date of grant. None of the stock options outstanding at December 31, 2012 are subject to performance or market-based vesting conditions.

We measure and recognize compensation expense for all stock-based awards made to employees and directors, including stock options. Compensation expense is based on the calculated fair value of the awards as measured at the grant date and is expensed ratably over the service period of the awards (generally the vesting period).

#### Income Taxes.

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities at each balance sheet date using tax rates expected to be in effect in the year the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent that it is more likely than not that they will not be realized. Our policy is to record interest and penalties directly related to income taxes as income tax expense in the Consolidated Statements of Operations.

#### Net Sales Recognition.

Revenue is realized and earned when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;
- The seller's price to the buyer is fixed or determinable; and
- Collectability is reasonably assured.

Net sales from our Clinical Laboratories are recognized on an individual test basis and takes place when the test report is completed, reviewed and sent to the client less the reserve for insurance, Medicare and Medicaid contractual adjustments. There are no deferred net sales associated with our Clinical Laboratories. Adjustments to the allowances, based on actual receipts from third party payers, are recorded upon settlement.

In our Pharmacogenomics Services, we perform services on a project by project basis. When we receive payment in advance, we recognize revenue when we deliver the service. These projects typically do not extend beyond one year. At December 31, 2012 and 2011, deferred net sales associated with pharmacogenomics research projects, included in the balance sheet in deferred revenue, was \$0.2 million and \$0.1 million, respectively.

Net sales of Diagnostic Tools products are recognized in accordance with the terms of the sales arrangement. Such recognition is based on receipt of an unconditional customer order and transfer of title and risk of ownership to the

customer, typically upon shipment of the product under a purchase order. Our sales terms do not provide for the right of return unless the product is damaged or defective. Net sales from certain services associated with the analytical instruments, to be performed subsequent to shipment of the products, is deferred and recognized when the services are provided. Such services, mainly limited to installation and training

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services that are not essential to the functionality of the instruments, typically are performed in a timely manner subsequent to shipment of the instrument. We also enter into various service contracts that cover installed instruments. These contracts cover specific time periods and net sales associated with these contracts are deferred and recognized ratably over the service period. At December 31, 2012 and 2011, deferred net sales, mainly associated with our service contracts, included in the balance sheet in deferred revenue was approximately \$1.0 million and \$1.3 million, respectively.

Taxes collected from customers and remitted to government agencies for specific net sales producing transactions are recorded net with no effect on the income statement.

Research and Development.

Research and development and various collaboration costs are charged to expense when incurred.

Translation of Foreign Currency.

Our foreign subsidiary uses the local currency of the country in which it is located as its functional currency. Its assets and liabilities are translated into U.S. dollars at the exchange rates in effect at the balance sheet date. A translation gain of \$0.1 million is reported in other comprehensive income on the accompanying consolidated balance sheet as of December 31, 2012. A translation gain of \$0.1 million was reported in other comprehensive income on the accompanying consolidated balance sheet as of December 31, 2011. Revenues and expenses are translated at the average rates during the period. For transactions that are not denominated in the functional currency, we recognized \$0.1 million, less than \$0.1 million, and \$0.3 million as foreign currency transaction loss in the determination of net loss for the years ending December 31, 2012, 2011 and 2010, respectively.

Common Stock Warrants.

Our issued and outstanding warrants to purchase common stock do not qualify to be treated as equity, and accordingly, are recorded as a liability. The Common Stock Warrant liability was initially recorded at fair value using a Monte Carlo simulation model. We are required to present these instruments at fair value at each reporting date and any changes in fair values are recorded as an adjustment to earnings. The Common Stock Warrant liability is considered a level three financial instrument. See Footnote 12 -Fair Value.

Expense on Preferred Stock.

For 2011, we recorded expense associated with the Series A Preferred Stock and Series A Warrants of \$6.1 million, which is due to the change in fair value of the Series A Preferred Stock conversion feature and Series A Warrants liability of \$5.8 million and the issuance of \$0.3 million in common stock to the Series A Investors. The expense associated with the change in value of the Series A Preferred Stock conversion feature is a non-cash item. There was no expense on preferred stock in 2012 or 2010.

Other Income.

Other income in the years ended December 31, 2011 and 2010 includes an award of a federal grant under the Qualifying Therapeutic Discovery Project related to COLD-PCR, Surveyor Scan kit development for detecting key cancer pathway gene mutations and mtDNA damage assays. Income related to this federal grant net of consulting fees was \$0.2 million and \$0.6 million, respectively. There was no other income in the year ended December 31, 2012.

Comprehensive Income.

Accumulated other comprehensive income at December 31, 2012, 2011 and 2010 consisted of foreign currency translation adjustments, net of applicable tax of zero. We deem our foreign investments to be permanent in nature and do not provide for taxes on currency translation adjustments arising from converting investments in a foreign currency to U.S. dollars. During 2011, we reclassified \$1.3 million from accumulated other comprehensive income (loss) to accumulated deficit with no effect on total stockholders' equity or net loss.

Earnings Per Share.

Basic earnings per share is calculated based on the weighted-average number of common shares outstanding during each period. Diluted earnings per share include shares issuable upon exercise of outstanding stock options, warrants or

conversion rights that have exercise or conversion prices below the market value of our common stock, as long as the effect is not anti-dilutive. Options, warrants and conversion rights pertaining to 29,660,038, 17,648,273 and 18,607,229 shares of our common stock have been excluded from the computation of diluted earnings per share at December 31, 2012, 2011 and 2010, respectively. The options,

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warrants and conversion rights that were exercisable in 2012, 2011 and 2010 were not included because the effect would be anti-dilutive due to the net loss.

Recently Issued Accounting Pronouncements.

In May 2011, the FASB issued Accounting Standards Update No. 2011-04, "Fair Value Measurement" ("ASU 2011-04"). ASU 2011-04 amends ASC 820 to achieve common fair value measurement and disclosure requirements in U.S. Generally Accepted Accounting Principles (GAAP) and International Financial Reporting Standards (IFRS). The amended guidance requires information disclosure regarding transfers between Level 1 and Level 2 of the fair value hierarchy, information disclosure regarding sensitivity of a fair value measurement categorized within Level 3 of the fair value hierarchy to changes in unobservable inputs and any interrelationships between those unobservable inputs, and the categorization by level of the fair value hierarchy for items that are not measured at fair value. The amended guidance was effective for financial periods beginning after December 15, 2011. ASU 2011-04 did not have a material effect on our consolidated financial position or results of operations.

In June 2011, the FASB issued guidance on the presentation of comprehensive income. The new guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. Instead, an entity will be required to present either a continuous statement of net income and other comprehensive income or in two separate but consecutive statements. The new guidance is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2011 and will have presentation changes only. We elected to report other comprehensive income and its components in a separate statement of comprehensive income for the year ended December 31, 2012.

In July 2011, the FASB issued guidance on the presentation of net patient service revenue. The new guidance requires a change in presentation of the statement of operations by reclassifying the provision for bad debts associated with patient service revenue from an operating expense to a deduction from patient service revenue (net of contractual allowances and discounts). Additionally, enhanced disclosure about policies for recognizing revenue and assessing bad debts are required. Disclosures of patient service revenue (net of contractual allowances and discounts) as well as qualitative and quantitative information about changes in the allowance for doubtful accounts will be required. The new guidance is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2011. Our adoption of this guidance did not have a material impact on our consolidated financial statements.

In September 2011, the FASB issued guidance on intangibles including goodwill and other intangibles. The new guidance will allow an entity to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. The new guidance is effective for fiscal years beginning after December 15, 2011. We adopted this guidance in the fourth quarter of 2012.

In February 2013, the FASB issued Accounting Standards Update No. 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income, to improve the transparency of reporting reclassifications out of accumulated other comprehensive income. The amendments in the Update do not change the current requirements for reporting net income or other comprehensive income in financial statements. The new amendments will require an organization to present (either on the face of the statement where net income is presented or in the notes) the effects on the line items of net income of significant amounts reclassified out of accumulated other comprehensive income if the item reclassified is required under U.S. GAAP to be reclassified to net income in its entirety in the same reporting period. Additionally, for other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under U.S. GAAP to provide additional detail about those amounts. For public companies, the amendments are effective for reporting periods beginning after December 15, 2012. We do not expect that the adoption of this guidance will have a material impact on our consolidated financial statements.





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### 3. INVENTORIES

Inventories (net of allowance for obsolescence) consisted of the following:

	Dollars in Thousands	
	December 31, 2012	December 31, 2011
Finished goods	\$4,057	\$2,608
Raw materials and work in process	1,547	1,485
Demonstration inventory	104	277
	\$5,708	\$4,370
Less allowance for obsolescence	(616)	(511)
Total	\$5,092	\$3,859

### 4. INTANGIBLES AND OTHER ASSETS

Long-lived intangible assets and other assets consisted of the following:

	Dollars in Thousands			Dollars in Thousands		
	December 31, 2012			December 31, 2011		
	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Acquired technology	\$9,009	\$1,910	\$7,099	\$6,535	\$911	\$5,624
Assay royalties	1,434	410	1,024	1,434	205	1,229
Third party payor relationships	367	49	318	367	—	367
Tradenames and trademarks	824	115	709	344	49	295
Customer relationships	652	11	641	—	—	—
Covenants not to compete	184	15	169	—	—	—
Patents	929	280	649	703	267	436
Intellectual property	170	15	155	20	5	15
	\$13,569	\$2,805	\$10,764	\$9,403	\$1,437	\$7,966

	Estimated Useful Life
Acquired technology	7 – 8 years
Assay royalties	7 years
Third party payor relationships	15 years
Tradenames and trademarks	7 years
Customer relationships	15 years
Covenants not to compete	3 years
Patents	Life of the patent
Intellectual property	7 years

Other assets include U.S. security deposits and deferred tax assets, net of applicable valuation allowances.

Amortization expense for intangible assets was \$1.4 million, \$1.3 million and less than \$0.1 million during the years ended December 31, 2012, 2011 and 2010. Amortization expense for intangible assets is expected to be \$1.7 million in each of the years 2013 through 2017.



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5. DEBT

	Dollars in Thousands	
	Year Ended December 31,	
	2012	2011
PGxHealth note payable (the "First Note") <sup>(1)</sup>	\$6,171	\$8,640
PGxHealth note payable (the "Second Note") <sup>(2)</sup>	—	