

TRANSGENOMIC INC
Form 10-K
March 14, 2011
Table of Contents

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, 2010

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)

Edgar Filing: TRANSGENOMIC INC - Form 10-K

12325 Emmet Street

Omaha, NE 68164
(Address of Principal Executive Offices)

68164
(Zip Code)

(402) 452-5400

(Registrant's Telephone Number, Including Area Code)

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

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

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

Common Stock, par value \$.01 per share

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes _____ No X

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Yes _____ No X

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No _____

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes _____ No _____

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

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 x

(Do not check if a smaller reporting company)

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

Edgar Filing: TRANSGENOMIC INC - Form 10-K

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 \$10.0 million.

At March 14, 2011, the registrant had 49,299,672 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant Proxy Statement relating to its 2011 Annual Meeting of Stockholders (the Proxy Statement) have been incorporated into Part III of this Report on Form 10-K.

Table of Contents**TRANSGENOMIC, INC.****Index to Form 10-K for the Fiscal Year Ended December 31, 2010****PART I**

Item 1.	<u>Business</u>	K-2
Item 1A.	<u>Risk Factors</u>	K-6
Item 1B.	<u>Unresolved Staff Comments</u>	K-13
Item 2.	<u>Properties</u>	K-13
Item 3.	<u>Legal Proceedings</u>	K-14
Item 4.	<u>Removed and Reserved</u>	K-14

PART II

Item 5.	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	K-15
Item 6.	<u>Selected Consolidated Financial Data</u>	K-15
Item 7.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	K-17
Item 7A.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	K-27
Item 8.	<u>Financial Statements and Supplementary Data</u>	
	<u>Report of Independent Registered Public Accounting Firm</u>	K-28
	<u>Consolidated Balance Sheets as of December 31, 2010 and 2009</u>	K-29
	<u>Consolidated Statements of Operations for the Years Ended December 31, 2010 and 2009</u>	K-30
	<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2010 and 2009</u>	K-31
	<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2010 and 2009</u>	K-32
	<u>Notes to the Consolidated Financial Statements for the Years Ended December 31, 2010 and 2009</u>	K-33
Item 9	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosures</u>	K-57
Item 9A.	<u>Controls and Procedures</u>	K-57
Item 9B.	<u>Other Information</u>	K-58

PART III

Item 10.	<u>Directors, Executive Officers and Corporate Governance</u>	K-59
Item 11.	<u>Executive Compensation</u>	K-59
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	K-60
Item 13.	<u>Certain Relationships and Related Transactions, and Director Independence</u>	K-60
Item 14.	<u>Principal Accounting Fees and Services</u>	K-60

PART IV

Item 15.	<u>Exhibits, Financial Statement Schedules</u>	K-60
----------	--	------

SIGNATURES

K-64

This Annual Report on Form 10-K references the following registered trademarks which are the property of Transgenomic, Inc.: DNASEP® Cartidges, WAVE® System, WAVEMAKER® Software, TRANSGENOMIC® and the Globe Logo®; MutationDiscovery.com® Website, OLIGOSEP® Cartidges for Systems and Reagents, OPTIMASE® Polymerase, RNASEP® Cartidges, WAVE OPTIMIZED® reagents, WAVE® MD Systems, MitoScreen Kits, ProtocolWriter Software, Navigator Software, THE POWER OF DISCOVERY® for Lab Reagents and Educational Programs, SURVEYOR® Nuclease, and FAMILION®. All other trademarks or trade names referred to in this Annual Report on Form 10-K are the property of their respective owners.

Table of Contents

PART I

FORWARD-LOOKING STATEMENTS

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

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

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

The following discussion should be read together with our financial statements and related notes contained in this report. Results for the year ended December 31, 2010 are not necessarily indicative of results that may be attained in the future.

Item 1. Our Business

Transgenomic, Inc. (together with its Affiliates, the Company or Transgenomic) provides genetic variation analytical services to the medical research, clinical and pharmaceutical markets. Net sales are categorized as Laboratory Services and Instrument Related Business. We also provide innovative products for the purification and analysis of nucleic acids used in the life sciences industry for research focused on molecular genetics and diagnostics.

Laboratory Services:

Molecular Clinical Reference Laboratory. The molecular clinical reference laboratory specializes in genetic testing for oncology, cardiology, hematology, inherited disorders and

Table of Contents

diseases of aging. 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 accredited by CAP (College of American Pathologists).

Pharmacogenomics Research Services. Pharmacogenomics research services are provided by our Contract Research Organization located in Omaha, Nebraska. 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.

Instrument Related Business:

Bioinstruments. Our proprietary product is the WAVE[®] System which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. There is a worldwide installed base of over 1,500 WAVE Systems as of December 31, 2010. 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.

Bioconsumables. The installed WAVE base and some OEM 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.

Business Strategy

Our business strategy is to provide products and services to biomedical researchers, 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. Accordingly, a principal component of our strategy has and continues to be to establish our WAVE System as an industry standard in the biomedical research market and to develop additional markets for the WAVE System such as clinical research and diagnostics. For continued high quality support for our WAVE System and associated bioconsumables, we attained ISO90001:2000 certification for our Omaha manufacturing site in the fourth quarter of 2008 and have since been certified to the ISO9001:2008 standard in 2009.

Over the last few years an increasingly important part of our strategy has been to expand our two Laboratory Services businesses. We have gained exposure to the translational and clinical research markets, laying the foundation for increasing our participation in the full-value chain associated with activities ranging from basic biomedical research to development of diagnostic and therapeutic products to increasing opportunities for developing and manufacturing companion diagnostics. During the fourth quarter of 2005, our laboratory in Omaha, Nebraska was certified under the Clinical Laboratory Improvement Amendments and we received our first patient samples for molecular-based testing for hematology, oncology and certain inherited diseases for physicians and third-party laboratories to aid in patient diagnoses or pharmaceutical drug development and drug clinical trials. In

Table of Contents

December of 2008 our Omaha laboratory was awarded an accreditation by the Commission on Laboratory Accreditation of the College of American Pathologists (CAP) based on the results of an onsite inspection.

In December 2010 we acquired another CLIA certified laboratory in New Haven, Connecticut that specializes in genetic disorders associated with cardiomyopathies and channelopathies. We believe there is a significant opportunity for us to continue growing the demand for molecular-based testing by leveraging our technologies, experience and expertise in biomarker analysis. In addition, we continue to seek out and evaluate new technologies and new laboratory tests that will further extend our offerings in our Molecular Diagnostics Laboratory and our Pharmacogenomics Services Lab.

Sales and Marketing

Our Laboratory Services sales team consists of regionally based sales people in the United States and Canada. 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. Our sales and support team consists of regionally-based sales people, service engineers and applications scientists to support our sales and marketing activities throughout 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 testing 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, to 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 the laboratory's patient fee schedule, subject to third-party payer limitations. Revenues received from Medicare and Medicaid billings are based on government-set fee schedules and reimbursement rules.

Customers include numerous leading academic and medical institutions in the U.S. and abroad. In addition, our customers also include a number of large, established pharmaceutical, biotech and commercial companies both in the U.S. and abroad. No customer accounted for more than 10% of our consolidated net sales for the years ended December 31, 2010 and 2009. For the years ended December 31, 2010 and 2009 one customer made up 15% and 20% of the laboratory services net sales, respectively.

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 have significant commercial value. Major areas of focus include development of SURVEYOR based oncology mutation kits for therapeutic assessment of TKI inhibitors utilizing multiple instrument platforms; a new discovery in high sensitivity DNA mutation detection for Sanger Sequencing; development of ICE COLD PCR applications for ultra-high sensitivity mutation detection in tissue and blood; a toolbox of mitochondrial DNA assays to assess damage, copy number, deletion and mutation for applications ranging from toxicology to diabetes to aging; and development of a biomarker for FC Gamma receptor to aid in the selection of therapeutic options for monoclonal antibody cancer drugs.

Table of Contents

For the years ended December 31, 2010 and 2009, our research and development expenses were \$2.3 million and \$3.2 million, respectively.

Manufacturing

We manufacture bioconsumable products including our separation columns, liquid reagents, and enzymes. The major components of our WAVE Systems are manufactured for us by a third party. We integrate our own hardware and software with these third party manufactured components. Our manufacturing facilities for our 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, as well as confidentiality provisions in our contracts. Our WAVE System and related consumables are protected by patents and in-licensed technologies that expire in various periods beginning in 2013 through 2030. On December 29, 2010 we acquired the FAMILION family of genetic tests. As part of the transaction, we acquired the exclusive rights to the FAMILION family of genetic tests for inherited disease, including the patents protecting this technology. We will continue to file patent applications and seek new licenses as warranted to protect and develop new technologies of interest to our customer base in the coming years.

Competition

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

Our Laboratory Services division faces competition from a number of companies offering contract DNA sequencing and other genomic analysis services, including Genzyme, SeqWright and others. In addition, several clinical diagnostics service providers, such as Labcorp, Quest, Athena and Baylor College of Medicine, also offer related laboratory services. Finally, additional competition arises from academic core laboratory facilities. Competition for our WAVE Systems arises primarily from DNA sequencing and genotyping technologies. Competitors in these areas include Applied Biosystems, Idaho Technologies, 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, 2010 and 2009, we had employees focused in the following areas of our operation:

	December 31,	
	2010	2009
Manufacturing and Laboratory	62	36
Sales, Marketing and Administration	88	53
Research and Development	12	14
	162	103

Table of Contents

Our employees were employed in the following geographical locations:

	December 31,	
	2010	2009
United States	136	78
Europe (other than the United Kingdom)	15	12
United Kingdom	10	13
Canada	1	
	162	103

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 a CLIA laboratory in New Haven, Connecticut.

We make reports filed by us with the SEC available free of charge on our website as soon as reasonably practicable after these reports are filed. The address of our website is www.transgenomic.com. Information on our website, including any SEC report, is not part of this Annual Report on Form 10-K.

Item 1A. Risk Factors

We may not have adequate financial resources to execute our business plan.

We have historically operated at a loss and have not consistently generated sufficient cash from operating activities to cover our operating and other cash expenditures. On December 29, 2010 we acquired the FAMILION family of genetic tests from PGxHealth, a subsidiary of Clinical Data. At December 31, 2010, we had cash and cash equivalents of \$3.5 million. While we believe that existing sources of liquidity are sufficient to meet expected cash needs through 2011, we will need to increase our net sales and successfully integrate the FAMILION acquisition in order to be assured of meeting our liquidity needs on a long-term basis. This acquisition was funded with debt and preferred stock. However, we cannot assure you that we will be able to increase our net sales, further reduce our expenses, or raise further capital or equity and, accordingly, we may not have sufficient sources of liquidity to continue the operations indefinitely.

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 net loss for the years ended December 31, 2010 and 2009 were \$3.1 million and \$1.9 million, respectively. These historical losses have been due principally to the high levels of research and development expenses and sales and marketing expenses that we have incurred in order to develop and market our products, the fixed nature of our manufacturing costs, restructuring charges and impairment charges and merger and acquisition costs. On December 29, 2010 we acquired the FAMILION family of genetic tests. The acquisition was completed due to the opportunity for synergies in combining the laboratories and potential for revenue growth. We will need to quickly and

Table of Contents

successfully implement our integration plan to reduce the net loss in the future. In addition, markets for our products and services have developed more slowly than expected in many cases and may continue to do so. As a result, we may incur operating losses in the future.

We may not have adequate top executive talent to execute our business plan.

Prior to the acquisition of FAMILION, in order to reduce our operating costs, we have reduced the number of employees in most areas of our business. In addition, we may lose key management, scientific, technical, sales and manufacturing personnel from time to time. It may be difficult to recruit and retain executive management if they are needed in the future, and the loss of top executive talent could harm our business and operating results. We cannot assure you that our employee reductions will not impair our ability to develop new products and refine existing products in order to remain competitive or meet our customers' needs. In addition, these reductions could prevent us from successfully marketing our products and developing our customer base.

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

Edgar Filing: TRANSGENOMIC INC - Form 10-K

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

K-7

Table of Contents

significant out-of-pocket costs. If we fail to evaluate and execute acquisitions accurately, we could fail to achieve our anticipated level of growth and our business and operating results could be adversely affected.

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

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

Sales of our Laboratory Services have been variable.

Laboratory Services include services performed by both our Molecular Clinical Reference Laboratory and our Pharmacogenomics Research Services. Testing volumes at the Molecular Clinical Reference Laboratory are dependent on patient visits to doctors' offices and other providers of health care and tends to fluctuate on a seasonal basis. Testing volume generally declines during the year-end holiday periods, other major holidays and the summer. The Pharmacogenomics Research Services depends on project-based work that changes from quarter to quarter. Therefore, comparison of the results of successive quarters may not accurately reflect trends or results for the full year.

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

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

Governmental payers and healthcare 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 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, to impose more stringent cost controls and to 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.

The Clinical Laboratory Improvement Amendments of 1988 (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 also must undergo proficiency testing and are subject to inspections.

Table of Contents

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 protected health information and establish standards for electronic healthcare transactions in the United States. These privacy regulations establish federal standards regarding the uses and disclosures of protected health information. Our Molecular Clinical Reference Laboratory is 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 healthcare 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 healthcare reform.

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

We may be subject to client lawsuits.

Providers of clinical testing services may be subject to lawsuits alleging negligence or other similar 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. If net sales of our products and services continue at current levels, we may need to take steps to further reduce operating expenses or raise additional working capital. We cannot assure that sales will increase or that we will be able to reduce operating expenses or raise additional working capital.

Table of Contents

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 more than half of our total net sales. As a result, a major portion of our net sales are subject to risks associated with international sales and operations. These risks include:

payment cycles in foreign markets are typically longer than in the U.S., and capital spending budgets for research agencies can vary over time with foreign governments;

changes in foreign currency exchange rates can make our products more costly in local currencies since our foreign sales are typically paid for in British Pounds or the Euro;

the potential for changes in U.S. and foreign laws or regulations that result in additional import or export restrictions, higher tariffs or other taxes, more burdensome licensing requirements or similar impediments to our ability to sell products and services profitably in these markets; and

the fluctuation of foreign currency to the US Dollar and the Euro to the British Pound can cause our net sales and expenses to increase or decrease which adds risk to our financial statements.

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

We rely on a single supplier, Hitachi High Technologies America, to provide the basic instrument modules used in our WAVE Systems. While other suppliers of instrumentation are available, we believe that our arrangement with Hitachi offers strategic advantages. We have successfully converted the latest model of WAVE Systems to utilize Hitachi's newest instrument line. If we were required to seek alternative sources of supply, it could be more time consuming or expensive or 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 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.

Table of Contents

Our patents may not protect us from others using our technology that 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 our 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. The 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 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.

Table of Contents

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

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

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

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

a broker or dealer approve a person's account for transactions in penny stocks; and

the broker or dealer receives from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

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

obtain financial information and investment experience objectives of the person; and

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

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

sets forth the basis on which the broker or dealer made the suitability determination; and

that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

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.

Table of Contents

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

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

At December 31, 2010, we had obligations to issue 18,607,229 shares of common stock upon exercise of outstanding stock options representing 2,565,001 shares, convertible preferred stock representing 10,344,820 shares and warrants representing 5,697,408 shares. 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, 2010, we had 49,289,672 shares of common stock outstanding. Fewer than ten unrelated, institutional holders own more than 50% of these shares. The sale of a significant number of shares into the public market has 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. Such an event could place further downward pressure on the price of our common stock. This presents an opportunity for short sellers to contribute to the further decline of our stock price. If there are significant short sales of our stock, the price decline that would result from this activity will cause the share price to decline more so, which, in turn, may cause long holders of the stock to sell their shares thereby contributing to sales of stock in the market.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

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

Location	Function	Square Footage	2011	
			Scheduled Rent	Lease Term Expires
Omaha, Nebraska	WAVE and Consumable Manufacturing	25,000	\$ 81	July 2011
San Jose, California	Consumable Manufacturing	9,110	\$ 46	February 2016
Glasgow, Scotland	Multi Functional ⁽¹⁾	5,059	\$ 48	March 2012
Omaha, Nebraska	Multi Functional ⁽¹⁾	18,265	\$ 200	July 2012
New Haven, Connecticut	Laboratory	23,123	\$ 477	March 2013

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

Table of Contents

We believe that these facilities are adequate to meet our current and planned needs. We expect that the Omaha lease which expires in 2011 will be replaced with a lease of equivalent nature. We believe that if additional space is needed in the future, we could find alternate space at competitive market rates without substantial increase in cost.

Item 3. Legal Proceedings.

On January 23, 2009, Transgenomic and Power 3 Medical Products, Inc. (Power3) entered into a Collaboration and Exclusive License Agreement (the Agreement). On January 29, 2010, Transgenomic received a letter from Power3 terminating the Agreement. Power3 s alleged basis for terminating the Agreement was, among other claims, that Transgenomic committed a material breach of the Agreement by its alleged unauthorized disclosure of confidential information concerning the licensed technology. Transgenomic denies it has breached the Agreement. Transgenomic has sued Power 3 in the United States District Court for the District of Nebraska, Case No. 8:10CV-00079 (the Action) claiming that Power3 wrongfully terminated the Agreement. Power3 has not yet filed a counterclaim against Transgenomic in the action and no discovery has taken place in the Action. At this time, Transgenomic and Power3 have stayed the Action and have agreed to commence mediation proceedings to attempt to resolve the matters involved in the Action. Since Power3 has not filed a counterclaim against Transgenomic in the Action, we are not in a position to assess the merits of Power3 s threatened claims against Transgenomic. However, based upon the facts known to Transgenomic at this time, we do not believe the Action will have a material adverse effect on our financial position, results of operations or cash flows.

The Company is not a party to any other pending legal proceedings that, if decided adversely to the Company, will have a material adverse effect on our financial position, results of operations or cash flows.

Item 4. (Removed and Reserved)

Table of Contents**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

Market Information. Share price information for our common stock is available on the OTC Bulletin Board under the symbol TBIO.OB. The following table sets forth the high and low closing prices for our common stock during each of the quarters of 2010 and 2009.

	High	Low
Year Ended December 31, 2010		
First Quarter	\$ 0.88	\$ 0.61
Second Quarter	\$ 0.86	\$ 0.49
Third Quarter	\$ 0.59	\$ 0.33
Fourth Quarter	\$ 0.71	\$ 0.32
Year Ended December 31, 2009		
First Quarter	\$ 0.42	\$ 0.21
Second Quarter	\$ 0.58	\$ 0.32
Third Quarter	\$ 0.70	\$ 0.35
Fourth Quarter	\$ 0.74	\$ 0.58

Holders. At December 31, 2010, there are 49,289,672 shares of our common stock outstanding and approximately 2,800 holders of record.

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

Sale of Unregistered Securities. The Company made no sales of its common stock during the years ended December 31, 2010 and 2009 that were not registered under the Securities Act of 1933 (the "Securities Act"). On December 29, 2010 we issued 2,586,205 shares of Series A Convertible Preferred Stock that were not registered under the Securities Act. The issuance of such Convertible Preferred Stock was related to the financing for the Company's acquisition of assets from PGxHealth. Please refer to the Series A Convertible Preferred Stock Purchase Agreement with affiliates of Third Security dated December 29, 2010 (incorporated by reference to the Registrant's Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011).

Issuer Purchase of Equity Securities. The Company made no purchases of its common stock during the quarter ended December 31, 2010. Therefore, tabular disclosure is not presented.

Item 6. Selected Consolidated Financial Data.

The selected consolidated balance sheet data as of December 31, 2010 and 2009 and the selected consolidated statements of operations data for each year ended December 31, 2010 and 2009 have been derived from our audited consolidated financial statements that are included elsewhere in

Edgar Filing: TRANSGENOMIC INC - Form 10-K

- (3) Other income for all years presented primarily includes interest expense and interest income. Other income in 2010 includes \$0.6 million awarded in a federal grant under the Qualifying Therapeutic Discovery Project Program related to 2009 projects. Other income in 2007 includes \$.9 million from the sale of an investment security and \$.2 million in insurance proceeds related to equipment destroyed in fire at our Cramlington, England facility.

K-16

Table of Contents

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

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

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

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

Our continuing operations consist of Laboratory Services and Instrument Related Business, including the manufacture and sale of our WAVE System and related consumable products (see the description of our business in Item 1). We have broken out our business into two reportable segments: Laboratory Services and Instrument Related business. There are estimates involved in breaking out the expenses and other disclosures.

The following discussion should be read together with our financial statements and related notes contained in this report. Results for the year ended December 31, 2010 are not necessarily indicative of results that may be attained in the future.

Executive Summary

2010 Results

Full year net sales for 2010 of \$20.0 million decreased by 9% compared with total net sales for 2009 of \$22.0 million. Our Laboratory Services business grew 9% over the prior year, while the Instrument Related Business decreased 14% from 2009 to 2010. Overall gross margins decreased from 53% to 49%. Operating expenses were \$13.4 million for the year ended December 31, 2010 compared

Table of Contents

to \$13.5 million for the same period of 2009, but note that 2010 included \$0.8 million in deal costs related to our acquisition of the FAMILION family of genetic tests of PGxHealth and \$0.1 million in restructuring costs related to the consolidation of our Gaithersburg, Maryland facility into Omaha that was offset by a decrease in research and development costs of \$0.9 million.

On December 29, 2010 we acquired the FAMILION family of genetic tests from PGxHealth, a subsidiary of Clinical Data. This strategic acquisition provided us with proprietary genetic commercial tests that have an established revenue base, proprietary biomarker assays, an additional fully integrated CLIA certified laboratory operation, and established test reimbursement and coverage policies that offer access to testing.

2011 Outlook

We continue to leverage our core instrument business for on-going instrument sales worldwide as well as employing our instruments and related expertise in our two laboratory services businesses. We anticipate strengthening growth in both of our laboratory services businesses and we continue to seek out new assay technologies and tests to license or develop internally to expand our menu offerings for both of these service businesses. In particular, we have substantially increased our footprint in the molecular diagnostics laboratory market through our recent acquisition of the Clinical Data FAMILION product line, which includes a CLIA laboratory business. This acquisition brings us approximately \$13.0 million in new annual revenues and a much larger presence both with insurers and patients. This acquisition also provides us access to higher throughput technologies and an expert staff to aid us in growing our reference laboratory business.

In our Pharmacogenomics Lab, we have completed cancer pathway gene mutation projects for a number of high visibility pharmaceutical companies. Employing our recently licensed ultra sensitive DNA mutation detection technology, termed Cold-PCR, we have added the significant addition of utilizing blood as a mutation detection sample source rather than just testing patients' tumors. This is a significant achievement and should, we believe, lead to much faster expansion of our service testing for pharmaceutical partners as they adopt this novel approach. In addition to Cold-PCR, which offers sensitivity improvements as much as 10,000 times higher than routine testing technology, we have recently discovered a technique to further improve mutation detection sensitivity of standard sequencing technology. We are combining this new discovery with our Cold-PCR program to bring what we believe to be the most accurate and sensitive mutation detection technology available in the market today. We believe that this combination of technologies will offer us the ability to develop tests for earlier cancer detection using blood or even saliva and to measure recurrence for a very early warning to better manage patients suffering from cancer as well as support earlier drug selection or drug resistance determinations for these patients.

Although the WAVE System is a fully matured technology, and both it and its corresponding consumable sales growth in our traditional markets are shrinking, we are expanding our opportunities by selling systems into new geographic areas, including the Middle East and Asia, to continue the revenue from our instrument related business segment. We continue to look for emerging markets and novel applications to provide us with new opportunities for our WAVE System such as our newly launched K-RAS mutation detection kit. We have launched our CE IVD labeled K-RAS mutation detection kit into Europe and the U.S. and will soon follow that with additional assay kits for BRAF, PIK3CA and P-53 mutation assay kits. These are all key cancer pathway mutation assessment tools and through our proprietary technologies bring noteworthy improvements in sensitivity and cost

Table of Contents

efficiency to the market compared to competing technologies. We intend to continue to look for opportunities to diversify into new markets, including the personalized medicine market, particularly in oncology, where the sensitivities of our technologies are essential. A recently licensed technology that could provide the highest sensitivity available in the marketplace is being refined for use on our Wave Systems. In addition, we are also selling refurbished WAVE Systems in order to allow an opportunity for customers who may not be able to afford the full cost of a new system to purchase and utilize our WAVE technology. Additionally, we have developed credibility and momentum with third-party platforms that will allow us to leverage our direct sales force and distribution network.

We have historically operated at a loss and have not consistently generated sufficient cash from operating activities to cover our operating and other cash expenditures. On December 29, 2010 we acquired the FAMILION family of genetic tests from PGxHealth, a subsidiary of Clinical Data. At December 31, 2010, we had cash and cash equivalents of \$3.5 million. While we believe that existing sources of liquidity are sufficient to meet expected cash needs through 2011, we will need to increase our net sales and successfully integrate the FAMILION acquisition in order to be assured of meeting our liquidity needs on a long-term basis. This acquisition was funded with debt and preferred stock. However, we cannot assure that we will be able to increase our net sales, further reduce our expenses, or raise further capital or equity and, accordingly, we may not have sufficient sources of liquidity to continue operations indefinitely.

Results of Continuing Operations**Years Ended December 31, 2010 and 2009**

Net Sales. Net sales for the years ended December 31, 2010 and 2009 consisted of the following (dollars in thousands):

	2010	2009	Change \$	%
Laboratory Services:				
Molecular Clinical Reference Laboratory Services	\$ 3,606	\$ 3,541	\$ 65	2%
Pharmacogenomics Research Services	1,373	1,025	348	34%
	4,979	4,566	413	9%
Instrument Related Business:				
Bioinstruments	8,320	10,175	(1,855)	(18)%
Bioconsumables	6,749	7,282	(533)	(7)%
	15,069	17,457	(2,388)	(14)%
Total Net Sales	\$ 20,048	\$ 22,023	\$ (1,975)	(9)%

Laboratory Services net sales increased during the year ended December 31, 2010 compared to 2009 by \$0.4 million or 9%. Laboratory Services sales includes both the Molecular Clinical Reference Laboratory Services and the Pharmacogenomics Research Services. The Molecular Clinical Reference Laboratory Services net sales of \$3.6 million increased 2% over the year ended December 31, 2009. The Molecular Clinical Reference Laboratory average revenue per test has decreased by 4% due to the mix of tests performed and the increased Medicare and Medicaid test volumes which generates lower reimbursement for these tests. The decrease in average revenue per test is offset by a 6% increase in volume. The Pharmacogenomics Research Services net sales of \$1.4 million during 2010 increased

Table of Contents

34% over the year ended December 31, 2009. The increase in Pharmacogenomics Research Services is largely due to an increase in the number of clients and average revenue billed per client for the year ended December 31, 2010 compared to the same period of 2009. The Pharmacogenomics Research Services net sales have peaks due to the nature of this project-related business. Each period for Pharmacogenomics Research Services should be considered on a stand-alone basis and is not indicative of future net sales.

Bioinstrument sales consist of sales of our WAVE System and associated equipment that we manufacture or assemble, net sales from service contracts that we enter into with purchasers of our instruments, as well as sales of instruments we distribute for other manufacturers (OEM equipment). We also sell refurbished WAVE Systems in order to access customers that may not be able to afford new systems. Bioinstrument net sales are down \$1.9 million, or 18% during the year ended December 31, 2010 as compared to the same period in 2009. We sold 25 WAVE Systems during the year ended December 31, 2010 compared to 32 systems during 2009. We sold 10 OEM instruments during the year ended December 31, 2010 compared to 11 in the same period of 2009. The decrease in bioinstrument net sales was due to the lower volume of instruments sold and lower average sales price on both our WAVE and OEM instruments. Service contract sales were down \$0.2 million for the year ended December 31, 2010 compared to the same period of 2009 due to lower volumes in both the European and U.S. markets. Parts, freight and miscellaneous income was lower by \$0.5 million for the year ended December 31, 2010 as compared to the same period of 2009. Demand for WAVE Systems continues to be affected by significant competitive challenges from traditional (i.e. sequencing) and evolving technologies. Instrument related revenue is subject to many factors such as type of instrument sold and the country of sale. Due to these factors each period should be considered on a stand alone basis and is not indicative of future net sales streams.

Bioconsumable net sales decreased during the year ended December 31, 2010 compared to 2009 by \$0.5 million or 7%. The primary decrease in consumables is due to lower volume in our European market offset by higher volume in our U.S. market.

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, test outsourcing fees, rent, supplies and depreciation) associated with our Laboratory Services operations. Cost of goods sold for the years ended December 31, 2010 and 2009 consisted of the following (dollars in thousands):

	2010	2009	Change	
			\$	%
Laboratory Services:				
Molecular Clinical Reference Laboratory Services	\$ 2,125	\$ 2,018	\$ 107	5%
Pharmacogenomics Research Services	1,416	820	596	73%
	3,541	2,838	703	25%
Instrument Related Business:				
Bioinstruments	3,560	3,801	(241)	(6)%
Bioconsumables	3,183	3,779	(596)	(16)%
	6,743	7,580	(837)	(11)%
Total Cost of Goods Sold	\$ 10,284	\$ 10,418	\$ (134)	(1)%

Table of Contents

Gross profit equaled \$9.8 million or 49% of total net sales during the year ended December 31, 2010 compared to \$11.6 million or 53% during the same period of 2009. The decrease in gross profit as a percent of net sales is largely attributable to changes in the composition of products sold. The Laboratory Services business segment margins decreased for the year ended December 31, 2010 to 29% as compared to 38% for the year ended December 31, 2009. The erosion in the Laboratory Services gross margin is driven by the lower average net sales reimbursement per test due to increased Medicare and Medicaid test volume. In addition, Laboratory Services had higher operating supplies cost in 2010 than the same period in 2009 related to the higher volume of tests and work required on the Pharmacogenomic projects. Margins on bioinstruments declined from 63% to 57% from 2009 to 2010 due to fewer instruments sold, a decline in service contract revenue and lower parts, freight and miscellaneous income. The instruments business has a fixed cost component in cost of goods sold, therefore lower revenue will cause the margin to deteriorate. Margins on bioconsumables increased from 48% in 2009 to 53% in 2010 primarily related to a 2009 one time obsolescence reserve of \$0.4 million for control plasmids used in our SURVEYOR kits and the transition from a steel syringe delivery method to a disposable delivery method.

Selling, General and Administrative Expenses. Selling, general and administrative expenses primarily include personnel costs, marketing, travel and entertainment costs, professional fees, facility costs and foreign currency revaluation. Selling, general and administrative expenses increased as a percentage of net sales from 47% in 2009 to 55% in 2010. For the year ended December 31, 2010 we incurred \$0.8 million in expenses that related to our acquisition of the FAMILION family of genetic tests. Selling, general and administrative expenses would have been \$10.3 million for the year ended December 31, 2010 excluding the deal costs to acquire the FAMILION family of genetic tests which would be comparable to SG&A expenses for the year ended December 31, 2009 of \$10.3 million. Foreign currency translation expense was \$0.3 million in each of the periods ended December 31, 2010 and 2009. We recorded restructuring charges of \$0.1 million in 2010 related to the consolidation of research and development into Omaha, which included closing the Gaithersburg, Maryland facility and the elimination of positions in our manufacturing group. There were no restructuring charges in 2009.

Research and Development Expenses. Research and development expenses primarily include personnel costs, collaboration costs, legal fees, supplies, and facility costs. These costs totaled \$2.3 million during the year ended December 31, 2010 compared to \$3.2 million during the same period of 2009, a decrease of \$0.9 million or 28%. The decrease is primarily due to expenses in 2009 related to collaboration expenses for NuroPro assay development related to the diagnosis of Alzheimer's and Parkinson's diseases, the development of high sensitivity mutation detection technology called Cold-PCR and purchases of samples related to research work in progress. As a percentage of net sales, research and development expenses totaled 11% and 14% of net sales during the year ended December 31, 2010 and 2009 respectively. Research and development expenses are expensed in the year in which they are incurred.

Other Income (Expense). Other income consists primarily of interest income from cash and cash equivalents invested in overnight instruments. Other income in the year ended December 31, 2010 includes an award of a federal grant under the Qualifying Therapeutic Discovery Project. Other income related to this federal grant was \$0.6 million net of consulting fees. Other income for the year ended December 31, 2009 was less than \$0.1 million.

Income Tax Expense. Income tax expense recorded during the years ended December 31, 2010 and 2009 related to income taxes in states, foreign countries and other local jurisdictions and

Table of Contents

totaled less than \$0.2 million and \$0.1 million, respectively. The effective tax rate for the year ended December 31, 2010 is 5.0%, which is primarily the result of valuation allowances against net operating losses for the United States, partially adjusted by permanent differences related to intercompany foreign currency exchange of our subsidiary outside the United States. The effective tax rate for the year ended December 31, 2009 was 2.2%.

A net deferred tax liability was recorded during 2010 relating to the UK income taxes of less than \$0.1 million compared to a net deferred tax liability of \$0.1 million at year end 2009. 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 carryforwards from continuing and discontinued operations of \$104.3 million will expire at various dates from 2012 through 2029, if not utilized. We also had state income tax loss carryforwards from continuing and discontinued operations of \$36.0 million at December 31, 2010. These carryforwards will also expire at various dates if not utilized.

Liquidity and Capital Resources

Our working capital positions at December 31, 2010 and 2009 were as follows (in thousands):

	December 31,		
	2010	2009	Change
Current assets (including cash and cash equivalents of \$3,454 and \$5,642, respectively)	\$ 15,034	\$ 14,454	\$ 580
Current liabilities	8,253	4,103	(4,150)
Working capital	\$ 6,781	\$ 10,351	\$ (3,570)

We have historically operated at a loss and have not consistently generated sufficient cash from operating activities to cover our operating and other cash expenses. In 2010 we had a net loss of \$3.1 million and needed to use \$1.7 million in operating activities. While we have been able to historically finance our operating losses through borrowings or from the issuance of additional equity, we currently have no plans to increase borrowings or to issue additional equity securities for this purpose. At December 31, 2010 and December 31, 2009, we had cash and cash equivalents of \$3.5 and \$5.6 million, respectively. While we believe that existing sources of liquidity are sufficient to meet expected cash needs during 2011, we will need to increase our net sales and focus on the integration of the FAMILION acquisition to reduce our operating expenses in order to meet our liquidity needs on a long-term basis. However, we cannot assure you that we will be able to increase our net sales or further reduce our expenses, or raise further capital or equity and, accordingly, we may not have sufficient sources of liquidity to continue operations indefinitely. We continue to explore additional sources of liquidity.

Analysis of Cash Flows**Years Ended December 31, 2010 and 2009**

Net Change in Cash and Cash Equivalents. Cash and cash equivalents decreased \$2.2 million during the year ended December 31, 2010 primarily as a result of \$1.7 million being used in operating

Table of Contents

activities, net cash used in investing activities of \$6.2 million and \$5.8 million provided by financing activities. Cash and cash equivalents increased \$0.9 million during the year ended December 31, 2009 as a result of net cash of \$1.3 million being provided by operating activities and net cash used in investing activities of \$0.4 million.

Cash Flows Used In Operating Activities. Cash flows used in operating activities totaled \$1.7 million for the year ended December 31, 2010 compared to cash flows provided in operating activities of \$1.3 million during the year ended December 31, 2009. The cash flows used in operating activities in 2010 relate to the net loss of \$3.1 million which is offset by an increase in accounts payable of \$0.4 million and noncash items of \$0.7 million. The cash flows provided by operating activities in 2009 primarily relate to the increased accounts receivable collections of \$1.1 million, the decrease in inventory of \$1.3 million and noncash items of \$1.1 million, offset by the loss of \$1.9 million and lower accrued expenses of \$0.4 million.

Cash Flows Used In Investing Activities. Cash flows used in investing activities totaled \$6.2 million during the year ended December 31, 2010. This included the acquisition costs for FAMILION of \$6.0 million and purchases of property and equipment of \$0.2 million. Cash flows used in investing activities totaled \$0.4 million during the year ended December 31, 2009. Cash flows used in investing activities in 2009 consisted primarily of purchases of property and equipment.

Cash Flows Provided by Financing Activities. Cash flows provided by financing activities were \$5.8 million for the year ended December 31, 2010. This resulted in the issuance of preferred stock to fund the acquisition of FAMILION. Also, we issued common stock due to the exercise of stock options for 100,000 shares during the second quarter of 2010. There were no cash flows provided by or used in financing activities for the year ended December 31, 2009.

Off Balance Sheet Arrangements

At December 31, 2010 and 2009, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

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. 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. Accounts receivable are shown net of an allowance for doubtful accounts. In determining an allowance for doubtful accounts, we consider the age of the accounts receivable, customer credit history, customer financial information, reasons for non-payment, and our knowledge of the customer. Management also evaluates contract terms and history of collections with third party payors. If our customers' financial condition were to deteriorate, resulting in a change in their ability to make payment, additional allowances may be required.

Table of Contents

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.

Depreciation and Amortization of Long-Lived Assets. Our long-lived assets consist primarily of property and equipment, patents and intellectual property. We believe the useful lives we assigned to these assets are reasonable. If our assumptions about these assets change as a result of events or circumstances and we believe the assets may have declined in value we may record impairment charges resulting in an increase to operating expenses. Property and equipment are carried at cost. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the related assets ranging from 1 to 10 years. We capitalize legal costs and filing fees associated with obtaining patents on our 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. Intellectual property is recorded at cost and is amortized over its estimated useful life.

Preferred Stock. We entered into a Series A Convertible Preferred Stock Purchase Agreement on December 29, 2010, as discussed in Note L, selling shares of preferred stock and issuing warrants to purchase a certain number of shares of Series A Preferred Stock. The Series A Preferred Stock meets the definition of mandatorily redeemable stock as it is preferred capital stock which is redeemable at the option of the holder and should be reported outside of equity. Preferred stock is accreted to its redemption value. The warrants do not qualify to be treated as equity, and accordingly, are recorded as a liability. A preferred stock conversion feature is embedded within the Series A Preferred Stock that meets the definition of a derivative. The preferred stock, warrant liability and preferred stock conversion feature are all recorded separately and were initially recorded at fair value using the Black Scholes model. We are required to record these instruments at fair value at each reporting date and changes will be recorded as an adjustment to earnings. The warrant liability and preferred stock conversion feature are considered level three financial instruments.

Impairment of Long-Lived Assets. We evaluate long lived assets including such things as goodwill for impairment on an annual basis. We assess the recoverability of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

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.

K-24

Table of Contents

Net sales of our instrument and bioconsumable 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. Our normal sales terms do not provide for the right of return unless the product is damaged or defective. Net Sales from certain services associated with our 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 period and net sales associated with these contracts are deferred and ratably recognized over the service period.

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

In our Pharmacogenomics research group we perform services on a project by project basis. When payment is received in advance, revenue is recognized upon delivery of the service. These projects typically do not extend beyond one year.

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.

Recently Issued Accounting Pronouncements

In October 2009, the FASB issued ASU No. 2009-13, *Revenue Recognition (ASC 605): Multiple-Deliverable Revenue Arrangements (a consensus of the FASB Emerging Issues Task Force)*; effective for years beginning after June 15, 2010. This standard update became effective for us on January 1, 2011. Vendors often provide multiple products and/or services to their customers as part of a single arrangement. These deliverables may be provided at different points in time or over different time periods. The existing guidance regarding how and whether to separate these deliverables and how to allocate the overall arrangement consideration to each was originally captured in EITF Issue 00-21, *Revenue Arrangements with Multiple Deliverables*, which is now codified at ASC 605-25, *Revenue Recognition Multiple-Element Arrangements*. The issuance of ASU 2009-13 amends ASC (FASB Accounting Standards Codification) 605-25 and represents a significant shift from the existing guidance that was considered abuse-preventative and heavily geared toward ensuring that revenue recognition was not accelerated. The application of this new guidance is expected to result in accounting for multiple-deliverable revenue arrangements that better reflects their economics as more arrangements will be separated into individual units of accounting. We are in the final stages of analyzing the impact of ASU 2009-13.

In October 2009, the FASB issued ASU No. 2009-14, *Software (ASC 985): Certain Revenue Arrangements That Include Software Elements (a consensus of the FASB Emerging Issues Task Force)*; effective for years beginning after June 15, 2010. This standard update became effective for us on January 1, 2011. ASU 2009-14 modifies the existing scope guidance in ASC 985-605, *Software Revenue Recognition*, for revenue arrangements with tangible products that include software elements.

Table of Contents

This modification was made primarily due to the changes in ASC 605-25 noted previously, which further differentiated the separation and allocation guidance applicable to non-software arrangements as compared to software arrangements. Prior to the modification of ASC 605-25, the separation and allocation guidance for software and non-software arrangements was more similar. Under ASC 985-605, which was originally issued as AICPA Statement of position 97-2, *Software Revenue Recognition*, an arrangement to sell a tangible product along with software was considered to be in its scope if the software was more than incidental to the product as a whole. We are in the final stages of analyzing the impact of ASU 2009-14.

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 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. Actual results could differ from the estimates and assumptions used in preparing these financial statements.

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

You are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements 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 for a number of reasons including those described in Part I, Item 1A, Risk Factors, of this report.

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

Impact of Inflation

We do not believe that price inflation or deflation had a material adverse effect on our financial condition or results of operations during the periods presented.

Table of Contents

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

Foreign Currency Translation Risk. During the last two fiscal years, our international sales have represented more than 50% of our net sales. These 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 operation and the Balance Sheet are translated from the functional currency of the subsidiary to our reporting currency of the US Dollar. Results of operations for the Company's foreign subsidiaries are 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 Euro. As a result we are subject to exchange rate risk.

K-27

Table of Contents

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 as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes 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, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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, 2010 and 2009, and the results of their operations and their cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

Omaha, Nebraska

March 14, 2011

K-28

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS**

As of December 31, 2010 and 2009

(Dollars in thousands except per share data)

	2010	2009
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 3,454	\$ 5,642
Accounts receivable (net of allowances for bad debts of \$334 and \$310, respectively)	7,601	4,522
Inventories (net of allowances for obsolescence of \$518 and \$507, respectively)	3,344	3,552
Other current assets	635	738
Total current assets	15,034	14,454
PROPERTY AND EQUIPMENT:		
Equipment	9,820	9,972
Furniture, fixtures and leasehold improvements	3,479	3,834
	13,299	13,806
Less: accumulated depreciation	(11,697)	(12,839)
	1,602	967
OTHER ASSETS:		
Goodwill	6,275	
Intangibles (net of accumulated amortization of \$519 and \$525, respectively)	8,962	383
Other assets	154	200
	\$ 32,027	\$ 16,004
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 1,360	\$ 1,013
Accrued compensation	875	573
Short term debt	989	
Accrued expenses	3,231	2,517
Contractual obligation	1,628	
Current portion of lease obligations	170	
Total current liabilities	8,253	4,103
Long term debt less current maturities	8,640	
Redeemable Series A convertible preferred stock, \$.01 par value, 3,879,307 shares authorized, 2,586,205 shares issued and outstanding	1,457	
Preferred stock conversion feature	1,983	
Warrant liability	2,351	
Other long term liabilities	843	239
Total liabilities	23,527	4,342
STOCKHOLDERS EQUITY:		
Preferred stock, \$.01 par value, 15,000,000 shares authorized, 2,586,205 shares issued and outstanding		
Common stock, \$.01 par value, 100,000,000 shares authorized, 49,289,672 shares issued and outstanding	498	497

Edgar Filing: TRANSGENOMIC INC - Form 10-K

Additional paid-in capital	139,730	139,703
Accumulated other comprehensive income	1,589	1,645
Accumulated deficit	(133,317)	(130,183)
Total stockholders' equity	8,500	11,662
	\$ 32,027	\$ 16,004

See notes to consolidated financial statements.

K-29

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

Years Ended December 31, 2010 and 2009

(Dollars in thousands except per share data)

	2010	2009
NET SALES	\$ 20,048	\$ 22,023
COST OF GOODS SOLD	10,284	10,418
Gross profit	9,764	11,605
OPERATING EXPENSES:		
Selling, general and administrative	10,933	10,319
Research and development	2,305	3,182
Restructuring charges	138	
	13,376	13,501
LOSS FROM OPERATIONS	(3,612)	(1,896)
OTHER INCOME:		
Interest income (expense)	(4)	15
Other, net	632	3
	628	18
LOSS BEFORE INCOME TAXES	(2,984)	(1,878)
INCOME TAX EXPENSE	150	42
NET LOSS	\$ (3,134)	\$ (1,920)
BASIC AND DILUTED LOSS PER SHARE	\$ (0.06)	\$ (0.04)
BASIC AND DILUTED WEIGHTED AVERAGE SHARES OUTSTANDING	49,243,839	49,189,672
	See notes to consolidated financial statements.	

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY****Years Ended December 31, 2010 and 2009****(Dollars in thousands except share data)**

	Common Stock				Accumulated Other Comprehensive Income (Loss)	Total
	Outstanding Shares	Par Value	Additional Paid in Capital	Accumulated Deficit		
Balance, January 1, 2009	49,189,672	\$ 497	\$ 139,501	\$ (128,263)	\$ 1,470	\$ 13,205
Other comprehensive income (loss):						
Net loss				(1,920)	(1,920)	(1,920)
Foreign currency translation adjustment					175	175
Comprehensive loss					(1,745)	
Non-cash stock based compensation			202			202
Balance, December 31, 2009	49,189,672	\$ 497	\$ 139,703	\$ (130,183)	\$ 1,645	\$ 11,662
Other comprehensive income (loss):						
Net loss				(3,134)	(3,134)	(3,134)
Foreign currency translation adjustment					(56)	(56)
Comprehensive loss					(3,190)	
Non-cash stock based compensation			(14)			(14)
Issuance of shares for employee stock options	100,000	1	41			42
Balance, December 31, 2010	49,289,672	\$ 498	\$ 139,730	\$ (133,317)	\$ 1,589	\$ 8,500

See notes to consolidated financial statements.

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

Years Ended December 31, 2010 and 2009

(Dollars in thousands except share data)

	2010	2009
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES:		
Net loss	\$ (3,134)	\$ (1,920)
Adjustments to reconcile net loss to net cash flows provided by (used in) operating activities:		
Depreciation, amortization and disposals	708	852
Non-cash stock based compensation	(14)	202
Changes in operating assets and liabilities, net of effects of acquisition:		
Accounts receivable	72	1,113
Inventories	97	1,290
Prepaid expenses and other current assets	95	(60)
Accounts payable	364	60
Accrued expenses and accrued compensation	92	(401)
Other long term liabilities	(24)	109
Deferred income taxes	26	22
Net cash flows provided by (used) in operating activities	(1,718)	1,267
CASH FLOWS USED IN INVESTING ACTIVITIES:		
Acquisition	(6,000)	
Purchase of property and equipment	(192)	(351)
Change in other assets	(34)	(26)
Net cash flows used in investing activities	(6,226)	(377)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:		
Issuance of preferred stock and related warrants	6,000	
Stock issuance costs	(209)	
Issuance of common stock	42	
Principal payments on capital lease obligations	(72)	
Net cash flows provided by financing activities	5,761	
EFFECT OF FOREIGN CURRENCY EXCHANGE RATE CHANGES ON CASH	(5)	(19)
NET CHANGE IN CASH AND CASH EQUIVALENTS	(2,188)	871
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	5,642	4,771
CASH AND CASH EQUIVALENTS AT END OF YEAR	\$ 3,454	\$ 5,642
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid during the year for:		
Interest	\$ 7	\$
Income taxes	29	163
SUPPLEMENTAL DISCLOSURE OF NON-CASH INFORMATION		
Acquisition of equipment through capital leases	\$ 394	\$

See notes to consolidated financial statements.

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2010 and 2009

A. BUSINESS DESCRIPTION

Business Description.

Transgenomic, Inc. provides innovative products for the purification and analysis of nucleic acids used in the life sciences industry for research focused on molecular genetics and diagnostics. We also provide genetic variation analytical services to the medical research, clinical and pharmaceutical markets. Net sales are categorized as Laboratory Services and Instrument Related Business.

Laboratory Services:

Molecular Clinical Reference Laboratory. The molecular clinical reference laboratory specializes in genetic testing for oncology, hematology and inherited disorders. 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 accredited by CAP (College of American Pathologists).

Pharmacogenomics Research Services. Pharmacogenomics research services are provided by our Contract Research Organization located in Omaha, Nebraska. 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.

Instrument Related Business:

Bioinstruments. Our proprietary product is the WAVE® System which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. There is a worldwide installed base of over 1,500 WAVE Systems as of December 31, 2010. 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.

Bioconsumables. The installed WAVE base and some OEM 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.

Although we have experienced declining sales and recurring net losses (resulting in an accumulated deficit of \$133.3 million at December 31, 2010), management believes existing sources of liquidity, including cash and cash equivalents of \$3.5 million, are sufficient to meet expected cash needs during 2011. Our business consolidation efforts have helped control our operating costs, however we will need to increase net sales in order to meet our liquidity needs on a long-term basis. If

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued

Years Ended December 31, 2010 and 2009

we cannot increase net sales, further reductions to operating expenses will be needed. In future periods, there is no assurance that we will be able to increase net sales or further reduce expenses and, accordingly, we may not have sufficient sources of liquidity to continue operations indefinitely.

B. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation.

The consolidated financial statements include the accounts of Transgenomic, Inc. and its wholly-owned subsidiary. All intercompany 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.

1. 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 financial statements.

2. Concentration of Revenue Risk.

No customer accounted for more than 10% of consolidated net sales during the years ended December 31, 2010 and 2009. For the year ended December 31, 2010 one customer made up 15% of the Laboratory Services net sales. For the year ended December 31, 2009 one customer made up more than 20% of the Laboratory Services net sales.

Fair Value.

Unless otherwise specified, book value approximates fair market value.

Cash and Cash Equivalents.

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

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009***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, 2010.

Accounts Receivable.

The following is a summary of activity for the allowance for doubtful accounts during the years ended December 31, 2010 and 2009:

	Dollars in Thousands			
	Beginning Balance	Provision	Write Offs	Ending Balance
Year Ended December 31, 2010	\$ 310	\$ 28	\$ (4)	\$ 334
Year Ended December 31, 2009	\$ 388	\$ (8)	\$ (70)	\$ 310

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 may be greater than 90 days. Accounts receivable are carried at original invoice 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. Account receivables are written off when deemed uncollectible. Recoveries of account receivables previously written off are recorded when received. Management also evaluates contract terms and history of collections with third party payors. We do not charge interest on past due accounts.

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.

The following is a summary of activity for the allowance for obsolete inventory during the twelve months ended December 31, 2010 and 2009:

	Dollars in Thousands			
	Beginning Balance	Provision	Write Offs	Ending Balance
Year Ended December 31, 2010	\$ 507	\$ 100	\$ (89)	\$ 518
Year Ended December 31, 2009	\$ 108	\$ 482	\$ (83)	\$ 507

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

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009***Property and Equipment.*

Property and equipment are carried at cost less accumulated depreciation. 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 of property and equipment totaled \$0.4 million in the year ended 2010 and \$0.6 million in the year ended 2009. Included in depreciation for the year ended December 31, 2010 is less than \$0.1 million related to capital leases. We did not have any capital leases during 2009.

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 which 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, 2010.

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. **Intangibles.** As a part of the FAMILION acquisition we acquired technology, in process technology, trademarks/tradenames and third party relationships. These costs will be amortized straight line over their estimated economic life of seven to eight years. See Footnote F.

These assets are treated as long-lived assets. Long-lived assets will be tested for impairment on an annual basis or when a significant event occurs, which may impact impairment. We quarterly review the carrying value of our long-lived assets to assess recoverability and impairment. We recorded no impairments during 2010. In 2009 we recorded less than \$0.1 million related to accelerated amortization on two license agreements that we terminated in the first quarter of 2010.

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued

Years Ended December 31, 2010 and 2009

Other Long Term Assets.

Other long term assets include US security deposits and deferred tax assets.

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, 2010 had vesting periods of three years from date of grant. None of the stock options outstanding at December 31, 2010 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).

For the year ended December 31, 2010, we recorded compensation expense recovery of less than \$0.1 million within selling, general and administrative expense. Two executive officers departed during the second quarter of 2010. All stock options that were unvested were forfeited at the time of their departure as their requisite services period was not completed. The vesting of options exercisable for the purchase of 1.3 million shares was offset by the expense recovery for stock options that were forfeited due to the requisite service not being rendered. For the year ended December 31, 2009, we recorded compensation expense of \$0.2 million within selling, general and administrative expense as a result of the vesting of options exercisable for the purchase of 1.7 million shares during the year. As of December 31, 2010, there was \$0.1 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of nearly three years.

The fair value of the options granted during 2010 was estimated on their respective grant dates using the Black-Scholes option pricing model. The Black-Scholes model was used with the following assumptions: risk-free interest rates of 1.17% to 1.98%, based on the U.S. Treasury yield in effect at the time of grant; dividend yields of zero percent; expected lives of 5 years, based on historical exercise activity; and volatility of 103% to 105% for grants made during the year ended December 31, 2010 based on the historical volatility of our stock over a time that is consistent with the expected life of the option. A small group of senior executives hold the majority of the stock options and are expected to hold the options until they are vested. Forfeitures of 2.2% to 2.5% have been assumed in the calculation due to the turnover of senior executives in 2010.

The fair value of the options granted during 2009 was estimated on their respective grant dates using the Black-Scholes option pricing model. The Black-Scholes model was used with the following assumptions: risk-free interest rates of 2.12% to 3.99%, based on the U.S. Treasury yield in effect at the time of grant; dividend yields of zero percent; expected lives of 5 to 10 years, based on historical exercise activity; and volatility of 80.03% to 106.00% for grants made during the year ended December 31, 2009 based on the historical volatility of our stock over a time that is consistent with the expected life of the option. A small group of senior executives held the majority of the stock options and are expected to hold the options until they are vested therefore no forfeitures were assumed in 2009.

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued

Years Ended December 31, 2010 and 2009

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. We had no material unrecognized tax benefits, interest, or penalties during fiscal 2010 or fiscal 2009, 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 on the sales of 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 normal 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 ratably recognized over the service period. Deferred net sales mainly associated with our service contracts, included in the balance sheet in other accrued expenses, was approximately \$1.4 million for each of the years ended December 31, 2010 and 2009.

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

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued

Years Ended December 31, 2010 and 2009

In our Pharmacogenomics Research Services Group, we perform services on a project by project basis. When payment is received in advance, revenue is recognized upon delivery of the service. These projects typically do not extend beyond one year. At December 31, 2010 and 2009, deferred net sales associated with the pharmacogenomics research projects included in the balance sheet in other accrued expenses, was less than \$0.1 million for each 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.

Preferred Stock.

We entered into a Series A Convertible Preferred Stock Purchase Agreement on December 29, 2010, as discussed in Note L, selling shares of preferred stock and issuing warrants to purchase a certain number of shares of Series A Preferred Stock. The Series A Preferred Stock meets the definition of mandatorily redeemable stock as it is preferred capital stock which is redeemable at the option of the holder and should be reported outside of equity. Preferred stock is accreted to its redemption value. The warrants do not qualify to be treated as equity, and accordingly, are recorded as a liability. A preferred stock conversion feature is embedded within the Series A Preferred Stock that meets the definition of a derivative. The preferred stock, warrant liability and preferred stock conversion feature are all recorded separately and were initially recorded at fair value using the Black Scholes model. We are required to record these instruments at fair value at each reporting date and changes will be recorded as an adjustment to earnings. The warrant liability and preferred stock conversion feature are considered level three financial instruments.

Translation of Foreign Currency.

Our foreign subsidiary uses the local currency of the country in which they are located as their functional currency. Its assets and liabilities are translated into U.S. dollars at the exchange rates in effect at the balance sheet date. Cumulative translation losses of less than \$0.1 are reported as accumulated other comprehensive loss on the accompanying consolidated balance sheets for the year ended December 31, 2010. Cumulative translation gains of \$0.2 million were reported as accumulated other comprehensive income for the year ended December 31, 2009. Revenues and expenses are translated at the average rates during the period. For transactions that are not denominated in the functional currency, we recognized net losses of \$0.3 million as foreign currency transaction losses in the determination of net loss for each of the years ending December 31, 2010 and 2009.

Other Income.

Other income consists primarily of interest income from cash and cash equivalents invested in overnight instruments. Other income in the year ended December 31, 2010 includes an award of a

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued

Years Ended December 31, 2010 and 2009

federal grant under the Qualifying Therapeutic Discovery Project related to COLD-PCR, Surveyor Scan kit development for key cancer pathway gene mutations and mtDNA damage assays. Other income related to this federal grant was \$0.6 million net of consulting fees. Other income for the year ended December 31, 2009 was less than \$0.1 million.

Comprehensive Income.

Accumulated other comprehensive income at December 31, 2010 and 2009 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.

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. Options, warrants and conversion rights pertaining to 18,607,229 and 11,309,887 shares of our common stock have been excluded from the computation of diluted earnings per share at December 31, 2010 and 2009, respectively. The options, warrants and conversion rights that were exercisable in 2010 and 2009 were not included because the effect would be anti-dilutive due to the net loss. As a result, none of our outstanding options, warrants or conversion rights affect the calculation of diluted earnings per share.

Recently Issued Accounting Pronouncements.

In October 2009, the FASB issued ASU No. 2009-13, *Revenue Recognition (ASC 605): Multiple-Deliverable Revenue Arrangements (a consensus of the FASB Emerging Issues Task Force)*; effective for years beginning after June 15, 2010. This standard update became effective for us on January 1, 2011. Vendors often provide multiple products and/or services to their customers as part of a single arrangement. These deliverables may be provided at different points in time or over different time periods. The existing guidance regarding how and whether to separate these deliverables and how to allocate the overall arrangement consideration to each was originally captured in EITF Issue 00-21, *Revenue Arrangements with Multiple Deliverables*, which is now codified at ASC 605-25, *Revenue Recognition Multiple-Element Arrangements*. The issuance of ASU 2009-13 amends ASC 605-25 and represents a significant shift from the existing guidance that was considered abuse-preventative and heavily geared toward ensuring that revenue recognition was not accelerated. The application of this new guidance is expected to result in accounting for multiple-deliverable revenue arrangements that better reflects their economics as more arrangements will be separated into individual units of accounting. We are in the final stages of analyzing the impact of ASU 2009-13.

In October 2009, the FASB issued ASU No. 2009-14, *Software (ASC 985): Certain Revenue Arrangements That Include Software Elements (a consensus of the FASB Emerging Issues Task Force)*; effective for years beginning after June 15, 2010. This standard update became effective for us

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued

Years Ended December 31, 2010 and 2009

on January 1, 2011. ASU 2009-14 modifies the existing scope guidance in ASC 985-605, *Software Revenue Recognition*, for revenue arrangements with tangible products that include software elements. This modification was made primarily due to the changes in ASC 605-25 noted previously, which further differentiated the separation and allocation guidance applicable to non-software arrangements as compared to software arrangements. Prior to the modification of ASC 605-25, the separation and allocation guidance for software and non-software arrangements was more similar. Under ASC 985-605, which was originally issued as AICPA Statement of position 97-2, *Software Revenue Recognition*, an arrangement to sell a tangible product along with software was considered to be in its scope if the software was more than incidental to the product as a whole. We are in the final stages of analyzing the impact of ASU 2009-14.

C. ACQUISITION

We acquired the FAMILION family of genetic tests from PGxHealth. PGxHealth is a subsidiary of Clinical Data, Inc. (NasdaqGM:CLDA) with a sales price of \$18.8 million. We secured \$6.0 million of financing from entities affiliated with Third Security, LLC, a leading life sciences investment firm, to fund the cash portion of our acquisition of Clinical Data's diagnostic business. This strategic acquisition provides us with proprietary genetic commercial tests that have an established revenue base, proprietary biomarker assays, an additional CLIA-certified laboratory operation and established test reimbursement and coverage policies that offer access to testing. The acquired assets and liabilities assumed are reported as a component of our laboratory services segment.

Under the terms of the financing with entities affiliated with Third Security, we issued an aggregate of 2,586,205 shares of the Company's newly created Series A convertible preferred stock to certain affiliates of Third Security. Additionally we issued such affiliates of Third Security warrants to purchase an aggregate of up to 1,293,102 shares of Series A preferred stock at an exercise price of \$2.32 per share. The Series A preferred shares issuable pursuant to the purchase agreement and upon exercise of the warrants are convertible into shares of our common stock at a conversion price of \$0.58 per share, for an aggregate of 15,517,228 million shares of common stock. Upon full exercise of the warrants, we will receive approximately \$3.0 million. These securities were issued for an aggregate purchase price of \$6.0 million.

We entered into two notes payable with PGxHealth as a part of the acquisition. The first note is a three year secured promissory note in the amount of \$8.6 million with interest accruing at 10%. The second note is a one year secured promissory note for facility improvements of \$1.0 million with interest payable at 6.5%. See further information in Note G to the financial statements. Certain liabilities were assumed and various contingent liabilities recorded. The contingent liabilities include payments owed upon the collection of certain accounts receivable, retention bonuses for certain employees and royalties due to vendors based on milestone considerations.

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009**

The following table summarizes the consideration paid for the acquired assets and liabilities assumed at the acquisition date.

<u>Consideration</u>	Dollars in Thousands	
Cash	\$	6,000
Notes payable		9,628
Assumed liabilities		452
Contingent liabilities		2,736
Fair value of consideration transferred	\$	18,816

Acquisition related costs included in selling, general and administrative expenses in our Statement of Operations for the year ended December 31, 2010 were \$0.8 million. We incurred \$0.2 million in acquisition related costs to issue preferred stock which were recorded against the proceeds received upon the issuance of such preferred stock.

<u>Recognized Amounts of Identifiable Assets Acquired and Liabilities Assumed</u>	Dollars in Thousands	
Working capital, net	\$	3,222
Property and Equipment		639
Identifiable intangible assets		8,680
Total identifiable net assets		12,541
Goodwill		6,275
Total purchase price		18,816

The fair value of the financial assets acquired includes accounts receivable with a fair value of \$3.1 million. The gross amount due is \$7.0 million, of which \$3.9 million is expected to be uncollectible.

The goodwill arising from the acquisition primarily relates to synergies of the combined companies. The goodwill has been assigned to our Laboratory Services segment and is expected to be deductible for tax purposes.

The fair value of the preferred stock and related securities issued as a part of the consideration paid was determined on the basis of the closing market price of our common stock on the acquisition date, December 29, 2010.

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009**

The following table sets forth the pro forma revenue and earnings of the combined entity if the acquisition had occurred as of the beginning of our prior fiscal year. No revenue or net income was included in our actual results for the year ended December 31, 2010 or 2009. These pro forma amounts do not purport to be indicative of the actual results that would have been obtained had the acquisition occurred at that time.

	Dollars in Thousands	
	Year Ended December 31, 2010	2009
Revenue Supplemental pro forma results	\$ 33,733	\$ 35,112
Net loss Supplemental pro forma results	(7,716)	(13,071)
D. RESTRUCTURING CHARGES		

In the third quarter of 2010 we made a decision to consolidate our research and development activities in Omaha, Nebraska. We substantially completed the transition at December 31, 2010. We have recognized expenses for restructuring, including but not limited to, severance, facility costs and costs to move equipment from Gaithersburg, Maryland to Omaha, Nebraska. These restructuring charges are attributable to our lab services and instrument segments.

Restructuring charges include:

	Dollars in Thousands		
	Costs Incurred in the Three Months Ended December 31, 2010	Cumulative Costs Incurred at December 31, 2010	Total Expected Costs
Severance and related costs	\$ 12	\$ 53	\$ 53
Facility closure costs	22	45	63
Other	32	40	66
Restructuring charges	\$ 66	\$ 138	\$ 182

In the fourth quarter of 2010 we had a reduction in workforce of five employees with severance payments of less than \$0.1 million which was attributable to our instrument segment.

E. INVENTORIES

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

	Dollars in Thousands	
	December 31, 2010	December 31, 2009

Edgar Filing: TRANSGENOMIC INC - Form 10-K

Finished goods	\$ 2,119	\$ 2,322
Raw materials and work in process	1,531	1,588
Demonstration inventory	212	149
	\$ 3,862	\$ 4,059
Less allowance for obsolescence	(518)	(507)
Total	\$ 3,344	\$ 3,552

K-43

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009****F. INTANGIBLES AND OTHER ASSETS**

Finite lived intangible assets and other assets consisted of the following:

	Dollars in Thousands					
	December 31, 2010			December 31, 2009		
	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Intellectual property	\$ 290	\$ 274	\$ 16	\$ 310	\$ 284	\$ 26
Patents	511	245	266	598	241	357
Intangibles acquired technology	6,535		6,535			
Intangibles third party payor relationships	367		367			
Intangibles assay royalties	1,434		1,434			
Intangibles tradenames and trademarks	344		344			
	9,481	519	8,962	908	525	383
Other assets	154		154	200		200
Total	\$ 9,635	\$ 519	\$ 9,116	\$ 1,108	\$ 525	\$ 583

	Estimated Useful Life
Intellectual property	10 years
Patents	7 years
Intangibles acquired technology	7 - 8 years
Intangibles third party payor relationships	N/A
Intangibles assay royalties	7 years
Intangibles tradenames and trademarks	7 years

During 2009 we accelerated amortization on two intellectual property license agreements that we terminated in the first quarter of 2010. In addition we accelerated amortization on another license agreement, however; we are not terminating that agreement. In total the change to the net book value of intellectual property was less than \$0.1 million. We wrote off less than \$0.1 million in patents that we are no longer using.

Other assets include US security deposits and deferred tax assets.

Amortization expense for intangible assets was less than \$0.1 million during both years ended December 31, 2010 and 2009. Amortization expense for intangible assets is expected to be \$1.2 million in each of years 2011 through 2017.

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009****G. DEBT**

	Dollars in Thousands	
	Year Ended December 31,	
	2010	2009
PGxHealth note payable ⁽¹⁾	\$ 8,640	\$
PGxHealth note payable ⁽²⁾	989	
	\$ 9,629	\$

(1) The First Note is a three year senior secured promissory note to PGxHealth, LLC entered into on December 29, 2010 in conjunction with our acquisition of the FAMILION family of genetic tests from PGxHealth. Interest is payable at 10% per year with quarterly interest payments through March 29, 2012. Thereafter, quarterly installments will include both principal and interest through December 30, 2013.

(2) The Second Note is a one year senior secured promissory note to PGxHealth, LLC entered into on December 31, 2010 for facility improvements made to the CLIA certified laboratory in New Haven, Connecticut. Interest is payable at 6.5% per year with the principal and interest payable in twelve monthly installments with the final payment due on December 31, 2011.

The entire unpaid balance of the Notes will become immediately due and payable if: (i) we fail to make timely payments under the Notes; (ii) we make an assignment for the benefit of creditors; (iii) we file for bankruptcy; or (iv) upon any event of default under the Security Agreement. Additionally, under the terms of the First Note, if we consummate an equity financing that involves the receipt by us of net proceeds of not less than \$6,000,000, then we shall, upon the consummation of such equity financing, pay to PGxHealth the lesser of: (i) 25% of the gross proceeds received from such financing; and (ii) the then-outstanding balance under the First Note. Under the terms of the Second Note, in the event of a sale of all or substantially all of the assets of the Company, we shall pay PGxHealth the lesser of: (i) 100% of the proceeds, less certain fees, received pursuant to such sale; and (ii) the then-outstanding balance under the Second Note.

The notes are secured by the assets of Transgenomic.

The aggregate minimum principal maturities of the debt for each of the three fiscal years following December 31, 2010 are as follows:

2011	\$ 989
2012	3,703
2013	4,937
	\$ 9,629

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009****H. CAPITAL LEASES**

The following is an analysis of the leased property under capital leases.

<u>Classes of Property</u>	Dollars in Thousands	
	Asset Balances at December 31	
	2010	2009
Equipment	\$ 394	\$
Less: Accumulated amortization	13	
Total	\$ 381	\$

The following is a schedule by years of future minimum lease payments under capital leases together with the present value of the net minimum lease payments as of December 31, 2010.

Year ending December 31:

	Dollars in Thousands	
2011	\$	190
2012		92
2013		76
Total minimum lease payments	\$	358
Less: Amount representing interest		(32)
Present value of net minimum lease payments	\$	326

I. COMMITMENTS AND CONTINGENCIES

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

We lease certain equipment, vehicles and operating facilities under non-cancellable operating leases that expire on various dates through 2016. The future minimum lease payments required under these leases are approximately \$1.2 million in 2011, \$0.8 million in 2012, \$0.2 million in 2013, \$0.1 million in 2014, \$0.1 million in 2015 and less than \$0.1 million in 2016. Rent expense for each of the years ended December 31, 2010 and 2009 was \$0.8 million.

We have entered into an employment agreement with Craig J. Tuttle, our President and Chief Executive Officer. The current term of Mr. Tuttle's employment agreement ends on July 12, 2011. The employment agreement provides that Mr. Tuttle will be entitled to receive severance payment from the Company if his employment is terminated involuntarily except if such termination is based on just cause, as that term is defined in his employment agreement. The severance payment payable in the event of involuntary termination without just cause is equal to his annual base salary at the time of termination and will be paid over a twelve-month period. The employment agreement provides that the

severance payment provision will be honored if the Company is acquired by, or merged into, another

K-46

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009**

company and his position is eliminated as a result of such acquisition or merger. In addition we have one employee who is entitled to a severance payment of less than \$0.1 million if the employee's position is eliminated prior to July 2012.

At December 31, 2010, firm commitments to vendors to purchase components used in WAVE Systems and instruments manufactured by others totaled \$0.1 million.

J. INCOME TAXES

The Company's provision for income taxes for the years ended December 31, 2010 and 2009 relates to income taxes in states, foreign countries and other local jurisdictions and differs from the amounts determined by applying the statutory Federal income tax rate to loss before income taxes for the following reasons:

	Dollars in Thousands	
	2010	2009
Benefit at federal rate	\$ (1,015)	\$ (639)
Increase (decrease) resulting from:		
State income taxes net of federal benefit	20	(10)
Foreign subsidiary tax rate difference	(27)	(50)
Tax contingency	45	48
Net operating loss expiration		1,258
Earnings repatriation	1,479	
Miscellaneous permanent differences	60	93
Other net	86	(33)
Valuation allowance	(498)	(625)
Current income tax expense	\$ 150	\$ 42

	Dollars in Thousands	
	2010	2009
Federal:		
Current	\$ 4	\$ (58)
Deferred		
Total Federal	\$ 3	\$ (58)
State:		
Current	\$ 29	\$ (16)
Deferred		
Total State	\$ 29	\$ (16)
Foreign:		
Current	\$ 111	\$ (60)
Deferred	6	176

Edgar Filing: TRANSGENOMIC INC - Form 10-K

Total Foreign	\$ 117	\$ 116
Total Tax Provision	\$ 150	\$ 42

K-47

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009**

The Company's deferred income tax asset from continuing and discontinued operations at December 31, 2010 and 2009 is comprised of the following temporary differences:

	Dollars in Thousands	
	2010	2009
Deferred Tax Asset:		
Net operating loss carryforward	\$ 38,201	\$ 38,688
Research and development credit carryforwards	1,232	1,355
Deferred net sales	151	194
Inventory	188	186
Other	473	350
	40,245	40,773
Less valuation allowance	(40,141)	(40,639)
Deferred Tax Asset	\$ 104	\$ 134
Deferred Tax Liability:		
Uninstalled instruments	\$ 159	\$ 183
Deferred Tax Liability	\$ 159	\$ 183
Net Deferred Liability	\$ (55)	\$ (49)

At December 31, 2010, we had total unused federal tax net operating loss carryforwards from continuing and discontinued operations of \$104.3 million of which \$2.8 million expires in 2012, \$1.8 million expires in 2018, \$8.2 million expires in 2019, \$9.7 million expires in 2020, \$8.2 million expires in 2021, \$16.9 million expires in 2022, \$16.2 million expires in 2023, \$17.4 million expires in 2024, \$8.2 million expires in 2025, \$6.8 million expires in 2026, \$3.2 million expires in 2027, \$1.3 million expires in 2028, \$2.1 million expires in 2029, and \$1.5 million expires in 2030. Of these federal net operating loss carryforwards, \$6.4 million were obtained in the acquisition of Annovis, Inc. and may be subject to certain restrictions. At December 31, 2010, we had unused state tax net operating loss carryforwards from continuing and discontinued operations of approximately \$36.0 million that expire at various times beginning in 2011. At December 31, 2010, we had unused research and development credit carryforwards from continuing and discontinued operations of \$1.2 million that expire at various times between 2011 and 2024. A net deferred tax liability was recorded during 2010 related to the UK income taxes for \$0.1 million. A valuation allowance has been provided for the remaining deferred tax assets, due to the cumulative losses in recent years and an inability to utilize any additional losses as carrybacks. We will continue to assess the recoverability of deferred tax assets and the related valuation allowance. To the extent we begin to generate income in future years and it is determined that such valuation allowance is no longer required, the tax benefit of the remaining deferred tax assets will be recognized at such time.

We had no material unrecognized tax benefits, interest, or penalties during fiscal 2009 or 2008, 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. We file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009**

and various foreign jurisdictions. We have statutes of limitation open for Federal income tax returns related to tax years 2007, 2008 and 2009. We have state income tax returns subject to examination primarily for tax years 2006 through 2009. Open tax years related to foreign jurisdictions remain subject to examination. Our primary foreign jurisdiction is the United Kingdom which has open tax years for 2006 through 2009.

During the years ended December 31, 2010 and 2009, there were no material changes to the liability for uncertain tax positions. The liability for uncertain tax positions relates to potential uncertain tax positions in foreign jurisdictions.

K. EMPLOYEE BENEFIT PLAN

We maintain an employee 401(k) retirement savings plan that allows for voluntary contributions into designated investment funds by eligible employees. Prior to October 1, 2010 we matched the employee's contributions at the rate of 50% on the first 6% of contributions. Effective October 1, 2010, Transgenomic discontinued matching employee 401(k) contributions. We may, at the discretion of our Board of Directors, make additional contributions on behalf of the Plan's participants. Contributions to the 401(k) plan were \$0.1 million for the year ended December 31, 2010. Contributions to the 401(k) plan were less than \$0.1 million for the year ended December 31, 2009.

L. STOCKHOLDERS EQUITY*Common Stock.*

The Company's Board of Directors is authorized to issue up to 100,000,000 shares of common stock, from time to time, as provided in a resolution or resolutions adopted by the Board of Directors.

Common Stock Warrants.

Warrants covering 5,172,408 shares of common stock were issued during 2010. No common stock warrants were exercised during 2010. No common stock warrants were issued or exercised during 2009. At December 31, 2010, there were warrants outstanding that were exercisable to purchase 5,697,408 shares of common stock.

Warrant Holder	Issue Year	Expiration Year	Underlying Shares	Exercise Price
Laurus Master Fund, Ltd. ⁽¹⁾	2004	2011	125,000	\$ 2.39
Laurus Master Fund, Ltd. ⁽¹⁾	2004	2011	400,000	\$ 1.13
Affiliates of Third Security, LLC ⁽²⁾	2010	2015	5,172,408	\$.58
Total			5,697,408	

- (1) These warrants were issued in conjunction with two loans that had been made to us by Laurus Master Fund, Ltd. (the Laurus Loans), and subsequent modifications of these loans. In conjunction with the 2005 private placement, the exercise prices of these warrants were adjusted according to repricing provisions contained in the original warrant agreements.

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued

Years Ended December 31, 2010 and 2009

While the Laurus Loans have been terminated, the warrants remain outstanding. Due to the repricing provision, these warrants are considered liabilities for financial reporting purposes.

- (2) These warrants were issued in conjunction with the Series A stock financing with certain entities affiliated with Third Security. The number of shares shown reflects the post conversion shares.

Preferred Stock.

The Company's Board of Directors is authorized to issue up to 15,000,000 shares of preferred stock in one or more series, from time to time, with such designations, powers, preferences and rights and such qualifications, limitations and restrictions as may be provided in a resolution or resolutions adopted by the Board of Directors. The authority of the Board of Directors includes, but is not limited to, the determination or fixing of the following with respect to shares of such class or any series thereof: (i) the number of shares; (ii) the dividend rate, whether dividends shall be cumulative and, if so, from which date; (iii) whether shares are to be redeemable and, if so, the terms and amount of any sinking fund providing for the purchase or redemption of such shares; (iv) whether shares shall be convertible and, if so, the terms and provisions thereof; (v) what restrictions are to apply, if any, on the issue or reissue of any additional preferred stock; and (vi) whether shares have voting rights. The preferred stock may be issued with a preference over the common stock as to the payment of dividends. Classes of stock such as the preferred stock may be used, in certain circumstances, to create voting impediments on extraordinary corporate transactions or to frustrate persons seeking to effect a merger or otherwise to gain control of the Company. For the foregoing reasons, any preferred stock issued by the Company could have an adverse effect on the rights of the holders of the common stock.

On December 29, 2010, we entered into a Series A Convertible Preferred Stock Purchase Agreement with Third Security pursuant to which we: (i) sold an aggregate of 2,586,205 shares of Series A Convertible Preferred Stock; and (ii) issued warrants to purchase up to an aggregate of 1,293,102 shares of Series A Preferred Stock with an exercise price of \$2.32 per share. The 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 Stock issuable pursuant to the Series A Purchase Agreement and upon exercise of the Warrants are initially convertible into shares of our 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. The aggregate gross proceeds from the issuance was \$6.0 million.

The Series A Preferred Stock meets the definition of mandatorily redeemable stock as it is preferred capital stock which is redeemable at the option of the holder and should be reported outside of equity. Preferred stock is accreted to its redemption value. The warrants do not qualify to be treated as equity, and accordingly, are recorded as a liability. A preferred stock conversion feature is embedded within the Series A Preferred Stock that meets the definition of a derivative. The preferred stock, warrant liability and preferred stock conversion feature are all recorded separately and were initially recorded at fair value using the Black Scholes model. We are required to record these instruments at fair value at each reporting date and changes will be recorded as an adjustment to earnings. The warrant liability and preferred liability are considered level three financial instruments.

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009**

The analysis produced a valuation for the three components of the instrument:

Redeemable Preferred Stock	\$ 1,666
Preferred Stock Conversion Feature	1,983
Warrants	2,351
	\$ 6,000

The costs to secure the Preferred Stock were taken against the preferred stock. For the year ended December 31, 2010 these costs were \$0.2 million.

We used the net proceeds from the financing to acquire the FAMILION family of genetic tests from PGxHealth, a subsidiary of Clinical Data.

In connection with the Financing, we filed a Certificate of Designation of Series A Convertible Preferred Stock with the Secretary of State of the State of Delaware, designating 3,879,307 shares of our Preferred Stock as Series A Preferred Stock. Certain rights of the holders of the Series A Preferred Stock are senior to the rights of the holders of Common Stock. The Series A Preferred Stock has a liquidation preference equal to its original price per share, plus any accrued and unpaid dividends thereon. The Series A Preferred Stock accrues cumulative dividends at the rate of 10.0% of the original price per share per annum.

Generally, the holders of the Series A Preferred Stock are entitled to vote together as a single group with the holders of Common Stock on an as-converted basis. However, the Certificate of Designation provides that we shall not perform some activities, subject to certain exceptions, without the affirmative vote of a majority of the holders of the outstanding shares of Series A Preferred Stock.

In connection with the Financing, we also entered into a registration rights agreement with the Investors (the Registration Rights Agreement). Pursuant to the terms of the Registration Rights Agreement, the Company has granted the Investors certain demand, piggyback and S-3 registration rights covering the resale of the shares of Common Stock underlying the Series A Preferred Stock issued pursuant to the Series A Purchase Agreement and issuable upon exercise of the Warrants and all shares of Common Stock issuable upon any dividend or other distribution with respect thereto. The holders of the Series A Preferred Stock are entitled to receive quarterly dividends which will accrue whether or not declared, shall compound annually and shall be cumulative. In any calendar quarter we shall be required to pay from funds legally available a cash dividend in the amount of 50% of the distributable cash flow or aggregate amount of dividends accrued on the Series A Preferred Stock.

M. EQUITY INCENTIVE PLAN

The Company's 2006 Equity Incentive Plan (the Plan) allows the Company to make awards of various types of equity-based compensation, including stock options, dividend equivalent rights (DERs), stock appreciation rights (SARs), restricted stock, restricted stock units, performance units, performance shares and other awards, to employees and directors of the Company. The Plan was adopted in 2006 as a modification of the Company's 1997 Stock Option Plan (the Prior Plan). In addition to providing for additional types of equity-based awards, the Plan increased the total number

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued

Years Ended December 31, 2010 and 2009

of shares of common stock that the Company may issue from 7,000,000 under the Prior Plan to 10,000,000 shares under the Plan; provided, that no more than 5,000,000 of such shares may be used for grants of restricted stock, restricted stock units, performance units, performance shares and other awards.

The Plan is administered by the Compensation Committee of the Board of Directors (the Committee) which has the authority to set the number, exercise price, term and vesting provisions of the awards granted under the Plan, subject to the terms thereof. Either incentive or non-qualified stock options may be granted to employees of the Company, but only nonqualified stock options may be granted to nonemployee directors and advisors. However, in either case, the Plan requires that stock options must be granted at exercise prices not less than the fair market value of the common stock on the date of the grant. Options issued under the plan vest over periods as determined by the Compensation Committee and expire 10 years after the date the option was granted. To date, the only awards made under the Plan (and the Prior Plan) have been non-incentive stock options.

For the year ended December 31, 2010, we recorded compensation expense recovery of less than \$0.1 million within selling, general and administrative expense. Two executive officers departed during the second quarter of 2010. All stock options that were unvested were forfeited at the time of their departure as their requisite services periods were not completed. The vesting of options exercisable for the purchase of 1.3 million shares was offset by the expense recovery for stock options that were forfeited due to the requisite service not being rendered. For the year ended December 31, 2009, we recorded compensation expense of \$0.2 million within selling, general and administrative expense as a result of the vesting of options exercisable for the purchase of 1.7 million shares. As of December 31, 2010, there was less than \$0.1 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of nearly three years.

The fair value of the options granted during 2010 was estimated on their respective grant dates using the Black-Scholes option-pricing model. The Black-Scholes model was used with the following assumptions: risk-free interest rates of 1.17% to 1.98%, based on the U.S. Treasury yield in effect at the time of grant; dividend yields of zero percent; expected lives of five years, based on historical exercise activity; and volatility of 103% to 105% for grants made during the year ended December 31, 2010 based on the historical volatility of our stock over a time that is consistent with the expected life of the option. A small group of senior executives hold the majority of the stock options and are expected to hold the options until they are vested. Forfeitures of 2.2% to 2.5% have been assumed in the calculation.

The fair value of the options granted during 2009 was estimated on their respective grant dates using the Black-Scholes option pricing model. The Black-Scholes model was used with the following assumptions: risk-free interest rates of 2.12% to 3.99%, based on the U.S. Treasury yield in effect at the time of grant; dividend yields of zero percent; expected lives of 5 to 10 years, based on historical exercise activity; and volatility of 106.08% to 80.03% for grants made during the year ended December 31, 2009 based on the historical volatility of our stock over a time that is consistent with the expected life of the option. A small group of senior executives hold the majority of the stock options and are expected to hold the options until they are vested therefore minimal forfeitures were assumed in 2009.

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009**

The following table summarizes activity under the Plan (and the Prior Plan) during the year ended December 31, 2010:

	Number of Options	Weighted Average Exercise Price
Balance at January 1, 2010:	3,331,731	\$ 2.39
Granted	125,000	.50
Exercised	(100,000)	(.42)
Forfeited	(593,499)	(.73)
Expired	(198,231)	(11.07)
Balance at December 31, 2010:	2,565,001	\$ 2.08
Exercisable at December 31, 2010	2,358,334	\$ 2.22

The following table summarizes activity under the Plan (and the Prior Plan) during the year ended December 31, 2009:

	Number of Options	Weighted Average Exercise Price
Balance at January 1, 2009:	3,531,064	\$ 2.54
Granted	70,000	.42
Exercised		
Forfeited	(72,833)	(1.39)
Expired	(196,500)	(4.85)
Balance at December 31, 2009:	3,331,731	\$ 2.39
Exercisable at December 31, 2009	2,518,671	\$ 2.96

The following table summarizes the stock options that were issued during the year ended December 31, 2010:

	Number of Options	Exercise Price
June 7, 2010	75,000	\$ 0.58
October 29, 2010	50,000	\$ 0.39
	125,000	

The weighted average grant date fair value per share of options granted during the years ended December 31, 2010 and 2009 was \$0.38 and \$0.33 respectively.

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009**

The following summarizes all stock options outstanding at December 31, 2010:

Exercise Price Range	Number of Options Outstanding	Remaining Weighted-Average Contractual Life	Weighted Average Exercise Price	Number of Options Exercisable
\$ 0.00 \$ 1.30	1,755,668	5.8 years	\$ 0.80	1,549,001
\$ 1.31 \$ 2.60	308,333	1.9 years	\$ 1.94	308,333
\$ 2.61 \$ 3.90	10,000	0.0 years	\$ 2.90	10,000
\$ 5.21 \$ 6.50	401,500	.4 years	\$ 6.07	401,500
\$ 7.81 \$ 9.10	10,000	.4 years	\$ 9.00	10,000
\$ 9.11 \$10.00	79,500	.5 years	\$ 9.90	79,500
	2,565,001			2,358,334

All stock options outstanding were issued to employees or outside directors.

The aggregate intrinsic value of stock options exercisable was less than \$0.1 million at December 31, 2010. The aggregate intrinsic value of stock options outstanding was less than \$0.1 million at December 31, 2010. During the year ended December 31, 2010, 100,000 stock options were exercised. No stock options were exercised in the year ended December 31, 2009.

N. OPERATING SEGMENT AND GEOGRAPHIC INFORMATION

Our chief decision-maker is the Chief Executive Officer, who regularly evaluates our performance based on net sales and gross profit. The preparation of this segment analysis required management to make estimates and assumptions around expense below the gross profit level. While we believe the segment information to be directionally correct, actual results could differ from the estimates and assumptions used in preparing this information.

The accounting policies of the segments are the same as the policies discussed in Footnote B Summary of Significant Accounting Policies.

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009**

Segment information for the years ended December 31, 2010 and 2009 is as follows:

	Dollars in Thousands					
	2010			2009		
	Lab Services	Instrument Business	Total	Lab Services	Instrument Business	Total
Net Sales	\$ 4,979	\$ 15,069	\$ 20,048	\$ 4,566	\$ 17,457	\$ 22,023
Gross Profit	1,438	8,326	9,764	1,728	9,877	11,605
Net Income/(Loss) before Taxes	(2,526)	(459)	(2,984)	(2,273)	395	(1,878)
Income Taxes		150	150		42	42
Net Income/(Loss)	\$ (2,526)	\$ (608)	\$ (3,134)	\$ (2,273)	\$ 353	\$ (1,920)
Depreciation/Amortization	304	190	495	296	450	746
Restructure	65	73	138			
Interest Income (Expense)	(1)	(3)	(4)	4	11	15
Net Assets	\$ 24,631	\$ 7,396	\$ 32,027	\$ 7,457	\$ 8,547	\$ 16,004

We have two reportable operating segments. Net sales by product were as follows:

	Dollars in Thousands	
	Years Ended December 31, 2010	2009
Laboratory Services:		
Molecular Clinical Reference Laboratory	\$ 3,606	\$ 3,541
Pharmacogenomics Research Services	1,373	1,025
	4,979	4,566
Instrument Related Business:		
Bioinstruments	8,320	10,175
Bioconsumables	6,749	7,282
	15,069	17,457
Total Net Sales	\$ 20,048	\$ 22,023

Table of Contents**TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - Continued****Years Ended December 31, 2010 and 2009**

Net cost of goods sold were as follows:

	Dollars in Thousands	
	Years Ended December 31,	
	2010	2009
Laboratory Services:		
Molecular Clinical Reference Laboratory	\$ 2,125	\$ 2,018
Pharmacogenomics Research Services	1,416	820
	3,541	2,838
Instrument Related Business:		
Bioinstruments	3,560	3,801
Bioconsumables	3,183	3,779
	6,743	7,580
Total Cost of Goods Sold	\$ 10,284	\$ 10,418

Net sales for the year ended December 31, 2010 and 2009 by country were as follows:

	Dollars in Thousands	
	Years Ended December 31,	
	2010	2009
United States	\$ 8,729	\$ 8,777
Italy	3,294	3,683
United Kingdom	1,412	842
Germany	1,366	1,383
France	1,160	1,545
Netherlands	56	1,464
All Other Countries	4,031	4,329
Total	\$ 20,048	\$ 22,023

No other country accounted for more than 5% of total net sales.

No customer accounted for more than 10% of consolidated net sales during the years ended December 31, 2010 and 2009. For the year ended December 31, 2010 one customer made up 15% of the Laboratory Services net sales. For the year ended December 31, 2009 one customer made up 20% of the Laboratory Services net sales.

More than 95% of our long-lived assets are within the United States. Substantially all of the remaining long-lived assets are within Europe.

O. SUBSEQUENT EVENTS

Edgar Filing: TRANSGENOMIC INC - Form 10-K

Events or transactions that occur after the balance sheet date, but before the financial statements are complete, are reviewed to determine if they should be recognized. On February 19, 2011, 125,000 common stock warrants to Laurus Fund, Ltd expired unexercised. We have no other material subsequent events to be disclosed.

K-56

Table of Contents

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures.

None.

Item 9A. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report, management performed, with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the report we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's forms, and that such information is accumulated and communicated to management including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosures. Based on the evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2010, Transgenomic's disclosure controls and procedures were effective.

(b) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting. Our system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Our internal control over financial reporting includes those policies and procedures that:

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;

provide reasonable assurance that our transactions are recorded as necessary to permit preparation of our financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Further, because of changes in conditions, effectiveness of internal controls over financial reporting may vary over time. Our system contains self-monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

Table of Contents

Management has conducted, with the participation of our Chief Executive Officer and our Chief Financial Officer, an assessment, including testing of the effectiveness of our internal control over financial reporting as of December 31, 2010. Management's assessment of internal control over financial reporting was conducted using the criteria in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2010.

This Annual Report does not include an attestation report of Transgenomic's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to Item 308(b) of Regulation S-K which permits the Company to provide only management's report in this Annual Report.

(c) *Changes in internal control over financial reporting*

There have been no changes in internal control over financial reporting that occurred during the quarter ended December 31, 2010 that have materially affected, or are reasonably likely to materially affect, Transgenomic's internal control over financial reporting.

Item 9B. Other Information.

None.

Table of Contents**Part III****Item 10. Directors, Executive Officers and Corporate Governance.**

Information relating to our Board of Directors, including information regarding Craig Tuttle, our President and Chief Executive Officer who is also a director, and other information related to corporate governance, required by this item is incorporated by reference to the Proxy Statement for the Company's 2011 Annual Meeting of Stockholders (the "Proxy Statement") under the caption "Board of Directors and Committees." Information regarding our other executive officers who are not directors is set forth below.

Chad Richards. Mr. Richards, age 41, joined Transgenomic in October 2007 as Senior Vice President, Sales and Marketing and was promoted to Chief Commercial Officer in January 2011. Before joining Transgenomic, 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.

Brett Frevert. Mr. Frevert, age 48, was appointed as the Chief Financial Officer of Transgenomic by the Board of Directors on June 28, 2010. Since 2004 Mr. Frevert has been Managing Director of CFO Systems, LLC, which he founded in 2004. During that time he has served as CFO of several Midwestern companies, including SEC registrants and private companies. Prior to founding CFO Systems, Mr. Frevert was CFO of a regional real estate firm and also served as Interim CFO of First Data Europe. Mr. Frevert began his career with Deloitte & Touche, serving primarily SEC clients in the food and insurance industries.

Item 11. Executive Compensation.

Certain information required by this Item is incorporated by reference to the Proxy Statement under the caption "Executive Compensation."

Securities authorized for issuance under equity compensation plans.

The following equity compensation plan information summarizes plans and securities approved and not approved by security holders as of December 31, 2010.

PLAN CATEGORY	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders ⁽¹⁾	2,565,001	\$ 2.08	6,581,230
Equity compensation plans not approved by security holders			
Total	2,565,001	\$ 2.08	6,581,230

(1) Consists of our 2006 Equity Compensation Plan

Table of Contents

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this Item is incorporated by reference to the Proxy Statement under the caption Voting Securities and Beneficial Ownership by Principal Stockholders and our Directors and Officers.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this Item is incorporated by reference to the Proxy Statement under the captions Certain Relationships and Related Transactions and Board of Directors and Committees .

Item 14. Principal Accounting Fees and Services.

Information required by this Item is incorporated by reference to the Proxy Statement under the caption Accounting Fees and Services.

Part IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

1. Financial Statements. The following financial statements of the Registrant are included in response to Item 8 of this report: Report of Independent Registered Public Accounting Firm.

Consolidated Balance Sheets of the Registrant and Subsidiary as of December 31, 2010 and 2009.

Consolidated Statements of Operations of the Registrant and Subsidiary for the years ended December 31, 2010 and 2009.

Consolidated Statements of Stockholders' Equity of the Registrant and Subsidiary for the years ended December 31, 2010 and 2009.

Consolidated Statements of Cash Flows of the Registrant and Subsidiary for the years ended December 31, 2010 and 2009.

Notes to Consolidated Financial Statements of the Registrant and Subsidiary.

2. Financial Statement Schedules.

None.

K-60

Table of Contents

3. Exhibits. The following exhibits were filed as required by Item 15(a)(3) of this report. Exhibit numbers refer to the paragraph numbers under Item 601 of Regulation S-K:
- 3.1 Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to Registrant's Report on Form 10-Q (Registration No. 000-30975) filed on November 14, 2005).
- 3.2 Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to Registration Statement on Form S-1 (Registration No. 333-32174) filed on March 10, 2000).
4. Form of Certificate of the Registrant's Common Stock (incorporated by reference to Exhibit 4 to Registration Statement on Form S-1 (Registration No. 333-32174) filed on March 10, 2000).
- 10.1 2006 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 4(b) to Registration on Form S-8 (Registration No. 333-139999) filed on January 16, 2007).
- 10.2 1999 UK Approved Stock Option Sub Plan of the Registrant (incorporated by reference to Exhibit 10.7 to Registration Statement on Form S-1 (Registration No. 333-32174) filed on March 10, 2000).
- 10.3 Employment Agreement between the Company and Craig J. Tuttle dated July 12, 2006 (incorporated by reference to Exhibit 10.1 to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on July 12, 2006).
- 10.4 Amendment No. 1 to the Employment Agreement between the Company and Craig J. Tuttle, effective July 12, 2006 (incorporated by reference to Exhibit 10.1 to Registrant's Report on Form 10-Q (Registration No. 000-30975) filed on November 14, 2006).
- 10.5 Employment Agreement between the Company and Debra A. Schneider, effective December 4, 2006, (incorporated by reference to Exhibit 10.1 to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on November 15, 2006).
- 10.6 License Agreement, dated September 1, 1994, between Registrant and Professor Dr. Gunther Bonn, et. al. and Amendment thereto, dated March 14, 1997 (incorporated by reference to Exhibit 10.14 to Registration Statement on Form S-1 (Registration No. 333-32174) filed on March 10, 2000).
- 10.7 License Agreement, dated August 20, 1997, between the Registrant and Leland Stanford Junior University (incorporated by reference to Exhibit 10.15 to Registration Statement on Form S-1 (Registration No. 333-32174) filed on March 10, 2000).
- 10.8 License Agreement, dated December 1, 1989, between Cruachem Holdings Limited (a wholly owned subsidiary of the Registrant) and Millipore Corporation (incorporated by reference to Exhibit 10.13 to Registrant's Annual Report on Form 10-K filed on March 25, 2002).

Table of Contents

10.9 Sublicense Agreement, dated October 1, 1991, between Cruachem Holdings Limited (a wholly owned subsidiary of the Registrant) and Applied Biosystems, Inc. (incorporated by reference to Exhibit 10.14 to Registrant's Annual Report on Form 10-K filed on March 25, 2002).

10.10 Missives, dated May 17, 2002, between Cruachem Limited (a wholly-owned subsidiary of the Registrant) and Robinson Nugent (Scotland) Limited (incorporated by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q filed on August 14, 2002).

10.11 License Amendment Agreement, dated June 2, 2003, by and between Geron Corporation and the Registrant (incorporated by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q filed on August 12, 2003).

10.12 Supply Agreement, dated January 1, 2000, between the Registrant and Hitachi Instruments (incorporated by reference to Exhibit 10.16 to Registration Statement on Form S-1 (Registration No. 333-32174) filed on March 10, 2000).

10.13 Common Stock Purchase Warrant by and between the Registrant and Laurus Master Fund, Ltd., dated December 3, 2003 (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-3 of the Registrant (Registration No. 333-111442) filed on December 22, 2003).

10.14 Registration Rights Agreement by and between the Registrant and Laurus Master Fund, Ltd., dated December 3, 2003 (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-3 of the Registrant (Registration No. 333-111442) filed on December 22, 2003).

10.15 Securities Purchase Agreement by and between the Registrant and Laurus Master Fund, Ltd., dated February 19, 2004, as amended on April 15, 2004 (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-3 of the Registrant (Registration No. 333-114661) filed on April 21, 2004).

10.16 Amendment to Securities Purchase Agreement and Related Document by and between the Registrant and Laurus Master Fund, Ltd., dated August 31, 2004 (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-3 (Registration No. 333-118970) as filed on September 14, 2004).

10.17 Common Stock Purchase Warrant by and between the Registrant and Laurus Master Fund, Ltd., dated February 19, 2004, as amended on April 15, 2004 (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-3 of the Registrant (Registration No. 333-114661) filed on April 21, 2004).

10.18 Registration Rights Agreement by and between the Registrant and Laurus Master Fund, Ltd., dated February 19, 2004 (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-3 of the Registrant (Registration No. 333-114661) filed on April 21, 2004).

Table of Contents

10.19 Common Stock Purchase Warrant by and between the Registrant and Laurus Master Fund, Ltd., dated August 31, 2004 (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-3 (Registration No. 333-118970) as filed on September 14, 2004).

10.20 Form of Securities Purchase Agreement by and between the Registrant and various counterparties dated September 22, 2005 (incorporated by reference to Exhibit 10.1 to the Registrants Quarterly Report on Form 10-Q filed on November 14, 2005).

10.21 Common Stock Purchase Warrant by and between the Registrant and Oppenheimer & Co., Inc. dated October 27, 2005 (incorporated by reference to Exhibit 10.34 to the Registrants Annual Report on Form 10-K filed on March 31, 2006).

10.22 Letter Agreement by and between the Registrant and Laurus Master Fund, Ltd. dated October 31, 2005 (incorporated by reference to Exhibit 10.36 to the Registrants Annual Report on Form 10-K filed on March 31, 2006).

10.23 Employment Agreement Extension between the Company and Craig Tuttle dated July 12, 2008 (incorporated by reference to Registrant s Report on Form 8-K (Registration No. 000-30975) filed on July 16, 2008).

10.24 License Agreement between the Company and the Dana-Farber Cancer Institute dated October 8, 2009 (incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q filed on November 5, 2009).

10.25 License Agreement between the Company and Power3 Medical Products, Inc. dated January 23, 2009 (incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q filed on November 5, 2009).

10.26 Series A Convertible Preferred Stock Purchase Agreement with Third Security dated December 29, 2010 (incorporated by reference to the Registrant s Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011).

21 Subsidiaries of the Registrant.

23 Consent of Independent Registered Public Accounting Firm.

24 Powers of Attorney.

31 Certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32 Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 14th day of March 2011.

TRANSGENOMIC, INC.

By: /s/ CRAIG J. TUTTLE
Craig J. Tuttle,

President and Chief Executive Officer

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on this 14th day of March 2011.

Signature	Title
/s/ CRAIG J. TUTTLE Craig J. Tuttle	Director, President and Chief Executive Officer (Principal Executive Officer)
/s/ BRETT L. FREVERT Brett L. Frevert	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
/s/ RODNEY S. MARKIN* Rodney S. Markin	Director
/s/ ANTONIUS P. SCHUH* Antonius P. Schuh	Director
/s/ ROBERT M. PATZIG* Robert M. Patzig	Director
/s/ DOIT L. KOPPLER II* Doit L. Koppler II	Director
*By Craig J. Tuttle, as attorney-in-fact	
/s/ CRAIG J. TUTTLE Craig J. Tuttle	

Attorney-in-fact for the individuals as indicated.

