

TRANSGENOMIC INC  
Form 10-Q  
November 15, 2010  
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# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended September 30, 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)

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<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>911789357</b> (I.R.S. Employer Identification No.)
<b>12325 Emmet Street, Omaha, Nebraska</b> (Address of principal executive offices)	<b>68164</b> (Zip Code)
<b>(402) 452-5400</b> (Registrant's telephone number, including area code)	

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 and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

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 the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller Reporting Company <input checked="" type="checkbox"/>

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes  No

As of November 15, 2010, the number of shares of common stock outstanding was 49,289,672.

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**TRANSGENOMIC, INC.**

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**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****TRANSGENOMIC, INC. AND SUBSIDIARY****CONDENSED CONSOLIDATED BALANCE SHEETS****(Dollars in thousands except per share data)**

	<b>September 30, 2010 (unaudited)</b>	<b>December 31, 2009</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 4,589	\$ 5,642
Accounts receivable (net of allowances for bad debts of \$335 and \$310, respectively)	3,536	4,522
Inventories (net of allowances for obsolescence of \$520 and \$507, respectively)	3,658	3,552
Prepaid expenses and other current assets	646	738
Total current assets	12,429	14,454
<b>PROPERTY AND EQUIPMENT:</b>		
Equipment	10,371	9,972
Furniture, fixtures & leasehold improvements	3,836	3,834
	14,207	13,806
Less: accumulated depreciation	(13,160)	(12,839)
	1,047	967
<b>OTHER ASSETS:</b>		
Other assets (net of accumulated amortization of \$524 and \$525, respectively)	461	583
	\$ 13,937	\$ 16,004
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 889	\$ 1,013
Other accrued expenses	2,722	2,517
Accrued compensation	668	573
Total current liabilities	4,279	4,103
Other long-term liabilities	351	239
Total liabilities	4,630	4,342
<b>STOCKHOLDERS EQUITY:</b>		

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Preferred stock, \$.01 par value, 15,000,000 shares authorized, none outstanding		
Common stock, \$.01 par value, 100,000,000 shares authorized, 49,289,672 and 49,189,672 shares outstanding, respectively	498	497
Additional paid-in capital	139,715	139,703
Accumulated other comprehensive income	1,644	1,645
Accumulated deficit	(132,550)	(130,183)
<b>Total stockholders' equity</b>	<b>9,307</b>	<b>11,662</b>
	\$ 13,937	\$ 16,004

See notes to unaudited condensed consolidated financial statements.

**Table of Contents****TRANSGENOMIC, INC. AND SUBSIDIARY****UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Dollars in thousands except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
<b>NET SALES</b>	\$ 4,419	\$ 5,046	\$ 14,956	\$ 15,508
<b>COST OF GOODS SOLD</b>	2,402	2,293	7,568	7,291
Gross profit	2,017	2,753	7,388	8,217
<b>OPERATING EXPENSES:</b>				
Selling, general and administrative	2,159	2,215	7,623	7,922
Research and development	613	938	1,952	2,468
Restructuring charges	72		72	
	2,844	3,153	9,647	10,390
<b>LOSS FROM OPERATIONS</b>	(827)	(400)	(2,259)	(2,173)
<b>OTHER INCOME (EXPENSE):</b>				
Interest, net		1	1	14
Other, net		(1)		(4)
			1	10
<b>LOSS BEFORE INCOME TAXES</b>	(827)	(400)	(2,258)	(2,163)
<b>INCOME TAX EXPENSE (BENEFIT)</b>	71	(34)	109	(114)
<b>NET LOSS</b>	\$ (898)	\$ (366)	\$ (2,367)	\$ (2,049)
<b>BASIC AND DILUTED LOSS PER SHARE</b>	\$ (0.02)	\$ (0.01)	\$ (0.05)	\$ (0.04)
<b>BASIC AND DILUTED WEIGHTED AVERAGE SHARES OUTSTANDING</b>	49,289,672	49,189,672	49,228,561	49,189,672

See notes to unaudited condensed consolidated financial statements.

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## TRANSGENOMIC, INC. AND SUBSIDIARY

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

Nine Months Ended September 30, 2010

(Dollars in thousands except per share data)

	Common Stock				Accumulated	Other	
	Outstanding	Par	Additional	Accumulated	Comprehensive	Income	Total
	Shares	Value	Paid-in	Deficit	(Loss)		
Balance, January 1, 2010	49,189,672	\$ 497	\$ 139,703	\$ (130,183)	\$ 1,645		\$ 11,662
Net loss				(2,367)	(2,367)		(2,367)
Other comprehensive income (loss):							
Foreign currency translation adjustment, net of tax					(1)		(1)
Comprehensive loss					(2,368)		
Non-cash stock-based compensation				(29)			(29)
Issuance of shares for employee stock options	100,000	1	41				42
Balance, September 30, 2010	49,289,672	\$ 498	\$ 139,715	\$ (132,550)	\$ 1,644		\$ 9,307

See notes to unaudited condensed consolidated financial statements.

**Table of Contents****TRANSGENOMIC, INC. AND SUBSIDIARY****UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Dollars in thousands)

	<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,367)	\$ (2,049)
Adjustments to reconcile net loss to net cash flows provided by (used in) operating activities:		
Depreciation, amortization and disposals	523	615
Non-cash, stock based compensation	(29)	151
Changes in operating assets and liabilities:		
Accounts receivable	969	1,461
Inventories	(167)	709
Prepaid expenses and other current assets	90	20
Accounts payable	(121)	(142)
Accrued expenses and accrued compensation	242	(557)
Other long term liabilities	(44)	29
Long term deferred income taxes	20	
Net cash flows provided by (used in) operating activities	(884)	237
<b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(141)	(327)
Change in other assets	(25)	(20)
Net cash flows used in investing activities	(166)	(347)
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:</b>		
Issuance of common stock	42	
Principal payments on capital lease obligations	(57)	
Net cash flows provided by financing activities	(15)	
<b>EFFECT OF FOREIGN CURRENCY EXCHANGE RATE CHANGES ON CASH</b>	<b>12</b>	
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(1,053)</b>	<b>(110)</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>5,642</b>	<b>4,771</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 4,589</b>	<b>\$ 4,661</b>
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>		
Cash paid during the period for:		
Interest	\$	\$
Income taxes, net	4	163
<b>SUPPLEMENTAL DISCLOSURE OF NON-CASH INFORMATION</b>		
Acquisition of equipment through capital leases	\$ 286	

See notes to unaudited condensed consolidated financial statements.





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**TRANSGENOMIC, INC. AND SUBSIDIARY**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**Nine Months Ended September 30, 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 Instrument Related Business and Laboratory Services.

**Instrument Related Business:**

**Bioinstruments.** Our flagship product is the WAVE<sup>®</sup> System which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. There is a worldwide installed base of nearly 1,500 WAVE Systems as of September 30, 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 technical support personnel.

**Bioconsumables.** The installed WAVE base and some third-party installed 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<sup>®</sup> Nuclease and a range of HPLC separation columns.

**Laboratory Services:**

**Molecular Clinical Reference Laboratory.** The molecular clinical reference laboratory specializes in mitochondrial and molecular diagnostic testing including genetic testing for oncology, hematology and inherited disorders. Located in Omaha, Nebraska, the molecular clinical reference laboratory operates in a Good Laboratory Practices compliant environment and is certified under the Clinical Laboratory Improvement Amendment (CLIA) as a high complexity lab and 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. It 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.

Although we have experienced recurring net losses (resulting in an accumulated deficit of \$132.6 million at September 30, 2010) management believes existing sources of liquidity, including cash and cash equivalents of \$4.6 million, are sufficient to meet expected cash needs through 2011. We will need to increase net sales in order to meet our liquidity needs on a long-term basis. If 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**

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### *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.

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**TRANSGENOMIC, INC. AND SUBSIDIARY**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Nine Months Ended September 30, 2010 and 2009**

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 consolidated financial statements.

2. Concentration of Revenue Risk.

No customer accounted for more than 10% of consolidated net sales during the three and nine months ended September 30, 2010 and 2009. For the three and nine months ended September 30, 2010 one customer accounted for more than 10% of the Laboratory Services net sales. This customer represented 16% of the Laboratory Services net sales for the three months ended September 30, 2010 and 15% of the Laboratory Services net sales for the nine months ended September 30, 2010. For the three and nine months ended September 30, 2009 one customer accounted for more than 10% of the Laboratory Services net sales. This customer represented 18% of the Laboratory Services net sales for the three months ended September 30, 2009 and 20% for the nine months ended September 30, 2009.

*Fair Value.*

Unless otherwise specified, book value approximates fair market value.

*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 September 30, 2010.

*Basis of Presentation.*

The condensed consolidated balance sheet as of December 31, 2009 was derived from our audited balance sheet as of that date. The accompanying consolidated financial statements as of and for the three and nine months ended September 30, 2010 and 2009 are unaudited and reflect all adjustments which are, in the opinion of management, necessary for a fair presentation of the financial position and operating results for the interim periods. These unaudited consolidated financial statements and notes should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2009 contained in our Annual Report on Form 10-K. The results of operations for the interim periods presented are not necessarily indicative of the results for the entire year.

*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 temporary overnight investments.

*Accounts Receivable.*

The following is a summary of activity for the allowance for doubtful accounts during the three and nine months ended September 30, 2010 and 2009:

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	Dollars in Thousands			Ending Balance
	Beginning Balance	Provision	Write Offs	
Three Months Ended September 30, 2010	\$ 295	\$ 40	\$	\$ 335
Three Months Ended September 30, 2009	\$ 358	\$ (5)	\$ (8)	\$ 345
Nine Months Ended September 30, 2010	\$ 310	\$ 29	\$ (4)	\$ 335
Nine Months Ended September 30, 2009	\$ 388	\$ 27	\$ (70)	\$ 345

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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. 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 by regularly evaluating individual customer receivables and considering a customer's financial condition, credit history and current economic conditions. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

*Inventories.*

Inventories are stated at the lower of cost or market net of an 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 three and nine months ended September 30, 2010 and 2009:

	Dollars in Thousands			
	Beginning Balance	Provision	Write Offs	Ending Balance
Three Months Ended September 30, 2010	\$ 536	\$ 12	\$ (28)	\$ 520
Three Months Ended September 30, 2009	\$ 123	\$ 257	\$ (27)	\$ 353
Nine Months Ended September 30, 2010	\$ 507	\$ 78	\$ (65)	\$ 520
Nine Months Ended September 30, 2009	\$ 108	\$ 298	\$ (53)	\$ 353

We determine the allowance for obsolete inventory by evaluating quarterly the inventory for items deemed to be slow moving or obsolete. Included in our provision is the foreign currency impact of the consolidation of our subsidiary.

*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

*Other Assets.*

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Other assets include intellectual property, patents and other long-term assets.

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.

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Each of these assets is 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 recorded no impairment in the three or nine months ended September 30, 2010 or 2009.

3. Other Long-Term Assets.

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

*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 September 30, 2010 had vesting periods of three years from date of grant. None of the stock options outstanding at September 30, 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).

During the nine months ended September 30, 2010, we recorded compensation expense recovery of less than \$0.1 million within the selling, general and administrative expense. The vesting of options exercisable for the purchase of 1.3 million shares was offset by the expense recovery for stock options which were forfeited due to the requisite service not being rendered. During the nine months ended September 30, 2009, we recorded compensation expenses 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 September 30, 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.

No stock options were granted during the quarters ended September 30, 2010 and 2009. The fair value of the options granted during the nine months ended September 30, 2010 and 2009 was estimated on their respective grant dates using the Black-Scholes option pricing model. There were 75,000 stock options granted during the nine months ended September 30, 2010. The Black-Scholes model was used with the following assumptions: risk-free interest rates of 1.98% based on the U.S. Treasury yield in effect at the time of grant; dividend yields of zero percent; expected life of five years, based on 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% have been assumed in the calculation.

*Capital Leases*

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

Classes of Property	Dollars in Thousands	
	Asset Balances at September 30	
	2010	2009
Equipment	\$ 286	\$
Less: Accumulated amortization		



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Total	\$	286	\$
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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 September 30, 2010.

Year ending December 31:

	<b>Dollars in Thousands</b>	
2010	\$	14
2011		86
2012		86
2013		71
<b>Total minimum lease payments</b>	<b>\$</b>	<b>257</b>
Less: Amount representing interest		(28)
<b>Present value of net minimum lease payments</b>	<b>\$</b>	<b>229</b>

*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.

*Net Sales Recognition.*

Net 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 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. Net sales associated with these contracts are deferred and recognized ratably over the service period. At September 30, 2010 and September 30, 2009, deferred net sales, mainly associated with our service contracts, included in the balance sheet in other accrued expenses, was approximately \$1.5 million and \$1.4 million respectively for each of the periods.

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 less the reserve for insurance, Medicare and Medicaid expected reimbursement. There are no deferred net sales associated with our Molecular Clinical Reference Laboratory. Adjustments to the allowances, based on actual receipts from third party payers, are recorded upon settlement. In our Pharmacogenomics Research Services Group, we perform services on a project by project basis. When we get payment in advance we recognize revenue when we deliver the service. These projects typically do not extend beyond one year. At September 30, 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.

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

### *Research and Development.*

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

### *Translation of Foreign Currency.*

Our foreign subsidiary uses the local currency of the country in which 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 million are reported as accumulated other comprehensive income on the accompanying

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**TRANSGENOMIC, INC. AND SUBSIDIARY**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Nine Months Ended September 30, 2010 and 2009**

consolidated balance sheets for the nine months ended September 30, 2010. Revenues and expenses are translated at the average exchange 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 income for each of the nine months ending September 30, 2010 and 2009.

*Comprehensive Income.*

Accumulated other comprehensive income at September 30, 2010 and December 31, 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 10,598,156 and 11,383,720 shares of our common stock have been excluded from the computation of diluted earnings per share at September 30, 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 will be 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 currently evaluating the impact of adopting 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 will be 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. 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 currently evaluating the impact of adopting ASU 2009-14.

**C. RESTRUCTURING CHARGES**

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In the third quarter of 2010 we made a decision to consolidate our research and development activities in Omaha, Nebraska. We expect to substantially complete the transition by 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.

**Table of Contents****TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Nine Months Ended September 30, 2010 and 2009**

Restructuring charges include:

	Dollars in Thousands		
	Costs Incurred in the Three Months Ended September 30, 2010	Cumulative Costs Incurred at September 30, 2010	Total Expected Costs
Severance and related costs	\$ 40	\$ 40	\$ 53
Facility closure costs	24	24	63
Other	8	8	66
Restructuring charges	\$ 72	\$ 72	\$ 182

Liabilities recorded for the consolidation of our Gaithersburg, Maryland facility for the third quarter of 2010 consist of the following:

	Dollars in Thousands				
	Balance at June 30, 2010	Costs Incurred and Charged to Expense	Costs Paid or Otherwise Settled	Changes in Estimates	Balance at September 30, 2010
Severance and related costs	\$	\$ 40	\$	\$	\$ 40
Facility closure costs		24	(8)		16
Other		8	(8)		
Total	\$	\$ 72	\$ (16)	\$	\$ 56

**D. INVENTORIES**

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

	Dollars in Thousands	
	September 30, 2010	December 31, 2009
Finished goods	\$ 2,167	\$ 2,322
Raw materials and work in process	1,590	1,588
Demonstration inventory	421	149

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	4,178	4,059
Less allowance for obsolescence	(520)	(507)
Total	\$ 3,658	\$ 3,552

**Table of Contents****TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Nine Months Ended September 30, 2010 and 2009****E. OTHER ASSETS**

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

	Dollars in Thousands					
	September 30, 2010			December 31, 2009		
	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Intellectual property	\$ 290	\$ 273	\$ 17	\$ 310	\$ 284	\$ 26
Patents	531	251	280	598	241	357
Other	164		164	200		200
Total	\$ 985	\$ 524	\$ 461	\$ 1,108	\$ 525	\$ 583

Other assets include U.S. security deposits and deferred tax assets.

Amortization expense for intangible assets was less than \$0.1 million during the three and nine months ended September 30, 2010 and 2009, respectively. Amortization expense for intangible assets is expected to be less than \$0.1 million for each of the years 2010 and thereafter. During the nine months ended September 30, 2010 we abandoned patents of \$0.1 million.

**F. 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 \$0.3 million in 2010, \$0.6 million in 2011, \$0.3 million in 2012, less than \$0.1 million in each of the years 2013 through 2016. Rent expense for each of the three months ended September 30, 2010 and 2009 was \$0.2 million. Rent expense for each of the nine months ended September 30, 2010 and 2009 was \$0.6 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 payments from the Company if his employment is terminated involuntarily except if such termination is based on just cause, as that term is defined in the 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 provisions will be honored if the Company is acquired by, or merged into, another 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 September 30, 2010, firm commitments to vendors to purchase components used in WAVE Systems and instruments manufactured by others totaled \$0.3 million.



**G. INCOME TAXES**

We file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and various foreign jurisdictions. We have statutes of limitation open for Federal income tax returns related to tax years 2007 through 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.

Income tax expense for the nine months ended September 30, 2010 was \$0.1 million. This is the result of the change in deferred tax assets and liabilities reported in financial statements of our subsidiary outside the U.S. This tax expense

**Table of Contents****TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Nine Months Ended September 30, 2010 and 2009**

includes state and franchise taxes as well as reserves for uncertain income taxes. Income tax benefit for the nine months ended September 30, 2009 was \$0.1 million. The effective tax rate for the nine months ended September 30, 2010 is (4.84)% which is primarily the result of valuation allowances against the net operating losses for the U.S. partially adjusted by permanent differences related to intercompany foreign currency exchange of our subsidiary outside the U.S. The effective tax rate for the nine months ended September 30, 2009 was 5.27%.

During the three and nine months ended September 30, 2010, there were no material changes to the liability for uncertain tax positions.

**H. EMPLOYEE BENEFIT PLAN**

We maintain an employee 401(k) retirement savings plan that allows for voluntary contributions into designated investment funds by eligible employees. We currently match the employee's contributions at the rate of 50% on the first 6% of 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 less than \$0.1 million for each of the three and nine months ended September 30, 2010 and 2009.

**I. 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.*

No common stock warrants were issued or exercised during the three and nine months ended September 30, 2010 or 2009. At September 30, 2010, there were warrants outstanding which were exercisable to purchase 7,978,156 shares of common stock.

<b>Warrant Holder</b>	<b>Issue Year</b>	<b>Expiration</b>	<b>Underlying Shares</b>	<b>Exercise Price</b>
Various Institutional Holders (1)	2005	Oct. 2010	6,903,156	\$ 1.20
Laurus Master Fund, Ltd. (2)	2003	Dec. 2010	200,000	\$ 1.92
Laurus Master Fund, Ltd. (2)	2003	Dec. 2010	200,000	\$ 2.07
Laurus Master Fund, Ltd. (2)	2003	Dec. 2010	150,000	\$ 2.35
Laurus Master Fund, Ltd. (2)	2004	Feb. 2011	125,000	\$ 2.57
Laurus Master Fund, Ltd. (2)	2004	Aug. 2011	400,000	\$ 1.18
<b>Total</b>			<b>7,978,156</b>	

We are released from the liability when the stock warrants expire.

(1) These warrants were issued in conjunction with a private placement of common stock in October 2005.

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- (2) 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. 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. We have assessed and determined the fair value is \$0.

### *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

**Table of Contents****TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Nine Months Ended September 30, 2010 and 2009**

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. The Company has no current plans to issue any series of preferred stock. 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.

**J. STOCK OPTIONS**

The following table summarizes stock option activity during the nine months ended September 30, 2010:

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
Balance at January 1, 2010:	3,331,731	\$ 2.39
Granted	75,000	.58
Exercised	(100,000)	(.42)
Forfeited	(553,500)	(.75)
Expired	(133,231)	(12.50)
Balance at September 30, 2010:	2,620,000	\$ 2.24
Exercisable at September 30, 2010:	2,363,334	\$ 2.42

During the nine months ended September 30, 2010, we granted options exercisable to purchase 75,000 shares of common stock at a weighted average exercise price of \$0.58 under our 2006 Equity Incentive Plan.

**K. OPERATING SEGMENT AND GEOGRAPHIC INFORMATION**

Our company's chief operating 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 requires 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.

We have two reportable operating segments.

Segment information for the three months ended September 30, 2010 and 2009 is as follows:

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	Dollars in Thousands					
	2010			2009		
	Instrument Business	Lab Services	Total	Instrument Business	Lab Services	Total
Net Sales	\$ 3,155	\$ 1,264	\$ 4,419	\$ 3,852	\$ 1,194	\$ 5,046
Gross Profit	1,849	168	2,017	2,229	524	2,753
Net Income (Loss) before Taxes	(30)	(797)	(827)	70	(470)	(400)
Income Tax Expense (Benefit)	71		71	(34)		(34)
Net Income (Loss)	\$ (101)	\$ (797)	\$ (898)	\$ 104	\$ (470)	\$ (366)
Depreciation/Amortization	47	77	124	92	74	166
Restructuring Charges	38	34	72			
Interest Income, Net				1		1

**Table of Contents****TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Nine Months Ended September 30, 2010 and 2009**

Segment information for the nine months ended September 30, 2010 and 2009 is as follows:

	Dollars in Thousands					
	2010			2009		
	Instrument Business	Lab Services	Total	Instrument Business	Lab Services	Total
Net Sales	\$ 11,180	\$ 3,776	\$ 14,956	\$ 11,794	\$ 3,714	\$ 15,508
Gross Profit	6,320	1,068	7,388	6,692	1,525	8,217
Net Loss before Taxes	(343)	(1,915)	(2,258)	(451)	(1,712)	(2,163)
Income Tax Expense (Benefit)	109		109	(114)		(114)
<b>Net Loss</b>	<b>\$ (452)</b>	<b>\$ (1,915)</b>	<b>\$ (2,367)</b>	<b>\$ (337)</b>	<b>\$ (1,712)</b>	<b>\$ (2,049)</b>
Depreciation/Amortization	151	229	380	352	207	559
Restructuring Charges	38	34	72			
Interest Income	1		1	10	4	14
	<b>September 30, 2010</b>			<b>September 30, 2009</b>		
Total Assets	\$ 7,072	\$ 6,865	\$ 13,937	\$ 8,686	\$ 6,669	\$ 15,355

Net sales by product were as follows:

	Dollars in Thousands		Dollars in Thousands	
	Three Months Ended		Nine Months Ended	
	September 30, 2010	2009	September 30, 2010	2009
<b>Instrument Related Business:</b>				
Bioinstruments	\$ 1,356	\$ 1,999	\$ 5,925	\$ 6,215
Bioconsumables	1,799	1,853	5,255	5,579
	3,155	3,852	11,180	11,794
<b>Laboratory Services:</b>				
Molecular Clinical Reference Laboratory	918	923	2,790	2,886
Pharmacogenomics Research Services	346	271	986	828
	1,264	1,194	3,776	3,714
<b>Total Net Sales</b>	<b>\$ 4,419</b>	<b>\$ 5,046</b>	<b>\$ 14,956</b>	<b>\$ 15,508</b>

Net cost of goods sold was as follows:

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	Dollars in Thousands Three Months Ended September 30,		Dollars in Thousands Nine Months Ended September 30,	
	2010	2009	2010	2009
<b>Instrument Related Business:</b>				
Bioinstruments	\$ 532	\$ 526	\$ 2,487	\$ 2,167
Bioconsumables	774	1,097	2,373	2,935
	1,306	1,623	4,860	5,102
<b>Laboratory Services:</b>				
Molecular Clinical Reference Laboratory	670	479	1,631	1,607
Pharmacogenomics Research Services	426	191	1,077	582
	1,096	670	2,708	2,189
<b>Total Cost of Goods Sold</b>	<b>\$ 2,402</b>	<b>\$ 2,293</b>	<b>\$ 7,568</b>	<b>\$ 7,291</b>

**Table of Contents****TRANSGENOMIC, INC. AND SUBSIDIARY****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Nine Months Ended September 30, 2010 and 2009**

Net sales for the three and nine months ended September 30, 2010 and 2009 by country were as follows:

	Dollars in Thousands Three Months Ended September 30,		Dollars in Thousands Nine Months Ended September 30,	
	2010	2009	2010	2009
United States	\$ 2,082	\$ 1,920	\$ 6,483	\$ 6,254
Italy	813	913	2,300	2,676
France	209	386	812	1,175
Germany	194	441	1,099	973
United Arab Emirates	4		778	
United Kingdom	224	230	991	666
All Other Countries	893	1,156	2,493	3,764
Total	\$ 4,419	\$ 5,046	\$ 14,956	\$ 15,508

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

Approximately 80% of our long-lived assets are within the United States. Substantially all of the remaining long-lived assets are within Europe.

**L. SUBSEQUENT EVENTS**

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 October 27, 2010 6,903,156 common stock warrants to various institutional holders expired unexercised.

We have been awarded a federal grant under the Qualifying Therapeutic Discovery Project Program related to 2009 projects. Net of our consultant fees we expect to receive \$0.6 million cash in the fourth quarter of 2010.



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### **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Forward-Looking Information**

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 Part II, 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.

The following discussion should be read together with our financial statements and related notes contained in this report and with the financial statements, related notes, and Management's Discussion & Analysis in our annual report on Form 10-K for the fiscal year ended December 31, 2009. Results for the quarter ended September 30, 2010 are not necessarily indicative of results that may be attained in the future.

#### **Overview**

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 Instrument Related Business and Laboratory Services.

#### **Instrument Related Business:**

Bioinstruments. Our flagship product is the WAVE<sup>®</sup> System which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. There is a worldwide installed base of nearly 1,500 WAVE Systems as of September 30, 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 technical support personnel.

Bioconsumables. The installed WAVE base and some third-party installed 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<sup>®</sup> Nuclease and a range of HPLC separation columns.

#### **Laboratory Services:**

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Molecular Clinical Reference Laboratory. The molecular clinical reference laboratory specializes in mitochondrial and molecular diagnostic testing including genetic testing for oncology, hematology and inherited disorders. Located in Omaha, Nebraska the molecular clinical reference laboratory operates in a Good Laboratory Practices compliant environment and is certified under the Clinical Laboratory Improvement Amendment (CLIA) as a high complexity lab and is accredited by CAP (College of American Pathologists).

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

Although we have experienced recurring net losses (resulting in an accumulated deficit of \$132.6 million at September 30, 2010) management believes existing sources of liquidity, including cash and cash equivalents of \$4.6 million, are sufficient to meet expected cash needs during 2010. We will need to increase net sales in order to meet our liquidity needs on a long-term basis. If 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.

## **Executive Summary**

Net sales for the nine months ended September 30, 2010 were down 4% compared to the same period in 2009. Net sales in our Instrument Related Business were down 5% or \$0.6 million for the nine months ended September 30, 2010 compared to the same period in 2009. Net sales from bioinstruments were down 5% and net sales of consumables were down 6% for the comparable nine month periods. During the nine months ended September 30, 2010, net sales from Laboratory Services were up 2% compared to the same nine month period in 2009. The Clinical Reference Laboratory decreased 3% and net sales from Pharmacogenomics Research Services increased by 19%.

Our gross profit margin decreased by 4% for the nine months ended September 30, 2010 compared to the same period in 2009. The Instrument Related Business gross margin was flat at 57% for each of the nine months ended in 2010 and 2009. Laboratory Services gross margin decreased from 41% gross profit in the nine months ended September 30, 2009 to 28% for the same period in 2010. Net loss was \$2.4 million for the nine months ended September 30, 2010 compared to net loss of \$2.0 million for the nine months ended September 30, 2009.

## **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 continued 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 service businesses. And although challenges do exist for WAVE System and consumable sales growth in our traditional markets, we are having some success with selling systems into new geographic areas, including the Middle East, 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. During the third quarter we completed the requirements for CE IVD labeling of our SURVEYOR® Scan K-RAS mutation detection kit and have significantly expanded distribution throughout most of the European Union as a result. 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. As discussed below, 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.

On the Laboratory Services front, we have completed cancer pathway gene mutation projects for a number of high visibility pharmaceutical companies which have continued to demonstrate the unique sensitivity of detecting DNA mutations in cancer genes which are central to effective therapy selection for current and future cancer therapeutics. To this end, we are now gaining clinical trial program contracts which we believe will more rapidly impact our revenue opportunities from this segment. To compliment our mutation detection expertise, we also have strengthened our capabilities in biomarker development and mutation detection in novel cancer pathway genes which will aid in the development of true personalized medicine for our pharmaceutical partners. We recently licensed and are developing a new technology for even greater DNA mutation enrichment and detection sensitivity which could prove to be the highest sensitivity technology in the market. In our Molecular Clinical Reference Laboratory we have continued to seek out or develop new tests to further expand our menu and growth opportunities for this business, including a test that would determine the likelihood of the sibling of an autistic child also developing autism.

**Table of Contents****Uncertainties**

We have historically operated at a loss and have not consistently generated sufficient cash from operating activities to cover our operating expenses and other cash needs. While we have been able to historically finance our operating losses through borrowings or from the issuance of additional equity, there is the risk that we may not be able to obtain such funding in the future. At September 30, 2010 we had cash and cash equivalents of \$4.6 million. We do believe that existing sources of liquidity are sufficient to meet expected cash needs into 2011.

The uncertainty of the current general economic conditions could negatively impact our business in the future. There are many factors that affect the market demand for our products and services that we cannot control. Demand for our Instrument Related Business is affected by the needs and budgetary resources of research institutions, universities and hospitals. The instrument purchase represents a significant expenditure by these types of customers and often requires a long sales cycle. These customers may not have the funding available to purchase our instruments. Competition and new instruments in the marketplace also may impact our sales.

We have foreign currency revaluation risk, which occurs when a transaction occurs in a currency other than the entity's functional currency. The majority of our international sales are transacted in the euro, which must be first converted into British pound sterling, and then into U.S. dollars. At January 1, 2009 the Euro to Great British Pound exchange rate was .9690 as compared to the September 30, 2010 rate of .8613. The Great British Pound to U.S. Dollar exchange rate was 1.4501 at January 1, 2009 compared to 1.5809 at September 30, 2010. Fluctuations in the foreign exchange rates could impact our business results. Foreign currency revaluation adjustments decreased operating expenses and net loss by \$0.2 million and \$0.1 million for the three months ended September 30, 2010 and 2009, respectively and foreign currency revaluation adjustments increased operating expenses and net loss by \$0.3 million during each of the nine months ended September 30, 2010 and 2009.

**Results of Continuing Operations****Three Months Ended September 30, 2010 and 2009**

*Net Sales.* Net sales consisted of the following:

	Dollars in Thousands			
	Three Months Ended		Change	
	September 30, 2010	2009	\$	%
<b>Instrument Related Business:</b>				
Bioinstruments	\$ 1,356	\$ 1,999	\$ (643)	(32)%
Bioconsumables	1,799	1,853	(54)	(3)%
	3,155	3,852	(697)	(18)%
<b>Laboratory Services:</b>				
Molecular Clinical Reference Laboratory	918	923	(5)	(1)%
Pharmacogenomics Research Services	346	271	75	28%
	1,264	1,194	70	6%
<b>Total Net sales</b>	<b>\$ 4,419</b>	<b>\$ 5,046</b>	<b>\$ (627)</b>	<b>(12)%</b>

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 \$0.6 million, or 32%, during the three months ended September 30, 2010 as compared to the same period in 2009. The decrease in bioinstrument net sales was due to changes in the product mix sold during the quarter as well as fewer instruments sold. No OEM instruments were sold in 2010 compared to one OEM sale in the third quarter of 2009. We sold four WAVE instruments in the third quarter 2010 as compared to five WAVE instruments in the third quarter of 2009. The average sales price was higher in the third quarter of 2009 due to the geographic location of the sales. Service contract sales were flat during the three months ended September 30, 2010 as compared to the same

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period in 2009. Parts, freight and miscellaneous income was lower by \$0.1 million in the third quarter of 2010 as compared to the same period in 2009.

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Net sales of bioconsumables were down less than \$0.1 million, or 3%, during the three months ended September 30, 2010 compared to 2009. This decrease is related to lower sales volume in our European markets.

Net sales of Laboratory Services increased 6% during the three months ended September 30, 2010 compared to 2009. Laboratory Services sales includes both the Molecular Clinical Reference Laboratory Services and the Pharmacogenomics Research Services. The Molecular Clinical Reference Laboratory Services net sales were down 1% compared to the three months ended September 30, 2009. The Molecular Clinical Reference Laboratory average revenue per test has decreased by 4% due to the mix of tests performed and increased Medicare and Medicaid test volumes which generates lower reimbursement for these tests. The decrease in average revenue per test is offset by a 4% increase in sales volume. The Pharmacogenomics Research Services net sales of \$0.3 million during the three months ended September 30, 2010 was up 28% compared to 2009. The increase in Pharmacogenomics Research Services net sales is largely due to an increase in the number of customers for the third quarter of 2010 compared to 2009. The Pharmacogenomics Research Services net sales have peaks due to the project related nature of the business. Each period for Pharmacogenomics Research Services should be considered on a stand alone basis and is not indicative of future net sales.

*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). It also includes direct costs (primarily personnel costs, rent, supplies and depreciation) associated with our Laboratory Services operations. Cost of goods sold consisted of the following:

	Dollars in Thousands			
	Three Months Ended		Change	
	September 30, 2010	2009	\$	%
<b>Instrument Related Business:</b>				
Bioinstruments	\$ 532	\$ 526	\$ 6	1%
Bioconsumables	774	1,097	(323)	(29)%
	1,306	1,623	(317)	(20)%
<b>Laboratory Services:</b>				
Molecular Clinical Reference Laboratory	670	479	191	40%
Pharmacogenomics Research Services	426	191	235	123%
	1,096	670	426	64%
<b>Cost of goods sold</b>	<b>\$ 2,402</b>	<b>\$ 2,293</b>	<b>\$ 109</b>	<b>5%</b>

Gross profit was \$2.0 million or 46% of total net sales during the third quarter of 2010, compared to \$2.8 million or 55% during the same period of 2009. Margins on the instrument related business are up by 1% compared to the same period in 2009. The bioinstrument margin decreased from 74% in the three months ended September 30, 2009 to 61% in the same period of 2010. This decrease is driven by the composition of products sold and fewer instruments sold in the third quarter of 2010. Margins on bioconsumables increased from 41% for the three months ended September 30, 2009 to 57% in the same period of 2010. During the three months ended September 30, 2010, the gross margin for the Laboratory Services was 13% as compared to 44% in the same period of 2009. The gross margin on the Clinical Reference Laboratory was 27% for the third quarter of 2010 compared to 48% for the third quarter of 2009. Pharmacogenomics gross margin decreased from 30% for the three months ended September 30, 2009 to a negative 23% for the three months ended September 30, 2010. These decreases are due to staff added along with higher operating supplies cost.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses primarily consist of personnel costs, marketing, travel and entertainment costs, professional fees, and facility costs. In addition, foreign currency revaluation is included here. Excluding foreign currency revaluation gains or losses, our selling, general and administrative costs were down less than \$0.1 million compared to the same period of 2009. Foreign currency revaluation gains in the three months ended September 30, 2010 were \$0.2 million compared to \$0.1 million in revaluation gains for the three months ended September 30, 2009.

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*Research and Development Expenses.* Research and development expenses primarily include personnel costs, legal fees, outside services, collaboration expenses, supplies, and facility costs and are expensed in the period in which they are incurred. For the third quarter of 2010 and 2009 these costs totaled \$0.6 million and \$0.9 million respectively. The 2009 research and development costs included collaboration expenses with the Dana-Farber Cancer Institute related to the development of high sensitivity mutation detection technology called COLD-PCR (coamplification at lower denaturation temperature PCR).

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Research and development expenses totaled 14% and 19% of net sales during the three months ended September 30, 2010 and 2009, respectively.

*Other Income (Expense).* Other income consists primarily of interest income from cash and cash equivalents invested in overnight instruments. Other expense during the three months ended September 30, 2010 and 2009 was less than \$0.1 million for each period.

*Income Tax Expense (Benefit).* Income tax expense for the three months ended September 30, 2010 was less than \$0.1 million. This is the result of the change in deferred tax assets and liabilities reported in financial statements of our subsidiary outside the U.S. This tax expense includes state taxes as well as reserves for uncertain income taxes. Income tax benefit for the three months ended September 30, 2009 was less than \$0.1 million.

**Results of Continuing Operations****Nine Months Ended September 30, 2010 and 2009**

*Net Sales.* Net sales consisted of the following:

	Dollars in Thousands			
	Nine Months Ended		Change	
	September 30, 2010	September 30, 2009	\$	%
<b>Instrument Related Business:</b>				
Bioinstruments	\$ 5,925	\$ 6,215	\$ (290)	(5)%
Bioconsumables	5,255	5,579	(324)	(6)%
	11,180	11,794	(614)	(5)%
<b>Laboratory Services:</b>				
Molecular Clinical Reference Laboratory	2,790	2,886	(96)	(3)%
Pharmacogenomics Research Services	986	828	158	19%
	3,776	3,714	62	2%
<b>Total Net Sales</b>	<b>\$ 14,956</b>	<b>\$ 15,508</b>	<b>\$ (552)</b>	<b>(4)%</b>

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 \$0.3 million, or 5%, during the nine months ended September 30, 2010 as compared to the same period in 2009. The decrease in bioinstrument net sales was due to lower average sales price in the nine months ended September 30, 2010. We sold five OEM instruments in each of the nine months ended September 30, 2010 and September 30, 2009. The average sales price was lower on our OEM instruments sold in 2010 as compared to 2009. We sold twenty-two WAVE Systems in the nine months ended September 30, 2010 as compared to eighteen in the nine months ended September 30, 2009, and the average sales price was lower due to the geographic location of the sales. Service contract sales were down \$0.1 million for the nine months ended September 30, 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 \$0.3 million in the nine months ended September 30, 2010 as compared to the same period of 2009.

Net sales of bioconsumables decreased during the nine months ended September 30, 2010 compared to 2009. The primary decrease in consumables is due to lower volume in our European market offset by higher volume in our U.S. market.





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Net sales of Laboratory Services increased by 2% for the nine months ended September 30, 2010 compared to 2009. Sales of Laboratory Services include both the Molecular Clinical Reference Laboratory Services and the Pharmacogenomics Research Services. The Molecular Clinical Reference Laboratory Services net sales of \$2.8 million represented a decrease of 3% over the nine months ended September 30, 2009. The Molecular Clinical Reference Laboratory average revenue per test has decreased by 6% 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 3% increase in volume. The Pharmacogenomics Research Services net sales of \$1.0 million during the nine months ended September 30, 2010 represented an increase of 19% from the nine months ended September 30, 2009. The increase in Pharmacogenomics Research Services is largely due to an increase in the number of clients for the nine months ended September 30, 2010 compared to the same period of 2009. The Pharmacogenomics Research Services net sales have peaks due to the project related nature of the business. Each period for Pharmacogenomics Research Services should be considered on a stand alone basis and is not indicative of future net sales.

*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). It also includes direct costs (primarily personnel costs, rent, supplies and depreciation) associated with our Laboratory Services operations. Cost of goods sold consisted of the following:

	Dollars in Thousands			
	Nine Months Ended		Change	
	September 30, 2010	2009	\$	%
<b>Instrument Related Business:</b>				
Bioinstruments	\$ 2,487	\$ 2,167	\$ 320	15%
Bioconsumables	2,373	2,935	(562)	(19)%
	4,860	5,102	(242)	(5)%
<b>Laboratory Services:</b>				
Molecular Clinical Reference Laboratory	1,631	1,607	24	1%
Pharmacogenomics Research Services	1,077	582	495	85%
	2,708	2,189	519	24%
<b>Cost of goods sold</b>	<b>\$ 7,568</b>	<b>\$ 7,291</b>	<b>\$ 277</b>	<b>4%</b>

Gross profit was \$7.4 million or 49% of total net sales during the nine months ended September 30, 2010, compared to \$8.2 million or 53% during the same period of 2009. Margins on the Instrument Related Business were flat for the nine months ended September 30, 2010 compared to the same period in 2009. During the nine months ended September 30, 2010, the gross margin for the Laboratory Services was 28% as compared to 41% in the same period of 2009. The erosion in the gross margin is driven by the lower average net sales reimbursement per test due to increased Medicare and Medicaid test volume and higher operating costs.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses primarily consist of personnel costs, marketing, travel and entertainment costs, professional fees, and facility costs. In addition, foreign currency revaluation is included here. Excluding foreign currency revaluation losses, which was a loss of \$0.3 million in each of the nine months ended September 30, 2010, our selling, general and administrative costs decreased from \$7.7 million to \$7.3 million. The primary decrease is due to lower salary and stock option expense.

*Research and Development Expenses.* Research and development expenses primarily include personnel costs, legal fees, outside services, collaboration expenses, supplies, and facility costs and are expensed in the period in which they are incurred. Research and development expenses were \$2.0 million and \$2.5 million for the nine months ended September 30, 2010 and 2009, respectively.

Research and development expenses totaled 13% and 16% of net sales during the nine months ended September 30, 2010 and 2009, respectively.

*Other Income (Expense).* Other income consists primarily of interest income from cash and cash equivalents invested in overnight instruments. Other income during the nine months ended September 30, 2010 and September 30, 2009 was less than \$0.1 million for each period.



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*Income Tax Expense (Benefit).* Income tax expense for the nine months ended September 30, 2010 was \$0.1 million. This is the result of the change in deferred tax assets and liabilities reported in financial statements of subsidiaries outside the U.S. This tax expense includes state taxes as well as reserves for uncertain income taxes. Income tax benefit for the nine months ended September 30, 2009 was \$0.1 million.

**Liquidity and Capital Resources**

Our working capital positions at September 30, 2010 and December 31, 2009 were as follows:

	Dollars in Thousands		
	September 30, 2010	December 31, 2009	Change
Current assets (including cash and cash equivalents of \$4,589 and \$5,642, respectively)	\$ 12,429	\$ 14,454	\$ (2,025)
Current liabilities	4,279	4,103	176
<b>Working capital</b>	<b>\$ 8,150</b>	<b>\$ 10,351</b>	<b>\$ (2,201)</b>

The working capital decrease at September 30, 2010 compared to December 31, 2009 is primarily a result of our net loss of \$2.4 million for the nine months ended September 30, 2010.

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. While we have been able to historically finance our operating losses through borrowings or from the issuance of additional equity, we currently have no borrowings and have no plans to issue additional equity securities for this purpose. At September 30, 2010 we had cash and cash equivalents of \$4.6 million. We believe that existing sources of liquidity are sufficient to meet expected cash needs into 2011. We will need to increase our net sales, focus on receivables and inventory management or further reduce our operating expenses in order to be assured of meeting 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 our operations indefinitely.

**Analysis of Cash Flows****Nine Months Ended September 30, 2010 and 2009**

*Net Change in Cash and Cash Equivalents.* Cash and cash equivalents decreased by \$1.1 million during the nine months ended September 30, 2010 to \$4.6 million compared to a decrease of \$0.1 million in cash balances during the nine months ended September 30, 2009. In 2010 net cash used in operating activities was \$0.7 million and \$0.5 million was used in investing activities which was offset by less than \$0.1 million provided by financing activities. The impact of foreign currency exchange revaluation was nominal. In 2009 net cash provided by operating activities was \$0.2 million offset by \$0.3 million of net cash flow used in investing activities with minimal impact of foreign currency exchange rates.

*Cash Flows Used in Operating Activities.* Cash flows used in operating activities were \$0.7 million during the nine months ended September 30, 2010, compared to cash flows provided by operating activities of \$0.2 million during the same period of 2009. The cash flows used in operating activities in 2010 relate to the net loss of \$2.4 million which is offset by the timely collection of accounts receivable of \$1.0 million and noncash items of \$0.5 million. The cash flows provided by operating activities in 2009 primarily relate to the accounts receivable collections of \$1.5 million and noncash items of \$0.8 million offset by the loss of \$2.0 million.

*Cash Flows Used In Investing Activities.* Cash flows used in investing activities totaled \$0.5 million during the nine months ended September 30, 2010 compared to cash flows used in investing activities of \$0.3 million during the same period of 2009. Cash flows used in investing activities in 2010 and 2009 consisted primarily of purchases of property and equipment.

*Cash Flows Provided by Financing Activities.* Cash flows provided by financing activities were less than \$0.1 million for the nine months ended September 30, 2010. This resulted from the issuance of common stock due to the exercise of stock options for 100,000 shares during the second

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quarter of 2010. There were no cash flows provided by or used in financing activities for the nine months ended September 30, 2009.

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### **Off-Balance Sheet Arrangements**

At September 30, 2010 and December 31, 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 and Estimates**

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 judgments or estimates may vary under different assumptions or circumstances. Our critical accounting policies are discussed in our annual report on Form 10-K for the fiscal year ended December 31, 2009.

### **Recently Issued Accounting Pronouncements**

Please refer to our annual report on Form 10-K for the fiscal year ended December 31, 2009. There have been no changes to those accounting pronouncements listed except as noted in note B to the financial statements contained in this report.

### **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.

### **Item 4T. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.* Management performed, under the direction of our Chief Executive Officer and Interim 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 reports we file or submit under the Exchange Act are recorded, processed, summarized, and reported within the time periods specified in the SEC's forms, and that such information is accumulated and communicated to our management including our Chief Executive Officer and our Interim Chief Financial Officer, to allow timely decisions regarding required disclosures. Based on the evaluation, the Company's Chief Executive Officer and our Interim Chief Financial Officer concluded that, as of September 30, 2010 Transgenomic's disclosure controls and procedures were effective.

*Change in Internal Control Over Financial Reporting.* There have been no changes in our internal control over financial reporting during the quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

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

**Item 1A. Risk Factors**

An investment in our common stock involves a number of risks. You should carefully consider each of the risks described in Item 1A of our annual report on Form 10-K for the fiscal year ended December 31, 2009 before deciding to invest in our common stock. If any of the risks actually occur, our business, financial condition or results of operations could be negatively affected, the market price of our common stock or other securities could decline and you may lose all or part of your investment.

In addition to the risks described in Item 1A of our annual report on Form 10-K for the fiscal year Ended December 31, 2009 please consider the following risks before deciding to invest in our common stock:

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.

**Note Regarding Risk Factors**

The risk factors presented above and in Item 1A of our annual report on Form 10-K for the fiscal year ended December 31, 2009 are all of the ones that we currently consider material. However, they are not the only ones facing our company. Additional risks not presently known to us, or which we currently consider immaterial, may also adversely affect us. There may be risks that a particular investor views differently from us, and our analysis might be wrong. If any of the risks that we face actually occur, our business, financial condition and operating results could be materially adversely affected and could differ materially from any possible results suggested by any forward-looking statements that we have made or might make. In such case, the trading price of our common stock could decline, and you could lose part or all of your investment. **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.**

**Item 6. Exhibits**

(a) Exhibits

- 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 Amended and Restated Bylaws of the Registrant (incorporated by reference to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on May 25, 2007)
- 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)

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- 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



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**SIGNATURES**

Pursuant to the requirements 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.

TRANSGENOMIC, INC.

Date: November 15, 2010

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

*President and Chief Executive Officer*