

TRANSGENOMIC INC  
Form 10-Q  
November 05, 2009  
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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, 2009

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><br>(State or other jurisdiction of<br>incorporation or organization)   | <b>911789357</b><br>(I.R.S. Employer<br>Identification No.) |
| <b>12325 Emmet Street, Omaha, Nebraska</b><br>(Address of principal executive offices) | <b>68164</b><br>(Zip Code)                                  |
| <b>(402) 452-5400</b><br>(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 5, 2009, the number of shares of common stock outstanding was 49,189,672.

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**TRANSGENOMIC, INC.**

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**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****TRANSGENOMIC, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**

(Dollars in thousands except per share data)

|                                                                                             | September 30, 2009<br>(unaudited) | December 31,<br>2008 |
|---------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| <b>ASSETS</b>                                                                               |                                   |                      |
| <b>CURRENT ASSETS:</b>                                                                      |                                   |                      |
| Cash and cash equivalents                                                                   | \$ 4,661                          | \$ 4,771             |
| Accounts receivable (net of allowances for bad debts of \$345 and \$388, respectively)      | 4,145                             | 5,385                |
| Inventories (net of allowances for obsolescence of \$353 and \$108, respectively)           | 4,134                             | 4,775                |
| Prepaid expenses and other current assets                                                   | 655                               | 654                  |
| Total current assets                                                                        | 13,595                            | 15,585               |
| <b>PROPERTY AND EQUIPMENT:</b>                                                              |                                   |                      |
| Equipment                                                                                   | 10,276                            | 10,059               |
| Furniture, fixtures & leasehold improvements                                                | 3,931                             | 3,920                |
|                                                                                             | 14,207                            | 13,979               |
| Less: accumulated depreciation                                                              | (13,148)                          | (12,781)             |
|                                                                                             | 1,059                             | 1,198                |
| <b>OTHER ASSETS:</b>                                                                        |                                   |                      |
| Other assets (net of accumulated amortization of \$478 and \$425, respectively)             | 701                               | 773                  |
|                                                                                             | \$ 15,355                         | \$ 17,556            |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>                                                  |                                   |                      |
| <b>CURRENT LIABILITIES:</b>                                                                 |                                   |                      |
| Accounts payable                                                                            | \$ 795                            | \$ 905               |
| Other accrued expenses                                                                      | 2,330                             | 2,810                |
| Accrued compensation                                                                        | 538                               | 520                  |
| Total current liabilities                                                                   | 3,663                             | 4,235                |
| Other long-term liabilities                                                                 | 202                               | 116                  |
| Total liabilities                                                                           | 3,865                             | 4,351                |
| <b>STOCKHOLDERS EQUITY:</b>                                                                 |                                   |                      |
| Preferred stock, \$.01 par value, 15,000,000 shares authorized, none outstanding            |                                   |                      |
| Common stock, \$.01 par value, 100,000,000 shares authorized, 49,189,672 shares outstanding | 497                               | 497                  |
| Additional paid-in capital                                                                  | 139,652                           | 139,501              |
| Accumulated other comprehensive income                                                      | 1,653                             | 1,470                |
| Accumulated deficit                                                                         | (130,312)                         | (128,263)            |

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|                            |           |           |
|----------------------------|-----------|-----------|
| Total stockholders' equity | 11,490    | 13,205    |
|                            | \$ 15,355 | \$ 17,556 |

See notes to unaudited condensed consolidated financial statements.

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

(Dollars in thousands except per share data)

|                                                                  | Three Months Ended<br>September 30, |            | Nine Months Ended<br>September 30, |            |
|------------------------------------------------------------------|-------------------------------------|------------|------------------------------------|------------|
|                                                                  | 2009                                | 2008       | 2009                               | 2008       |
| <b>NET SALES</b>                                                 | \$ 5,046                            | \$ 5,367   | \$ 15,508                          | \$ 17,869  |
| <b>COST OF GOODS SOLD</b>                                        | 2,293                               | 2,448      | 7,291                              | 7,570      |
| Gross profit                                                     | 2,753                               | 2,919      | 8,217                              | 10,299     |
| <b>OPERATING EXPENSES:</b>                                       |                                     |            |                                    |            |
| Selling, general and administrative                              | 2,215                               | 2,757      | 7,922                              | 8,824      |
| Research and development                                         | 938                                 | 684        | 2,468                              | 1,816      |
| Restructuring Costs                                              |                                     |            |                                    | 8          |
|                                                                  | 3,153                               | 3,441      | 10,390                             | 10,648     |
| <b>LOSS FROM OPERATIONS</b>                                      | (400)                               | (522)      | (2,173)                            | (349)      |
| <b>OTHER INCOME (EXPENSE):</b>                                   |                                     |            |                                    |            |
| Interest income, net of interest expense                         | 1                                   | 22         | 14                                 | 80         |
| Other, net                                                       | (1)                                 | 14         | (4)                                | 13         |
|                                                                  |                                     | 36         | 10                                 | 93         |
| <b>LOSS BEFORE INCOME TAXES</b>                                  | (400)                               | (486)      | (2,163)                            | (256)      |
| <b>INCOME TAX EXPENSE (BENEFIT)</b>                              | (34)                                | 13         | (114)                              | 20         |
| <b>NET LOSS</b>                                                  | \$ (366)                            | \$ (499)   | \$ (2,049)                         | \$ (276)   |
| <b>BASIC AND DILUTED LOSS PER SHARE</b>                          | \$ (0.01)                           | \$ (0.01)  | \$ (0.04)                          | \$ (0.01)  |
| <b>BASIC AND DILUTED WEIGHTED AVERAGE SHARES<br/>OUTSTANDING</b> | 49,189,672                          | 49,189,672 | 49,189,672                         | 49,189,672 |

See notes to unaudited condensed consolidated financial statements.

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## TRANSGENOMIC, INC. AND SUBSIDIARIES

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Nine Months Ended September 30, 2009

(Dollars in thousands except per share data)

|                                                     | Common Stock          |              |                                  |                        | Accumulated                             | Total     |
|-----------------------------------------------------|-----------------------|--------------|----------------------------------|------------------------|-----------------------------------------|-----------|
|                                                     | Outstanding<br>Shares | Par<br>Value | Additional<br>Paid-in<br>Capital | Accumulated<br>Deficit | Other<br>Comprehensive<br>Income (Loss) |           |
| Balance, January 1, 2009                            | 49,189,672            | \$ 497       | \$ 139,501                       | \$ (128,263)           | \$ 1,470                                | \$ 13,205 |
| Net loss                                            |                       |              |                                  | (2,049)                | (2,049)                                 | (2,049)   |
| Other comprehensive income (loss):                  |                       |              |                                  |                        |                                         |           |
| Foreign currency translation adjustment, net of tax |                       |              |                                  |                        | 183                                     | 183       |
| Comprehensive (loss)                                |                       |              |                                  |                        | (1,866)                                 |           |
| Non-cash stock-based compensation                   |                       |              | 151                              |                        |                                         | 151       |
| Balance, September 30, 2009                         | 49,189,672            | \$ 497       | \$ 139,652                       | \$ (130,312)           | \$ 1,653                                | \$ 11,490 |

See notes to unaudited condensed consolidated financial statements.

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

(Dollars in thousands)

|                                                                                                 | Nine Months Ended<br>September 30, |          |
|-------------------------------------------------------------------------------------------------|------------------------------------|----------|
|                                                                                                 | 2009                               | 2008     |
| <b>CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES:</b>                                   |                                    |          |
| Net loss                                                                                        | \$ (2,049)                         | \$ (276) |
| Adjustments to reconcile net loss to net cash flows provided by (used in) operating activities: |                                    |          |
| Depreciation and amortization                                                                   | 615                                | 494      |
| Non-cash, stock based compensation                                                              | 151                                | 209      |
| Loss on sale of investment and assets                                                           |                                    | 6        |
| Changes in operating assets and liabilities:                                                    |                                    |          |
| Accounts receivable                                                                             | 1,461                              | 151      |
| Inventories                                                                                     | 709                                | (335)    |
| Prepaid expenses and other current assets                                                       | 20                                 | 32       |
| Accounts payable                                                                                | (142)                              | (429)    |
| Accrued expenses and accrued compensation                                                       | (557)                              | (324)    |
| Other long term liabilities                                                                     | 29                                 |          |
| Net cash flows provided by (used in) operating activities                                       | 237                                | (472)    |
| <b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>                                                 |                                    |          |
| Purchase of property and equipment                                                              | (327)                              | (215)    |
| Change in other assets                                                                          | (20)                               | (39)     |
| Net cash flows used in investing activities                                                     | (347)                              | (254)    |
| <b>EFFECT OF FOREIGN CURRENCY EXCHANGE RATE CHANGES ON CASH</b>                                 |                                    |          |
|                                                                                                 |                                    | (210)    |
| <b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>                                                  | (110)                              | (936)    |
| <b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>                                         | 4,771                              | 5,723    |
| <b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>                                               | \$ 4,661                           | \$ 4,787 |
| <b>SUPPLEMENTAL CASH FLOW INFORMATION</b>                                                       |                                    |          |
| Cash paid during the period for:                                                                |                                    |          |
| Interest                                                                                        | \$                                 | \$       |
| Income taxes, net                                                                               | 163                                | 61       |

See notes to unaudited condensed consolidated financial statements.



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### **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 over 1,450 WAVE Systems as of September 30, 2009. 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, 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 for disease research, drug and diagnostic development and clinical trial support.

Management believes existing sources of liquidity, including cash and cash equivalents of \$4.7 million, are sufficient to meet expected cash needs during 2009. Our business consolidation efforts, recent reduction in force and cost containment management over the last few years have helped control our operating costs, however, we have added sales and marketing costs over the last two years in an effort to drive increased sales. In addition we have increased our research expenditures to drive development of new products and to support business opportunities and collaborations. 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 subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

#### *Risks and Uncertainties.*

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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.

**Table of Contents****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 three and nine months ended September 30, 2009 and 2008. For the three and nine months ended September 30, 2009 one customer made up 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. For the three and nine months ended September 30, 2008 two customers each made up more than 10% of the Laboratory Services net sales. Combined for the nine months they represented 35% of the Laboratory Services net sales.

*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, 2009.

*Basis of Presentation.*

The consolidated balance sheet as of December 31, 2008 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, 2009 and 2008 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, 2008 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 only temporary overnight investments.

*Accounts Receivable.*

Accounts receivable are shown net of allowance for doubtful accounts. The following is a summary of activity for the allowance for doubtful accounts during the three and nine months ended September 30, 2009 and 2008:

|                   | Dollars in Thousands<br>Three Months Ended |                       | Dollars in Thousands<br>Nine Months Ended |                       |
|-------------------|--------------------------------------------|-----------------------|-------------------------------------------|-----------------------|
|                   | September 30,<br>2009                      | September 30,<br>2008 | September 30,<br>2009                     | September 30,<br>2008 |
| Beginning balance | \$ 358                                     | \$ 501                | \$ 388                                    | \$ 703                |
| Provision         | (5)                                        | 20                    | 27                                        | 185                   |
| Write offs        | (8)                                        | (20)                  | (70)                                      | (387)                 |
| Ending balance    | \$ 345                                     | \$ 501                | \$ 345                                    | \$ 501                |

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 amount less an estimate made for doubtful receivables based on a review of all outstanding amounts on a quarterly basis. We determine the allowance

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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.

**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.

The following is a summary of activity for the allowance for obsolete inventory during the three and nine months ended September 30, 2009 and 2008:

|                   | Dollars in Thousands<br>Three Months Ended<br>September 30, |       | Dollars in Thousands<br>Nine Months Ended<br>September 30, |       |
|-------------------|-------------------------------------------------------------|-------|------------------------------------------------------------|-------|
|                   | 2009                                                        | 2008  | 2009                                                       | 2008  |
| Beginning balance | \$ 123                                                      | \$ 13 | \$ 108                                                     | \$ 12 |
| Provision         | 257                                                         | 2     | 298                                                        | 2     |
| Write offs        | (27)                                                        | (1)   | (53)                                                       |       |
| Ending balance    | \$ 353                                                      | \$ 14 | \$ 353                                                     | \$ 14 |

We determine the allowance for obsolete inventory by regularly evaluating the inventory for items deemed to be slow moving or obsolete. During the three months ended September 30, 2009 we recorded \$0.2 million related to control plasmids used for our surveyor kits.

*Property and Equipment.*

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

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

Depreciation during the three months ended September 30, 2009 and 2008 was \$0.1 million and \$0.2 million, respectively. Depreciation during both the nine months ended September 30, 2009 and 2008 was \$0.5 million related to depreciation of property and equipment.

*Other Assets.*

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

**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.

**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. We expense all costs incurred prior to the filing of the patent application.

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 periodically review the carrying value of our long-lived assets to assess recoverability and impairment. We recorded no impairment in the three and nine months ended September 30, 2009 and 2008.

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Other Assets. Other 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 September 30, 2009 had vesting periods of three years from date of grant. None of the stock options outstanding at September 30, 2009 are subject to performance or market-based vesting conditions.

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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, 2009, we recorded compensation expense of \$0.2 million within the selling, general and administrative expense as a result of the vesting of options exercisable for the purchase of 1,745,000 shares. During the nine months ended September 30, 2008, 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 1,560,000 shares. As of September 30, 2009, there was \$0.2 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 the quarter ended September 30, 2008 was estimated on their respective grant dates using the Black-Scholes option pricing model. There were no options granted during the quarter ended September 30, 2009. 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 2 to 10 years, based on historical exercise activity behavior; and volatility of 106.08% and 80.03% 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, no forfeitures were assumed.

### *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 and net sales associated with these contracts are deferred and recognized over the service period. At September 30, 2009 and September 30, 2008, deferred net sales, mainly associated with our service contracts, included in the balance sheet in other accrued expenses, were approximately \$1.4 million and \$1.6 million, respectively.

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 payment. There are no deferred net sales associated with our Molecular Clinical Reference Laboratory. In our Pharmacogenomics Research Services Group, we recognize net sales based on a proportionate performance measurement for each project. At September 30, 2009 and 2008, 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.

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*Translation of Foreign Currency.*

Financial statements of subsidiaries outside the U.S. are measured using the local currency as the functional currency. The adjustments to translate those amounts into U.S. dollars are accumulated in a separate account in stockholders' equity and are included in accumulated other comprehensive income. Foreign currency revaluation gains or losses resulting from changes in currency exchange rates are included in the determination of net income. Foreign currency revaluation adjustments decreased operating expenses and net loss by \$0.1 million for the three months ended September 30, 2009 and increased operating expenses and net loss by \$0.3 million for the nine months ended September 30, 2009, and decreased operating expenses and net loss by \$0.5 million during the nine months ended September 30, 2008. Foreign currency translation adjustments had a nominal impact on net loss for the three months ended September 30, 2008.

*Comprehensive Income.*

Accumulated other comprehensive income at September 30, 2009 and December 31, 2008 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 are 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. At September 30, 2009, there were outstanding options, warrants and conversion rights exercisable for 11,383,720 shares of our common stock all of which were excluded from the computation of diluted earnings per share because the effect would be anti-dilutive due to the net loss in that period. At September 30, 2008 there were outstanding options, warrants and conversion rights exercisable for 12,046,704 shares of our common stock all of which were excluded from the calculation of diluted earnings per share because the effect would be anti-dilutive due to the net loss in that period.

*Recently Issued Accounting Pronouncements.*

In June 2009, the FASB issued FASB ASC 105, Generally Accepted Accounting Principles, which establishes the FASB Accounting Standards Codification as the sole source of authoritative generally accepted accounting principles. Pursuant to the provisions of FASB ASC 105, the Company has updated references to GAAP in its financial statements issued for the period ended September 30, 2009. The adoption of FASB ASC 105 did not impact the Company's financial position or results of operations.

ASC 820, Fair Value Measurement and Disclosures defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. We have adopted ASC 820 with no impact on our financial statements.

ASC 350, Intangibles Goodwill and Other requires companies estimating the useful life of a recognized intangible asset to consider their historical experience in renewing or extending similar arrangements or, in the absence of historical experience, to consider assumptions that market participants would use about renewal or extension. ASC 350 was adopted on January 1, 2009 and had no impact on our financial statements.

ASC 815-40, Derivatives and Hedging addresses freestanding contracts that are indexed to, and potentially settled in, an entity's own stock. We adopted ASC 815-40 on January 1, 2009. We have assessed our warrants and determined the fair value is \$0 so there is no impact to our financial statements.

Accounting Standards Update No. 2009-13 addresses the accounting for multiple deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. This update is effective for fiscal years on or after June 15, 2010.

Accounting Standards Update No. 2009-05 provides amendments to ASC Topic 820, Fair Value Measurements and Disclosure for the fair value measurement of liabilities. We have implemented ASU 2009-05 with no impact on our financial statements.



**Table of Contents****C. INVENTORIES**

Inventories consisted of the following:

|                                   | Dollars in Thousands  |                      |
|-----------------------------------|-----------------------|----------------------|
|                                   | September 30,<br>2009 | December 31,<br>2008 |
| Finished goods                    | \$ 2,458              | \$ 2,911             |
| Raw materials and work in process | 1,300                 | 1,658                |
| Demonstration inventory           | 376                   | 206                  |
|                                   | \$ 4,134              | \$ 4,775             |

**D. OTHER ASSETS**

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

|                       | Dollars in Thousands |                             |                   |                   |                             |                   |
|-----------------------|----------------------|-----------------------------|-------------------|-------------------|-----------------------------|-------------------|
|                       | September 30, 2009   |                             |                   | December 31, 2008 |                             |                   |
|                       | Cost                 | Accumulated<br>Amortization | Net Book<br>Value | Cost              | Accumulated<br>Amortization | Net Book<br>Value |
| Intellectual property | \$ 310               | \$ 226                      | \$ 84             | \$ 310            | \$ 195                      | \$ 115            |
| Patents               | 664                  | 252                         | 412               | 679               | 230                         | 449               |
| Other                 | 205                  |                             | 205               | 209               |                             | 209               |
| Total                 | \$ 1,179             | \$ 478                      | \$ 701            | \$ 1,198          | \$ 425                      | \$ 773            |

Amortization expense for intangible assets was less than \$0.1 million during the three and nine months ended September 30, 2009 and 2008, respectively. Amortization expense for intangible assets is expected to be approximately \$0.1 million for each of the years 2009 through 2013.

**E. 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 2014. Some of our leases have early termination clauses. The future minimum lease payments required under these leases are approximately \$0.3 million for the remainder of 2009, \$0.8 million in 2010, \$0.6 million in 2011, \$0.3 million in 2012 and \$0.1 million in 2013. Rent expense for the three months ended September 30, 2009 and 2008 was approximately \$0.2 million for each period. Rent expense for each of the nine months ended September 30, 2009 and 2008 was \$0.6 million.

We have entered into employment agreements with Craig J. Tuttle, our President and Chief Executive Officer, Debra A. Schneider, our Chief Financial Officer, Vice President, Secretary and Treasurer, and Eric P. Kaldjian M.D., our Chief Scientific Officer. The current term of Mr. Tuttle's employment agreement ends on July 12, 2010. The current term of Ms. Schneider's employment agreement ends on December 4, 2009. The current term of Dr. Kaldjian's employment agreement ends on December 31, 2009. Each employment agreement provides that the executive officer will be entitled to receive severance payments from the Company if his or her 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 their annual base salary at the time of termination and will be paid to them over a twelve-month period. The employment agreements provide that the severance payment provisions will be honored if the Company is acquired by, or merged into, another company and their positions are eliminated as a result of such acquisition or merger. In addition we have one

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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.

We have entered into agreements for professional services related to our annual audit, quarterly SEC filings, tax preparation and Sarbanes Oxley compliance work. At September 30, 2009 our commitment for these services is \$0.2 million.

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At September 30, 2009, firm commitments to vendors to purchase components used in WAVE Systems and instruments manufactured by others totaled \$0.3 million.

**F. 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 and 2008. We have state income tax returns subject to examination primarily for tax years 2006 through 2008. 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 2005 through 2008.

Income tax benefit for the nine months ended September 30, 2009 was a benefit of \$0.1 million. This is partially the result of the change in deferred tax assets and liabilities reported in financial statements of subsidiaries outside the U.S due primarily to foreign currency exchange losses. A refundable tax credit related to the 2008 Federal and State Income Tax returns was also recorded. This credit is anticipated to continue for 2009. This tax benefit is partially offset by tax expense related to state taxes as well as reserves for uncertain income taxes. We believe the tax benefit recorded will be partially offset in future periods by a tax expense related to income reported in financial statements of subsidiaries outside the United States. Income tax expense for the nine months ended September 30, 2008 was less than \$0.1 million. The effective tax rate for the nine months ended September 30, 2009 is 5.3%, which is primarily the result of valuation allowances against the Net Operating Losses for the United States partially offset by the return to provision adjustment recorded in the financial statements and a refundable tax credit related to the 2008 Federal and State Income Tax returns.

During the three and nine months ended September 30, 2009, there were no material changes to the liability for uncertain tax positions.

**G. 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 June 1, 2009 we matched the employee's contributions at the rate of 50% on the first 6% of contributions. Effective June 1, 2009, 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. There were no contributions to the 401(k) plan in the third quarter of 2009. Contributions to the 401(k) plan were less than \$0.1 million for the nine months ended September 30, 2009. Contributions to the 401(k) plan were less than \$0.1 million for the three months ended September 30, 2008, and \$0.1 million for the nine months ended September 30, 2008.

**H. 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, 2009 and 2008. At September 30, 2009, there were warrants outstanding which were exercisable to purchase 7,978,156 shares of common stock.

| Warrant Holder                    | Issue Year | Expiration Year | Underlying Shares | Exercise Price |
|-----------------------------------|------------|-----------------|-------------------|----------------|
| Various Institutional Holders (1) | 2005       | 2010            | 6,903,156         | \$ 1.20        |
| Laurus Master Fund, Ltd. (2)      | 2003       | 2010            | 200,000           | \$ 1.92        |
| Laurus Master Fund, Ltd. (2)      | 2003       | 2010            | 200,000           | \$ 2.07        |
| Laurus Master Fund, Ltd. (2)      | 2003       | 2010            | 150,000           | \$ 2.35        |
| Laurus Master Fund, Ltd. (2)      | 2004       | 2011            | 125,000           | \$ 2.57        |
| Laurus Master Fund, Ltd. (2)      | 2004       | 2011            | 400,000           | \$ 1.18        |

|       |           |
|-------|-----------|
| Total | 7,978,156 |
|-------|-----------|

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

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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.

*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. 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.

**I. STOCK OPTIONS**

The following table summarizes stock option activity during the nine months ended September 30, 2009:

|                                    | Number<br>of<br>Options | Weighted Average<br>Exercise Price |
|------------------------------------|-------------------------|------------------------------------|
| Balance at January 1, 2009:        | 3,531,064               | \$ 2.54                            |
| Granted                            | 70,000                  | .42                                |
| Exercised                          |                         |                                    |
| Forfeited/Expired                  | 195,500                 | 3.81                               |
| Balance at September 30, 2009:     | 3,405,564               | \$ 2.42                            |
| Exercisable at September 30, 2009: | 2,425,838               | \$ 3.15                            |

During the nine months ended September 30, 2009, we granted options exercisable to purchase 70,000 shares of common stock at a weighted average exercise price of \$0.42 under our 2006 Equity Incentive Plan. The weighted average fair value per share on grant date of options granted during the nine months ended September 30, 2009 was \$0.35.

**J. OPERATING SEGMENT AND GEOGRAPHIC INFORMATION**

Our company's 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.

We have two reportable operating segments.



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Segment information for the three months ended September 30, 2009 and 2008 is as follows:

|                                | Dollars in Thousands   |                 |                 |                        |                 |                 |
|--------------------------------|------------------------|-----------------|-----------------|------------------------|-----------------|-----------------|
|                                | 2009                   |                 |                 | 2008                   |                 |                 |
|                                | Instrument<br>Business | Lab<br>Services | Total           | Instrument<br>Business | Lab<br>Services | Total           |
| Net Sales                      | \$ 3,852               | \$ 1,194        | \$ 5,046        | \$ 4,395               | \$ 972          | \$ 5,367        |
| Gross Profit                   | 2,229                  | 524             | 2,753           | 2,531                  | 388             | 2,919           |
| Net Income/(Loss) before Taxes | 70                     | (470)           | (400)           | (109)                  | (377)           | (486)           |
| Income Tax Expense (Benefit)   | (34)                   |                 | (34)            | 13                     |                 | 13              |
| <b>Net Income/(Loss)</b>       | <b>\$ 104</b>          | <b>\$ (470)</b> | <b>\$ (366)</b> | <b>\$ (122)</b>        | <b>\$ (377)</b> | <b>\$ (499)</b> |
| Depreciation/Amortization      | 92                     | 74              | 166             | 130                    | 53              | 183             |
| Restructure                    |                        |                 |                 |                        |                 |                 |
| Interest Income, Net           | 1                      |                 | 1               | 18                     | 4               | 22              |

Segment information for the nine months ended September 30, 2009 and 2008 is as follows:

|                                | Dollars in Thousands   |                   |                   |                        |                 |                 |
|--------------------------------|------------------------|-------------------|-------------------|------------------------|-----------------|-----------------|
|                                | 2009                   |                   |                   | 2008                   |                 |                 |
|                                | Instrument<br>Business | Lab<br>Services   | Total             | Instrument<br>Business | Lab<br>Services | Total           |
| Net Sales                      | \$ 11,794              | \$ 3,714          | \$ 15,508         | \$ 14,907              | \$ 2,962        | \$ 17,869       |
| Gross Profit                   | 6,692                  | 1,525             | 8,217             | 9,064                  | 1,235           | 10,299          |
| Net Income/(Loss) before Taxes | (451)                  | (1,712)           | (2,163)           | 539                    | (795)           | (256)           |
| Income Tax Expense (Benefit)   | (114)                  |                   | (114)             | 20                     |                 | 20              |
| <b>Net Income/(Loss)</b>       | <b>\$ (337)</b>        | <b>\$ (1,712)</b> | <b>\$ (2,049)</b> | <b>\$ 519</b>          | <b>\$ (795)</b> | <b>\$ (276)</b> |
| Depreciation/Amortization      | 352                    | 207               | 559               | 405                    | 152             | 557             |
| Restructure                    |                        |                   |                   | 8                      |                 | 8               |
| Interest Income, Net           | 10                     | 4                 | 14                | 67                     | 13              | 80              |

|              | September 30, 2009 |          |           | December 31, 2008 |          |           |
|--------------|--------------------|----------|-----------|-------------------|----------|-----------|
| Total Assets | \$ 8,686           | \$ 6,669 | \$ 15,355 | \$ 10,226         | \$ 7,330 | \$ 17,556 |

Net sales by product were as follows:

|                                     | Dollars in Thousands<br>Three Months Ended<br>September 30, |          | Dollars in Thousands<br>Nine Months Ended<br>September 30, |           |
|-------------------------------------|-------------------------------------------------------------|----------|------------------------------------------------------------|-----------|
|                                     | 2009                                                        | 2008     | 2009                                                       | 2008      |
| <b>Instrument Related Business:</b> |                                                             |          |                                                            |           |
| Bioinstruments                      | \$ 1,999                                                    | \$ 2,196 | \$ 6,215                                                   | \$ 7,987  |
| Bioconsumables                      | 1,853                                                       | 2,199    | 5,579                                                      | 6,920     |
|                                     | 3,852                                                       | 4,395    | 11,794                                                     | \$ 14,907 |
| <b>Laboratory Services:</b>         |                                                             |          |                                                            |           |

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|                                         |          |          |        |           |
|-----------------------------------------|----------|----------|--------|-----------|
| Molecular Clinical Reference Laboratory | 923      | 736      | 2,886  | 1,950     |
| Pharmacogenomics Research Services      | 271      | 236      | 828    | 1,012     |
|                                         | 1,194    | 972      | 3,714  | 2,962     |
| Total Net Sales                         | \$ 5,046 | \$ 5,367 | 15,508 | \$ 17,869 |



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Net cost of goods sold was as follows:

|                                         | Dollars in Thousands<br>Three Months Ended<br>September 30, |                 | Dollars in Thousands<br>Nine Months Ended<br>September 30, |                 |
|-----------------------------------------|-------------------------------------------------------------|-----------------|------------------------------------------------------------|-----------------|
|                                         | 2009                                                        | 2008            | 2009                                                       | 2008            |
| <b>Instrument Related Business:</b>     |                                                             |                 |                                                            |                 |
| Bioinstruments                          | \$ 526                                                      | \$ 767          | \$ 2,167                                                   | \$ 2,710        |
| Bioconsumables                          | 1,097                                                       | 1,097           | 2,935                                                      | 3,133           |
|                                         | \$ 1,623                                                    | \$ 1,864        | 5,102                                                      | 5,843           |
| <b>Laboratory Services:</b>             |                                                             |                 |                                                            |                 |
| Molecular Clinical Reference Laboratory | 479                                                         | 429             | 1,607                                                      | 1,196           |
| Pharmacogenomics Research Services      | 191                                                         | 155             | 582                                                        | 531             |
|                                         | 670                                                         | 584             | 2,189                                                      | 1,727           |
| <b>Total Cost of Goods Sold</b>         | <b>\$ 2,293</b>                                             | <b>\$ 2,448</b> | <b>\$ 7,291</b>                                            | <b>\$ 7,570</b> |

Net sales for the three and nine months ended September 30, 2009 and 2008 by country were as follows:

|                     | Dollars in Thousands<br>Three Months Ended<br>September 30, |                 | Dollars in Thousands<br>Nine Months Ended<br>September 30, |                  |
|---------------------|-------------------------------------------------------------|-----------------|------------------------------------------------------------|------------------|
|                     | 2009                                                        | 2008            | 2009                                                       | 2008             |
| United States       | \$ 1,920                                                    | \$ 2,180        | \$ 6,524                                                   | \$ 7,044         |
| Italy               | 913                                                         | 499             | 2,676                                                      | 2,321            |
| Germany             | 441                                                         | 359             | 973                                                        | 1,279            |
| France              | 386                                                         | 772             | 1,175                                                      | 2,082            |
| Netherlands         | 296                                                         | 71              | 388                                                        | 318              |
| United Kingdom      | 230                                                         | 315             | 666                                                        | 1,509            |
| China               | 82                                                          | 58              | 757                                                        | 249              |
| All Other Countries | 778                                                         | 1,113           | 2,349                                                      | 3,067            |
| <b>Total</b>        | <b>\$ 5,046</b>                                             | <b>\$ 5,367</b> | <b>\$ 15,508</b>                                           | <b>\$ 17,869</b> |

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 three and nine months ended September 30, 2009 and 2008. For the three and nine months ended September 30, 2009 one customer made up 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. For the three and nine months ended September 30, 2008 two customers each made up more than 10% of the Laboratory Services net sales. Combined they represent 35% of the Laboratory Services 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.

**K. SUBSEQUENT EVENTS**

We have no material subsequent events to be disclosed as of November 5, 2009 which is the date our financial statements were issued.



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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, 2008. Results for the quarter ended September 30, 2009 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 over 1,450 WAVE Systems as of September 30, 2009. 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, is

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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.

### **Executive Summary**

Net sales for the nine months ended September 30, 2009 decreased by \$2.4 million or 13% compared to the same period in 2008. Net sales in our Instrument Related Business were down 21% or \$3.1 million for the nine months ended September 30, 2009 compared to the same period in 2008. The difficult global economic climate has had an impact on our business in 2009. Net sales from bioinstruments were down 22% and net sales of consumables were down 19% for the comparable nine month periods. During the nine months ended September 30, 2009, net sales from Laboratory Services grew 25%, or \$0.8 million, compared to the same nine month period in 2008. The Clinical Reference Laboratory showed revenue growth of 48% and net sales from Pharmacogenomics Research Services decreased by 18%. Our gross profit margin decreased from 58% for the nine months ended September 30, 2008 to 53% for the same period in 2009. Our net loss was \$2.0 million for the nine months ended September 30, 2009 compared to net loss of \$0.3 million for the nine months ended September 30, 2008.

As of September 30, 2009, we had cash and cash equivalents of \$4.7 million, compared to \$4.8 million at December 31, 2008.

### **Outlook**

We continue to work toward our objective of generating income from continuing operations and positive cash flows from continuing operations. To accomplish these goals, we must generate sequential growth in net sales and continue to control manufacturing and other operating expenses.

### **Uncertainties**

The uncertainty of the current general global economic conditions could negatively impact our business in the future.

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 may not be able to obtain such funding due to the tightened credit markets. At September 30, 2009 we had cash and cash equivalents of \$4.7 million. We believe that existing sources of liquidity are sufficient to meet expected cash needs during 2009.

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 introduced in the marketplace also may impact our sales.

We have revaluation risk which occurs when the transaction is done in a currency other than the British Pound. 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. The foreign exchange rates have had large variances recently. At January 1, 2008 the Euro to Great British Pound exchange rate was .73650 as compared to September 30, 2009 rate of .91660. The Great British Pound to US Dollar exchange rate was 1.9970 at January 1, 2008 compared to 1.59220 at September 30, 2009. These large changes in foreign exchange rates may negatively impact our business in 2009.

**Table of Contents****Results of Continuing Operations****Three Months Ended September 30, 2009 and 2008**

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

|                                         | Dollars in Thousands                |                 |                 |             |
|-----------------------------------------|-------------------------------------|-----------------|-----------------|-------------|
|                                         | Three Months Ended<br>September 30, |                 | Change          |             |
|                                         | 2009                                | 2008            | \$              | %           |
| <b>Instrument Related Business:</b>     |                                     |                 |                 |             |
| Bioinstruments                          | \$ 1,999                            | \$ 2,196        | \$ (197)        | (9)%        |
| Bioconsumables                          | 1,853                               | 2,199           | (346)           | (16)%       |
|                                         | 3,852                               | 4,395           | (543)           | (12)%       |
| <b>Laboratory Services:</b>             |                                     |                 |                 |             |
| Molecular Clinical Reference Laboratory | 923                                 | 736             | 187             | 25%         |
| Pharmacogenomics Research Services      | 271                                 | 236             | 35              | 15%         |
|                                         | 1,194                               | 972             | 222             | 23%         |
| <b>Total Net sales</b>                  | <b>\$ 5,046</b>                     | <b>\$ 5,367</b> | <b>\$ (321)</b> | <b>(6)%</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 \$0.2 million, or 9%, during the three months ended September 30, 2009 as compared to the same period in 2008. In 2009 we sold 6 total instruments compared to 5 instruments in the same period of 2008. There was one OEM instrument sold in the third quarter of 2009 compared to three OEM instrument sales in the third quarter of 2008. Five WAVE systems were sold during the three months ended September 30, 2009, compared to two during the same period of 2008. The WAVE instruments have a lower average sales price compared to the OEM instruments. Accordingly, the combination of an increase in sales of WAVE instruments and the decrease in sales of OEM instruments in the third quarter of 2009 contributed to our overall decline in net sales for the three months ended September 30, 2009 compared to the same period of 2008. There was also a reduction in service contract net sales primarily in the European market. This reduction was due to lower sales volume and a foreign currency exchange impact of \$0.1 million. Instrument related revenue is subject to many factors such as type of instrument sold and the country of sale. Due to these factors each quarter should be considered on a stand alone basis and is not indicative of future net sales streams.

Net sales of bioconsumables decreased during the three months ended September 30, 2009 compared to 2008. The foreign currency exchange impact included in this decrease was \$0.2 million.

Net sales of Laboratory Services increased during the three months ended September 30, 2009 compared to 2008 by approximately \$0.2 million. 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 \$0.9 million increased 25% over the three months ended September 30, 2008. The Pharmacogenomics Research Services net sales of \$0.3 million increased 15% over the three months ended September 30, 2008. The Molecular Clinical Reference Laboratory revenue has increased due to increased test volume. Our test volume has increased by 42% due to our increased sales focus. The average revenue per test has decreased by 12% due to the mix of tests performed and increased Medicare and Medicaid test volumes which drives lower reimbursements for these tests. During the three months ended September 30, 2009 and 2008 Pharmacogenomics Research Services net sales consisted of many midsize customers. The Pharmacogenomics Research Services net sales have peaks due to the nature of project related business. Each quarter Pharmacogenomics Research Services should be considered on a stand alone basis and is not indicative of future net sales.

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*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, 2009   | 2008     | \$       | %     |
| <b>Instrument Related Business:</b>     |                      |          |          |       |
| Bioinstruments                          | \$ 526               | \$ 767   | \$ (241) | (31)% |
| Bioconsumables                          | 1,097                | 1,097    |          | %     |
|                                         | 1,623                | 1,864    | (241)    | (13)% |
| <b>Laboratory Services:</b>             |                      |          |          |       |
| Molecular Clinical Reference Laboratory | 479                  | 429      | 50       | 12%   |
| Pharmacogenomics Research Services      | 191                  | 155      | 36       | 23%   |
|                                         | 670                  | 584      | 86       | 15%   |
| Cost of goods sold                      | \$ 2,293             | \$ 2,448 | \$ (155) | (6)%  |

Gross profit was \$2.8 million or 55% of total net sales during the third quarter of 2009, compared to \$2.9 million or 54% during the same period of 2008. The gross margin for the Instrument Related Business was 58% for both the three months ended September 30, 2009 and 2008. Cost of sales for the Instrument Related Business decreased \$0.2 million for the third quarter of 2009 compared to the same period of 2008 which was offset by net sales which were lower by \$0.5 million. During the three months ended September 30, 2009, the gross margin for Laboratory Services was 44% as compared to 40% in the same period of 2008. The Laboratory Services gross margin increase is attributed to leverage in the organization. Net sales increased \$0.2 million and costs of goods increased less than \$0.1 million. The decrease in average net revenue per test is a result of test mix and increased Medicare and Medicaid test volume which drives lower reimbursements. Test volume during this period grew by 42% as compared to net sales growth of 25%.

*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, which was a gain of \$0.1 million in the three months ended September 30, 2009 and nominal in the same period of 2008, our selling, general and administrative costs decreased from \$2.8 million in 2008 to \$2.3 million in 2009. The primary decrease is due to open employment positions not being filled, lower commissions, and lower travel 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. For the three months ended September 30, 2009 these costs totaled \$0.9 million compared to \$0.7 million for the three months ended September 30, 2008. The increase is primarily due to 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).

Research and development expenses totaled 19% and 13% of net sales during the three months ended September 30, 2009 and 2008, respectively.

*Other Income (Expense).* Other income consists primarily of interest income from cash and cash equivalents invested in overnight instruments. Other income during the three months ended September 30, 2009 and September 30, 2008 was less than \$0.1 million for each period.

*Income Tax Expense (Benefit).* Income tax benefit for the three months ended September 30, 2009 was a benefit of less than \$0.1 million. This is primarily the result of a refundable tax credit anticipated for the 2009 Federal and State Income Tax returns recorded this period. This tax benefit is partially offset by tax expense related to subsidiaries outside the United States and state taxes as well as reserves for uncertain income taxes. We believe the tax benefit recorded will be partially offset in future periods by a tax expense, related to income reported in financial statements of subsidiaries outside the United States. Income tax expense for the three months ended September 30, 2008 was less than \$0.1 million.





**Table of Contents****Results of Continuing Operations****Nine Months Ended September 30, 2009 and 2008**

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

|                                         | Dollars in Thousands               |                  |                   |              |
|-----------------------------------------|------------------------------------|------------------|-------------------|--------------|
|                                         | Nine Months Ended<br>September 30, |                  | Change            |              |
|                                         | 2009                               | 2008             | \$                | %            |
| <b>Instrument Related Business:</b>     |                                    |                  |                   |              |
| Bioinstruments                          | \$ 6,215                           | \$ 7,987         | \$ (1,772)        | (22)%        |
| Bioconsumables                          | 5,579                              | 6,920            | (1,341)           | (19)%        |
|                                         | 11,794                             | 14,907           | (3,113)           | (21)%        |
| <b>Laboratory Services:</b>             |                                    |                  |                   |              |
| Molecular Clinical Reference Laboratory | 2,886                              | 1,950            | 936               | 48%          |
| Pharmacogenomics Research Services      | 828                                | 1,012            | (184)             | (18)%        |
|                                         | 3,714                              | 2,962            | 752               | 25%          |
| <b>Total Net Sales</b>                  | <b>\$ 15,508</b>                   | <b>\$ 17,869</b> | <b>\$ (2,361)</b> | <b>(13)%</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 \$1.8 million, or 22%, during the nine months ended September 30, 2009 as compared to the same period in 2008. The decrease in bioinstrument net sales was due to a change in product mix in the nine months ended September 30, 2009. We sold ten OEM instruments in the nine months ended September 30, 2008 compared to five in the nine months ended September 30, 2009. We sold eighteen WAVE Systems in the nine months ended September 30, 2009 as compared to sixteen in the nine months ended September 30, 2008. The WAVE instruments have a lower average sales price compared to the OEM instruments. The average sales price also was lower due to the geographic make up of the sales, which accounted for the majority of the decrease. The foreign currency conversion rate difference between 2009 and 2008 impacted the average net sales price on our European sales. There was also a reduction in service contract net sales, primarily in the European market. This reduction was primarily related to foreign currency exchange impact. 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 quarter should be considered on a stand alone basis and is not indicative of future net sales streams.

Net sales of bioconsumables decreased during the nine months ended September 30, 2009 compared to 2008. The primary decrease in consumables is due to the negative impact of the foreign currency exchange rates, primarily the Great British Pound to the US Dollar. There is also some negative volume impact in our European market.

Net sales of Laboratory Services increased during the nine months ended September 30, 2009 compared to 2008 by approximately \$0.8 million. 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 \$2.9 million increased 48% over the nine months ended September 30, 2008. The Pharmacogenomics Research Services net sales of \$0.8 million during the nine months ended September 30, 2009 decreased 18% from the nine months ended September 30, 2008. The decrease in Pharmacogenomics Research Services is due to one large customer in the first half of 2008 which has completed its project. The Pharmacogenomics Research Services net sales have peaks due to the nature of project related business. Each quarter Pharmacogenomics Research Services should be considered on a stand alone basis and is not indicative of future net sales.

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*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,<br>2009 | 2008            | \$              | %           |
| <b>Instrument Related Business:</b>     |                       |                 |                 |             |
| Bioinstruments                          | \$ 2,167              | \$ 2,710        | \$ (543)        | (20)%       |
| Bioconsumables                          | 2,935                 | 3,133           | (198)           | (6)%        |
|                                         | 5,102                 | 5,843           | (741)           | (13)%       |
| <b>Laboratory Services:</b>             |                       |                 |                 |             |
| Molecular Clinical Reference Laboratory | 1,607                 | 1,196           | 411             | 34%         |
| Pharmacogenomics Research Services      | 582                   | 531             | 51              | 10%         |
|                                         | 2,189                 | 1,727           | 462             | 27%         |
| <b>Cost of goods sold</b>               | <b>\$ 7,291</b>       | <b>\$ 7,570</b> | <b>\$ (279)</b> | <b>(4)%</b> |

Gross profit was \$8.2 million or 53% of total net sales during the nine months ended September 30, 2009, compared to \$10.3 million or 58% during the same period of 2008. Cost of sales for the Instrument Related Business decreased by 13% for the nine months ended September 30, 2009 compared to the same period of 2008 on a net sales decrease of 21%. This margin erosion is related to a lower average instrument sales price globally and lower service net sales, primarily in the European market. While we did reduce costs somewhat, we do have a fixed cost base related to the instrument related business in addition to more variable costs directly related to the acquisition of products. The Laboratory Services cost of goods sold increased 27% for the nine months ended September 30, 2009 over the same period of 2008. During the nine months ended September 30, 2009, the gross margin for the Laboratory Services was relatively flat at 41% as compared to 42% in the same period of 2008. Gross margin is impacted by the mix of tests sold and the lower average net sales reimbursement per test due to increased Medicare and Medicaid test volume which is largely offset by leverage on the cost side. Test volume during this nine month period grew by 80%. Our direct variable costs per test can be significantly different for some of the tests we offer. For instance, the CMA test, our fastest growing test, has a higher direct variable cost than many other of our tests.

*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, which was a loss of \$0.3 million in the nine months ended September 30, 2009 and a gain of \$0.5 million in the same period of 2008, our selling, general and administrative costs decreased from \$9.3 million to \$7.7 million. The primary decrease is due to no employee bonus accrual, reductions in staff and open positions not filled, lower travel expenses, lower stock option expense and a reduction in bad debt 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. For the nine months ended September 30, 2009 these costs totaled \$2.5 million compared to \$1.8 million for the nine months ended September 30, 2008. The increase is primarily due to collaboration expenses with Power3 for their NuroPro assay development related to the diagnosis of Alzheimer's and Parkinson's diseases, the Dana-Farber Cancer Institute related to the development of high sensitivity mutation detection technology called Cold-PCR and purchases of samples related to research work in progress.

Research and development expenses totaled 16% and 10% of net sales during the nine months ended September 30, 2009 and 2008, 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, 2009 and September 30, 2008 was less than \$0.1 million for each period.



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*Income Tax Expense (Benefit).* Income tax benefit for the nine months ended September 30, 2009 was a benefit of \$0.1 million. This is partially the result of the change in deferred tax assets and liabilities reported in financial statements of subsidiaries outside the U.S due primarily to foreign currency exchange losses. A refundable tax credit related to the 2008 Federal and State Income Tax returns was also recorded. This credit is anticipated to continue for 2009. This tax benefit is partially offset by tax expense related to state taxes as well as reserves for uncertain income taxes. We believe the tax benefit recorded will be partially offset in future periods by a tax expense, related to income reported in financial statements of subsidiaries outside the United States. Income tax expense for the nine months ended September 30, 2008 was less than \$0.1 million.

**Liquidity and Capital Resources**

Our working capital positions at September 30, 2009 and December 31, 2008 were as follows:

|                                                                                           | Dollars in Thousands  |                      |                   |
|-------------------------------------------------------------------------------------------|-----------------------|----------------------|-------------------|
|                                                                                           | September 30,<br>2009 | December 31,<br>2008 | Change            |
| Current assets (including cash and cash equivalents of \$4,661 and \$4,771, respectively) | \$ 13,595             | \$ 15,585            | \$ (1,990)        |
| Current liabilities                                                                       | 3,663                 | 4,235                | (572)             |
| <b>Working capital</b>                                                                    | <b>\$ 9,932</b>       | <b>\$ 11,350</b>     | <b>\$ (1,418)</b> |

The working capital decrease at September 30, 2009 compared to December 31, 2008 is a result of lower accounts receivable of \$1.2 million and lower inventories of \$0.6 million offset by lower accrued expenses of \$0.5 million.

Management believes existing sources of liquidity, including cash and cash equivalents of \$4.7 million, are sufficient to meet expected cash needs during 2009. We have added experienced sales staff in our business in an effort to drive improved sales in 2009. We have also increased our research costs to drive new products and collaborations which should drive future growth. As a result of the current economic outlook in 2009 we cannot assure you that we will be able to maintain our net sales or further reduce our expenses and, accordingly, we may not have sufficient sources of liquidity to continue operations indefinitely. If necessary, management believes they can further reduce costs and expenses to conserve working capital. However, such cost and expense reductions could have an adverse impact on our new product pipeline and ultimately net sales. We could also pursue additional financing, but optimally, our goal is to achieve sufficient net sales to consistently generate net income and positive cash flow.

**Analysis of Cash Flows****Nine Months Ended September 30, 2009 and 2008**

*Net Change in Cash and Cash Equivalents.* Cash and cash equivalents decreased \$0.1 million during the nine months ended September 30, 2009 compared to a decrease of \$0.9 million during the nine months ended September 30, 2008. 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 no impact of foreign currency exchange rates. In 2008 net cash used in operating activities was \$0.5 million and net cash flow used in investing activities was \$0.3 million. The impact of foreign currency exchange rates was a use of cash of \$0.2 million in 2008.

*Cash Flows Provided by Operating Activities.* Cash flows provided by operating activities totaled \$0.2 million during the nine months ended September 30, 2009. The cash flows provided by operating activities in 2009 primarily relate to the accounts receivable collections of \$1.5 million, the decrease in inventory of \$0.7 million and noncash items of \$0.8 million, offset by the loss of \$2.0 million and lower accrued expenses and accounts payable of \$0.7 million. Cash flows used in operating activities totaled \$0.5 million during the nine months ended September 30, 2008. The cash flows used in operating activities in 2008 primarily relate to the net loss of \$0.3 million. In addition, accounts receivable decreased by \$0.2 million, inventory increased by \$0.3 million, accounts payable decreased by \$0.4 million, accrued expenses decreased by \$0.3 million and noncash items totaled \$0.7 million.

*Cash Flows Used In Investing Activities.* Cash flows used in investing activities totaled \$0.3 million for each of the nine months ended September 30, 2009 and September 30, 2008. Cash flows used in investing activities in 2009 and 2008 consisted primarily of purchases of property and equipment.



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

At September 30, 2009 and December 31, 2008, 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, 2008.

### **Recently Issued Accounting Pronouncements**

Please refer to our annual report on Form 10-K for the fiscal year ended December 31, 2008. 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 had a material adverse effect on our financial condition or results of operations during the periods presented.

### **Item 3. Quantitative and Qualitative Disclosures 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 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, Great British Pounds, 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 done in a currency other than the British Pound. 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. The foreign exchange rates have had large variances recently. At January 1, 2008 the Euro to Great British Pound exchange rate was .73650 as compared to September 30, 2009 rate of .91660. The Great British Pound to US Dollar exchange rate was 1.9970 at January 1, 2008 compared to 1.59220 at September 30, 2009. These large changes in foreign exchange rates may negatively impact our business in 2009.

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

*Evaluation of Disclosure Controls and Procedures.* We evaluated the design and operating effectiveness of our disclosure controls and procedures as of September 30, 2009 pursuant to Rule 13a-15(b) of the Securities Exchange Act of 1934. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, because of the material weakness in our internal control over financial reporting described in item 9A(T) of our report on Form 10-K for the fiscal year ended December 31, 2008, our disclosure controls and procedures as defined in Rule 13a-15(e) continued to not be effective. To address the material weakness in our internal control over financial reporting, management performed additional manual procedures and analysis and other post-closing procedures in order to prepare the consolidated financial statements included in this report. Notwithstanding the material weakness in our internal control over financial reporting as of September 30, 2009, we believe that the consolidated financial statements contained in this report present fairly our financial condition, results of operations, and cash flows for the fiscal years covered thereby in all material respects.

*Change in Internal Control Over Financial Reporting.* There has been no change 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 a number of claims of various amounts which arise out of the normal course of our business. In our opinion, the disposition of pending claims will not have a material adverse effect on our financial position, results of operations or cash flows.

**Item 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, 2008 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, 2008 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 exposure on individual claims and, therefore, there is no assurance that such coverage will be adequate.

The clinical laboratory testing industry is subject to extensive regulation. Potential sanctions for violation of statutes and regulations include significant fines and the loss of various licenses, certificates and authorizations. We believe that we are in compliance in all material respects with all statutes, regulations and other requirements applicable to our clinical laboratory operations.

The United States government may pass a public health insurance option. In the event this occurs we would need to do extensive evaluation of the plan to determine the impact of our revenue streams.

**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, 2008 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 5. Other Information**  
**The Dana-Farber Cancer Institute**

On October 8, 2009 we announced that we licensed a high-sensitivity mutation detection technology called Cold-PCR from the Dana-Farber Cancer Institute (DFCI), Boston, MA. This variation of the standard PCR technology enriches mutations in DNA samples and is a much more sensitive technique for finding low level mutations in tissue and body fluids that are involved with a variety of diseases. Cold-PCR was invented at DFCI by Dr. Mike Makrigiorgos who has demonstrated its effectiveness in enriching for mutations in cancer-related genes in samples where standard DNA sequencing is not sensitive enough to detect these very low concentration somatic DNA mutations. The licensing terms include exclusive rights to commercialize Cold-PCR technology combined with Sanger sequencing as well as all applications for mitochondrial DNA analysis.





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Cold-PCR will have applicability in detection of cancer-related mutations where critical mutations are present at a very low percentage compared to normal DNA. Examples would be in blood and urine or where the tissue collected contains mostly normal cells. This would allow clinicians to use less intrusive methods for genetic analysis or allow more efficient use of tumor tissue samples. Additionally the method could enhance the detection of the emergence of cancer-drug resistance mutations, allowing early detection of relapse.

We believe that Cold-PCR is a critical addition to our high-sensitivity mutation detection portfolio of cutting edge technologies. It will allow us to continue offering affordable, state-of-the-art solutions to challenging areas of genetic analysis and, we hope, allow us to be able to screen patient blood for early detection of cancer, detect cancer drug resistance or relapse earlier as well as expand our mitochondrial DNA analysis toolbox. We have long wanted a technology that would permit us to screen patients earlier in their development of cancer and we hope that Cold-PCR provides us the sensitivity and analytical accuracy to achieve this goal. Discovering cancers at a much earlier phase of development will have a huge impact on cancer diagnosis and treatment.

The expense recorded for our license with the Dana-Farber Cancer Institute during the three and nine months ended September 30, 2009 was \$0.2 million.

### **Power3 Medical Products, Inc.**

On January 23, 2009 we signed a definitive collaboration and exclusive license agreement with Power3 Medical Products, Inc. for the rights to Power3 Medical's neurodegenerative biomarkers.

The agreement grants us exclusive rights in the U.S. and certain international markets to neurodegenerative biomarkers from Power3 Medical including NuroPro<sup>®</sup>, a proposed diagnostic for Alzheimer's and Parkinson's diseases based on Power3's proteomics platform. We will pay Power3 Medical an up-front license fee, milestone payments, royalties, and will also provide development funding and resources.

We will offer the NuroPro tests in our CLIA-certified molecular diagnostics laboratory and will add to our portfolio of molecular diagnostics used for mitochondrial disorders, oncology, hematology molecular pathology, and inherited diseases.

The expense recorded for payments made to Power3 Medical Products, Inc. during the three and nine months ended September 30, 2009 was less than \$0.1 million and \$0.2 million, respectively.

## **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)
- 10.1 License Agreement between the Company and the Dana-Farber Cancer Institute dated October 8, 2009
- 10.2 License Agreement between the Company and Power3 Medical Products, Inc. dated January 23, 2009
- 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 5, 2009

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

*President and Chief Executive Officer*