TRANSGENOMIC INC
Form 10-Q
November 10, 2011
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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Quarterly Period Ended September 30, 2011

Or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number: 000-30975

TRANSGENOMIC, INC.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	911789357 (I.R.S. Employer Identification No.)
12325 Emmet Street, Omaha, Nebraska (Address of principal executive offices)	68164 (Zip Code)

(402) 452-5400
(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 x No o

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

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 o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller Reporting Company x

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

As of November 9, 2011, the number of shares of common stock outstanding was 49,379,822.

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

	September 30, 2011 (unaudited)	December 31, 2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$1,423	$3,454
Accounts receivable, net	7,591	7,601
Inventories, net	3,306	3,344
Other current assets	1,336	635
Total current assets	13,656	15,034
PROPERTY AND EQUIPMENT:		
Equipment	10,105	9,820
Furniture, fixtures & leasehold improvements	3,723	3,479
	13,828	13,299
Less: accumulated depreciation	(12,231)	(11,697)
	1,597	1,602
OTHER ASSETS:		
Goodwill	6,275	6,275
Intangibles (net of accumulated amortization of $1,142 and $519, respectively)	8,325	8,962
Other assets	121	154
	$29,974	$32,027
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$1,721	$1,360
Accrued compensation	1,058	875
Short term debt	247	989
Current maturities of long term debt	1,234	—
Accrued liabilities	3,834	3,231
Contractual obligation	1,363	1,628
Current portion of lease obligations	197	170
Accrued preferred stock dividend	450	—
Total current liabilities	10,104	8,253
LONG TERM LIABILITIES:		
Long term debt less current maturities	7,405	8,640
Preferred stock conversion feature	8,000	1,983
Preferred stock warrant liability	3,200	2,351
Other long-term liabilities	974	843
Total liabilities	29,683	22,070
Redeemable Series A convertible preferred stock, $.01 par value, 3,879,307 shares authorized, 2,586,205 shares issued and outstanding	1,796	1,457
STOCKHOLDERS' EQUITY(DEFICIT):		
Preferred stock, $.01 par value, 15,000,000 shares authorized, 2,586,205 shares issued and outstanding	—	—
	499	498

Common stock, $.01 par value, 100,000,000 shares authorized, 49,379,822 and 49,289,672 shares issued and outstanding, respectively		
Additional paid-in capital	140,486	139,730
Accumulated other comprehensive income	1,675	1,589
Accumulated deficit	(144,165)	(133,317)
Total stockholders' equity (deficit)	(1,505)	8,500
	$29,974	$32,027

See notes to unaudited condensed consolidated financial statements.

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TRANSGENOMIC, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Dollars in thousands except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
NET SALES	$8,253	$4,419	$23,400	$14,956
COST OF GOODS SOLD	3,808	2,402	10,248	7,568
Gross profit	4,445	2,017	13,152	7,388
OPERATING EXPENSES:				
Selling, general and administrative	4,364	2,159	14,272	7,623
Research and development	515	613	1,650	1,952
Restructuring charges	5	72	40	72
	4,884	2,844	15,962	9,647
LOSS FROM OPERATIONS	(439)	(827)	(2,810)	(2,259)
OTHER INCOME (EXPENSE):				
Interest income (expense), net	(238)	—	(720)	1
Expense on preferred stock	(600)	—	(6,866)	—
Other, net	(2)	—	231	—
	(840)	—	(7,355)	1
LOSS BEFORE INCOME TAXES	(1,279)	(827)	(10,165)	(2,258)
INCOME TAX EXPENSE (BENEFIT)	(9)	71	(120)	109
NET LOSS	$(1,270)	$(898)	$(10,045)	$(2,367)
PREFERRED STOCK DIVIDENDS AND ACCRETION	(275)	—	(803)	—
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS	$(1,545)	$(898)	$(10,848)	$(2,367)
BASIC AND DILUTED LOSS PER COMMON SHARE	$(0.03)	$(0.02)	$(0.22)	$(0.05)
BASIC AND DILUTED WEIGHTED AVERAGE SHARES OF COMMON STOCK OUTSTANDING	49,327,527	49,289,672	49,306,861	49,228,561

See notes to unaudited condensed consolidated financial statements.

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TRANSGENOMIC, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
Nine Months Ended September 30, 2011
(Dollars in thousands except per share data)

	Common Stock					
	Outstanding Shares	Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance, January 1, 2011	49,289,672	$498	$139,730	$(133,317)	$ 1,589	$8,500
Net loss	—	—	—	(10,045)	(10,045)	(10,045)
Other comprehensive income (loss):						
Foreign currency translation adjustment, net of tax	—	—	—	—	86	86
Comprehensive loss					(9,959)	
Non-cash stock-based compensation	—	—	734	—	—	734
Issuance of shares of stock	90,150	1	22	—	—	23
Preferred stock accretion	—	—	—	(353)		(353)
Dividends on preferred stock	—	—	—	(450)	—	(450)
Balance, September 30, 2011	49,379,822	499	140,486	(144,165)	$ 1,675	$(1,505)

See notes to unaudited condensed consolidated financial statements.

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TRANSGENOMIC, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in thousands)

	Nine Months Ended September 30,	
	2011	2010
CASH FLOWS USED IN OPERATING ACTIVITIES:		
Net loss	$(10,045)	$(2,367)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation and amortization	1,506	523
Non-cash, stock based compensation	734	(29)
Provision for losses on doubtful accounts	1,432	29
Provision for losses on inventory obsolescence	47	78
Preferred stock revaluation	6,866	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,418)	940
Inventories	(44)	(245)
Prepaid expenses and other current assets	(269)	90
Accounts payable	137	(121)
Accrued liabilities	(131)	242
Other long term liabilities	268	(44)
Long term deferred income taxes	18	20
Net cash flows used in operating activities	(899)	(884)
CASH FLOWS USED IN INVESTING ACTIVITIES:		
Purchase of property and equipment	(147)	(141)
Change in other assets	(256)	(25)
Net cash flows used in investing activities	(403)	(166)
CASH FLOWS USED IN FINANCING ACTIVITIES:		
Principal payments on capital lease obligations	(165)	(57)
Issuance of common stock	23	42
Principal payment on note payable	(659)	—
Net cash flows used in financing activities	(801)	(15)
EFFECT OF FOREIGN CURRENCY EXCHANGE RATE CHANGES ON CASH	72	12
NET CHANGE IN CASH AND CASH EQUIVALENTS	(2,031)	(1,053)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,454	5,642
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$1,423	$4,589
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid during the period for:		
Interest	$495	$—
Income taxes, net	106	4
SUPPLEMENTAL DISCLOSURE OF NON-CASH INFORMATION		
Acquisition of equipment through capital leases	$388	$286
Dividends accrued on preferred stock	450	—

See notes to unaudited condensed consolidated financial statements.

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TRANSGENOMIC, INC. AND SUBSIDIARY
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
Three and Nine Months Ended September 30, 2011 and 2010

A. BUSINESS DESCRIPTION

Business Description.

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

- Clinical Laboratories. Our clinical laboratories specialize in genetic testing for cardiology, neurology, mitochondrial disorders, and oncology. Located in New Haven, Connecticut and Omaha, Nebraska the molecular clinical reference laboratories are certified under the Clinical Laboratory Improvement Amendment (CLIA) as high complexity labs and our Omaha facility is accredited by CAP (College of American Pathologists).
- Pharmacogenomics Services. Pharmacogenomics research services are provided by our Contract Research Organization located in Omaha, Nebraska. This lab specializes in pharmacogenomic, biomarker and mutation discovery research serving the pharmaceutical and biomedical industries world-wide for disease research, drug and diagnostic development and clinical trial support.
- Diagnostic Tools. Our proprietary product is the WAVE® System which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. There is a worldwide installed base of over 1,500 WAVE Systems as of September 30, 2011. We also distribute bioinstruments produced by other manufacturers ("OEM Equipment") through our sales and distribution network. Service contracts to maintain installed systems are sold and supported by our technical support personnel. The installed WAVE base and some OEM Equipment platforms generate a demand for consumables that are required for the continued operation of the bioinstruments. We develop, manufacture and sell these consumable products. In addition, we manufacture and sell consumable products that can be used on multiple, independent platforms. These products include SURVEYOR® Nuclease and a range of chromatography columns.

B. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation.

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

Risks and Uncertainties.

Certain risks and uncertainties are inherent in our day-to-day operations and to the process of preparing our financial statements.

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

Fair Value.

Unless otherwise specified, book value approximates fair market value. The preferred stock conversion feature and warrant liability are recorded at fair value. See Footnote I.

Basis of Presentation.

The condensed consolidated balance sheet as of December 31, 2010 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, 2011 and 2010 are unaudited and reflect all adjustments that are, in the opinion of management,

necessary for a fair presentation of the

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TRANSGENOMIC, INC. AND SUBSIDIARY
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
Three and Nine Months Ended September 30, 2011 and 2010

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, 2010 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 the date of acquisition of three months or less. Such investments presently consist of temporary overnight investments.

Accounts Receivable.

The following is a summary of activity for the allowance for doubtful accounts during the three and nine months ended September 30, 2011 and 2010:

	Dollars in Thousands			
	Beginning Balance	Provision	Write Offs	Ending Balance
Three Months Ended September 30, 2011	$1,387	$205	$(113)	$1,479
Three Months Ended September 30, 2010	$295	$40	$—	$335
Nine Months Ended September 30, 2011	$334	$1,433	$(288)	$1,479
Nine Months Ended September 30, 2010	$310	$29	$(4)	$335

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 and shown net of allowance for doubtful accounts and contractual allowances. The estimate made for doubtful accounts is based on a review of all outstanding amounts on a quarterly basis. We determine the allowance for doubtful accounts and contractual allowances by regularly evaluating individual customer receivables and considering a customer’s financial condition, credit history and current economic conditions. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

Inventories.

Inventories are stated at the lower of cost or market net of allowance for obsolete inventory. Cost is computed using standard costs for finished goods and average or latest actual cost for raw materials and work in process, which approximates the first-in, first-out (FIFO) method.

The following is a summary of activity for the allowance for obsolete inventory during the three and nine months ended September 30, 2011 and 2010:

	Dollars in Thousands			
	Beginning Balance	Provision	Write Offs	Ending Balance
Three Months Ended September 30, 2011	$520	$(2)	$(4)	$514
Three Months Ended September 30, 2010	$536	$12	$(28)	$520
Nine Months Ended September 30, 2011	$518	$47	$(51)	$514
Nine Months Ended September 30, 2010	$507	$78	$(65)	$520

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

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NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
Three and Nine Months Ended September 30, 2011 and 2010

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

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

Depreciation expense related to property and equipment during the three months ended September 30, 2011 and 2010 was $0.2 million and $0.1 million, respectively. Included in depreciation for the three months ended September 30, 2011 was less than $0.1 million related to equipment acquired under capital leases. Depreciation expense related to property and equipment during the nine months ended September 30, 2011 and 2010 was $0.5 million and $0.3 million, respectively. Included in depreciation for the nine months ended September 30, 2011 was $0.1 million related to equipment acquired under capital leases.

Goodwill.
Goodwill is the excess of the purchase price over fair value of assets acquired and is not amortized. Goodwill is tested for impairment annually. We perform this impairment analysis during the fourth quarter of each year or when a significant event occurs that may impact goodwill. Impairment occurs when the carrying value is determined to be not recoverable thereby causing the carrying value of the goodwill to exceed its fair value. If impaired, the asset's carrying value is reduced to its fair value. We recorded no impairment charges related to goodwill as of December 31, 2010. No events have transpired in the nine months ended September 30, 2011 that would require an impairment analysis prior to our scheduled review.

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, 2011 had vesting periods of one or three years from date of grant. None of the stock options outstanding at September 30, 2011 are subject to performance or market-based vesting conditions.

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

During the three months ended September 30, 2011, we recorded the recapture of compensation expense of less than $0.1 million within selling, general and administrative expense. During the nine months ended September 30, 2011, we recorded compensation expense of $0.7 million within selling, general and administrative expense as a result of the vesting of options exercisable for the purchase of 3.6 million shares. During the nine months ended September 30, 2010, we recorded compensation expense recovery of less than $0.1 million within selling, general and administrative expense as a result of the vesting of options exercisable for the purchase of 1.3 million shares. As of September 30, 2011, there was $1.2 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.

No stock options were granted during the quarters ended September 30, 2011 and 2010. The fair value of the options granted during the nine months ended September 30, 2011and 2010 was estimated on the respective grant dates using the Black-Scholes option pricing model. We granted 2.2 million stock options during the second quarter of 2011. These stock options were granted to our entire employee base with the bulk being granted to our senior management team. The Black-Scholes model was used with the following assumptions: risk-free interest rates of 1.87% based on the U.S. Treasury yield in effect at the time of grant; dividend yields of zero percent; expected lives of four years,

based on expected exercise activity behavior; and volatility of 105% 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 for five years. Forfeitures of 1.10% have been assumed. There were 75,000 stock options granted during the quarter ended June 30, 2010. The Black-Scholes model was used with

the following assumptions: risk-free interest rates of 1.98% based on the U.S. Treasury yield in effect at the time of grant; dividend yields of zero percent; expected life of five years, based on historical exercise activity behavior; and volatility of 102.69% based on the historical volatility of our stock over a time that is consistent with the expected life of the option. A small group of senior executives held the majority of the stock options and are expected to hold the options until they are vested. Forfeitures of 2.2% were assumed in the calculation.

Net Sales Recognition.

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

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

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

In our Pharmacogenomics Services, we perform services on a project by project basis. When we receive payment in advance, we recognize revenue when we deliver the service. These projects typically do not extend beyond one year. At September 30, 2011 and 2010, deferred net sales associated with pharmacogenomics research projects, included in the balance sheet in other accrued liabilities, was $0.1 million and less than $0.1 million, respectively.

Net sales of Diagnostic Tools products are recognized in accordance with the terms of the sales arrangement. Such recognition is based on receipt of an unconditional customer order and transfer of title and risk of ownership to the customer, typically upon shipment of the product under a purchase order. Our sales terms do not provide for the right of return unless the product is damaged or defective. Net sales from certain services associated with the analytical instruments, to be performed subsequent to shipment of the products, is deferred and recognized when the services are provided. Such services, mainly limited to installation and training services that are not essential to the functionality of the instruments, typically are performed in a timely manner subsequent to shipment of the instrument. We also enter into various service contracts that cover installed instruments. These contracts cover specific time periods and net sales associated with these contracts are deferred and recognized ratably over the service period. At September 30, 2011 and 2010, deferred net sales, mainly associated with our service contracts, included in the balance sheet in accrued liabilities, was approximately $1.4 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.

Preferred Stock.

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

Translation of Foreign Currency.

Our foreign subsidiary uses the local currency of the country in which it is located as its functional currency. Its assets and liabilities are translated into U.S. dollars at the exchange rates in effect at the balance sheet date. A cumulative translation gain of approximately $0.1 million is reported as accumulated other comprehensive income on the accompanying consolidated balance sheet as of September 30, 2011. A cumulative translation loss of less than $0.1 million was reported as accumulated other comprehensive income for the nine months ended September 30, 2010. Revenues and expenses are translated at the average rates during the period. For transactions that are not denominated in the functional currency, we recognized less than $0.1 million as

foreign currency transaction gain in the determination of net loss for the nine months ending September 30, 2011 and $0.3 million as foreign currency transaction loss in the determination of net loss for the nine months ending September 30, 2010.

Other Income.

Other income consists primarily of interest income from cash and cash equivalents invested in overnight instruments. Other income in the nine months ended September 30, 2011 includes an award of a federal grant under the Qualifying Therapeutic Discovery Project related to COLD-PCR, Surveyor Scan kit development for detecting key cancer pathway gene mutations and mtDNA damage assays. Income related to this federal grant was $0.2 million, net of consulting fees. Other income for the three months ended September 30, 2011 was less than $0.1 million. Other income for the three and nine months ending September 30, 2010 was less than $0.1 million.

Earnings Per Share.

Basic earnings per share is calculated based on the weighted-average number of common shares outstanding during each period. Diluted earnings per share include shares issuable upon exercise of outstanding stock options, warrants or conversion rights that have exercise or conversion prices below the market value of our common stock. Options, warrants and conversion rights pertaining to 17,751,940 and 10,598,156 shares of our common stock have been excluded from the computation of diluted earnings per share at September 30, 2011 and 2010, respectively. The options, warrants and conversion rights that were exercisable in 2011 and 2010 were not included because the effect would be anti-dilutive due to the net loss.

Recently adopted accounting pronouncements.

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

In October 2009, the FASB issued ASU No. 2009-14, Software (ASC 985): Certain Revenue Arrangements That Include Software Elements (a consensus of the FASB Emerging Issues Task Force); effective for years beginning after June 15, 2010. ASU 2009-14 modifies the existing scope guidance in ASC 985-605, Software Revenue Recognition, for revenue arrangements with tangible products that include software elements. This modification was made primarily due to the changes in ASC 605-25 noted previously, which further differentiated the separation and allocation guidance applicable to non-software arrangements as compared to software arrangements. Prior to the modification of ASC 605-25, the separation and allocation guidance for software and non-software arrangements was more similar. Under ASC 985-605, which was originally issued as AICPA Statement of position 97-2, Software Revenue Recognition, an arrangement to sell a tangible product along with software was considered to be in its scope if the software was more than incidental to the product as a whole. Our adoption of ASU No. 2009-14 did not have a material impact on our consolidated financial statements.

In January 2010, the FASB issued guidance to amend the disclosure requirements related to fair value measurements, effective for years beginning after December 15, 2010. The guidance requires the disclosure of roll forward activities on purchases, sales, issuance, and settlements of the assets and liabilities measured using significant unobservable inputs (Level Three fair value measurements). We adopted the new disclosure provisions with the filing of our Form 10-Q for the three months ended March 31, 2011.

Recently issued accounting pronouncements not yet adopted.
In June 2011, the FASB issued guidance on the presentation of comprehensive income. The new guidance eliminates the

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Three and Nine Months Ended September 30, 2011 and 2010

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

In July 2011, the FASB issued guidance on the presentation of net patient service revenue. The new guidance requires a change in presentation of the statement of operations by reclassifying the provision for bad debts associated with patient service revenue from an operating expense to a deduction from patient service revenue (net of contractual allowances and discounts). Additionally, enhanced disclosure about policies for recognizing revenue and assessing bad debts are required. Disclosures of patient service revenue (net of contractual allowances and discounts) as well as qualitative and quantitative information about changes in the allowance for doubtful accounts will be required. The new guidance is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2011.

In September 2011, the FASB issued guidance on Intangibles including goodwill and other intangibles. The new guidance will allow an entity to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. The new guidance is effective for fiscal years beginning after December 15, 2011. Early adoption is permitted.

C. INVENTORIES

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

	Dollars in Thousands	
	September 30, 2011	December 31, 2010
Finished goods	$2,063	$2,119
Raw materials and work in process	1,469	1,531
Demonstration inventory	288	212
	$3,820	$3,862
Less allowance for obsolescence	(514)	(518)
Total	$3,306	$3,344

D. INTANGIBLES AND OTHER ASSETS

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

	Dollars in Thousands					
	September 30, 2011			December 31, 2010		
	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Intangibles—acquired technology	$6,535	$683	$5,852	$6,535	$—	$6,535
Intangibles—assay royalties	1,434	154	1,280	1,434	—	1,434
Intangibles—third party payor relationships	367	—	367	367	—	367
Intangibles—tradenames and trademarks	344	37	307	344	—	344

Patents	767	263	504	511	245	266
Intellectual property	20	5	15	290	274	16
	$9,467	$1,142	$8,325	$9,481	$519	$8,962

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	Estimated Useful Life
Intellectual property	10 years
Patents	7 years
Intangibles—acquired technology	7 – 8 years
Intangibles—third party payor relationships	Indefinite
Intangibles—assay royalties	7 years
Intangibles—tradenames and trademarks	7 years

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

The intangible assets were each valued separately using valuation approaches most appropriate for each specific asset.

Intangibles—acquired technology	Income Approach - Multi-period Excess Earnings Method
Intangibles—third party payor relationships	Cost Approach - Replacement Cost Method
Intangibles—assay royalties	Income Approach - Multi-period Excess Earnings Method
Intangibles—tradenames and trademarks	Income Approach - Relief from Royalty Method

Income Approach
The income approach is based upon the economic principle of anticipation. In this approach, the value of the subject intangible asset is the present value of the expected economic income to be earned from that intangible asset. This expectation is then converted into a present value through the selection of an investor's required rate of return given the risk and/or uncertainty associated with the subject intangible asset. In valuing an intangible asset using the income approach, the following elements should be considered: (i) remaining useful life, (ii) legal rights, (iii) position of the intangible asset in its respective life cycle, (iv) appropriate capital charges, (v) allocations of income, and (vi) whether any tax amortization benefit should be included in the analysis.

Cost Approach
The cost approach to intangible asset analysis is based upon the economic principles of substitution and price equilibrium. These basic economic principles assert that an investor pay no more for an investment than the cost to obtain an investment of equal utility. Within the cost approach there are several related analytical methods. Two of the most common and widely accepted include the reproduction cost and replacement cost methods. All cost based approaches typically involve a comprehensive analysis of the relevant cost components, which typically include: (i) materials, (ii) labor, (iii) overhead, (iv) intangible asset developer's profit, and (v) an adequate return on the asset developer's capital.

Reproduction cost contemplates the construction of an exact replica of the subject intangible asset. Before appropriate adjustments are made for the purposes of deriving an indication of value, reproduction cost does not consider either the market demand for or the market acceptance of the subject intangible. Therefore, before the requisite adjustments, the reproduction cost estimate does not answer the question of whether anyone would be interested in an exact replica of the subject interest.

Unlike the reproduction cost method, the replacement cost method does consider market demand and market acceptance for the subject intangible. In other words, if there are elements or components of the subject intangible that generate little or no demand, they are not included in the subject intangible.

Excess Earnings Method

The Excess Earnings Method, a form of the Income Approach, reflects the present value of the projected cash flows that are expected to be generated by the intangible asset, less charges representing the contribution of other assets to those cash flows. As part of our analysis, we determined individual rates of return applicable to each acquired asset and estimate the effective “capital charge” to be applied to the earnings of the identified intangibles.

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Relief-from-Royalty Method
The Relief-from-Royalty method, a form of the Income Approach, estimates the cost of licensing the acquired intangible asset from an independent third party using a royalty rate. Since the company owns the intangible asset, it is relieved from making royalty payments. The resulting cash flow savings attributed to the owned intangible asset are estimated over the intangible asset's remaining useful life and discounted to present value.
Amortization expense for intangible assets was $0.3 million and less than $0.1 million during the three months ended September 30, 2011 and 2010, respectively. Amortization expense for intangible assets was $1.0 million and less than $0.1 million during the nine months ended September 30, 2011 and 2010, respectively. Amortization expense for intangible assets is expected to be $1.2 million in each of the years 2011 through 2017.

E. CAPITAL LEASES

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

	Dollars in Thousands	
Classes of Property	Asset Balances at September 30, 2011	December 31, 2010
Equipment	$782	$394
Less: Accumulated amortization	(119)	(13)
Total	$663	$381

The following is a schedule by years of future minimum lease payments under capital leases together with the present value of the net minimum lease payments as of September 30, 2011.
Year ending December 31:

	Dollars in Thousands
2011	$ 75
2012	224
2013	209
2014	35
Total minimum lease payments	$ 543
Less: Amount representing interest	(79)
Present value of net minimum lease payments	$ 464

F. COMMITMENTS AND CONTINGENCIES
We are subject to a number of claims of various amounts, which arise out of the normal course of business. In the opinion of management, the disposition of pending claims will not have a material adverse effect on our financial position, results of operations or cash flows.
We lease certain equipment, vehicles and operating facilities under non-cancellable operating leases that expire on various dates through 2016. The future minimum lease payments required under these leases are approximately $0.3 million in 2011, $1.1 million in 2012, $0.6 million in 2013, $0.4 million in 2014 , $0.4 million in 2015 and $0.3 million in 2016. Rent expense for the three months ended September 30, 2011 and 2010 was $0.2 million and $0.2 million, respectively. Rent expense for each of the nine months ended September 30, 2011 and 2010 was $0.7 million and $0.6 million, respectively.
We have entered into an employment agreement with Craig J. Tuttle, our President and Chief Executive Officer. The current term of Mr. Tuttle’s employment agreement ends on July 12, 2012. The employment agreement provides that

Mr. Tuttle will be entitled to receive a severance payment from the Company if his employment is terminated involuntarily except if such termination is based on “just cause”, as that term is defined in his employment agreement. The severance payment payable in the event of involuntary termination without just cause is equal to his annual base salary at the time of termination and will be paid over a twelve-month period. The employment agreement provides that the severance payment provision will be honored if the Company is acquired by, or merged into, another company and his position is eliminated as a result of such acquisition or merger. In addition

we have one employee who is entitled to a severance payment of less than $0.1 million if the employee's position is eliminated prior to July 2012.
At September 30, 2011, firm commitments to vendors to purchase components used in WAVE Systems and instruments manufactured by others totaled $0.5 million.

G. INCOME TAXES

We file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and various foreign jurisdictions. We have statutes of limitation open for federal income tax returns related to tax years 2007 through 2010. We have state income tax returns subject to examination primarily for tax years 2007 through 2010. Open tax years related to foreign jurisdictions, primarily the United Kingdom, remain subject to examination for the tax years 2007 through 2010.
Income tax benefit for the nine months ended September 30, 2011 was $0.1 million. This is the result of the change in deferred tax assets and liabilities reported in financial statements of our subsidiary outside the U.S. We believe the tax benefit recorded will be offset in future periods by a tax expense related to income reported in financial statements of our subsidiary outside the U.S. Income tax expense for the nine months ended September 30, 2010 was less than $0.1 million. The effective tax rate for the nine months ended September 30, 2011 is 1.14%, which is primarily the result of valuation allowances against the net operating losses for the U.S.
During the three and nine months ended September 30, 2011 and 2010, there were no material changes to the liability for uncertain tax positions.

H. STOCKHOLDERS' EQUITY

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 additional 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 additional preferred stock issued by the Company could have an adverse effect on the rights of the holders of the common stock.

On December 29, 2010, we entered into a transaction with affiliates of Third Security, LLC (the "Investors"), pursuant to the terms of Series A Convertible Preferred Stock Purchase Agreement ("Series A Purchase Agreement"), in which we: (i) sold an aggregate of 2,586,205 shares of Series A Convertible Preferred Stock (the "Series A Preferred") at a price of $2.32 per share; and (ii) issued a warrant to purchase up to an aggregate of 1,293,102 shares of Series A Preferred (the "Warrant") having an exercise price of $2.32 per share (the sale of Series A Preferred and issuance of the Warrant hereafter referred to as the "Financing"). The Warrant may be exercised at any time from December 29, 2010 until December 28, 2015 and contains a "cashless exercise" feature. The gross proceeds from the Financing were $6.0 million. The $0.2 million of costs incurred to complete the Financing were recorded as a reduction in the value of the

Series A Preferred. We used the net proceeds from the financing to acquire the FAMILION family of genetic tests from PGxHealth, a subsidiary of Clinical Data, Inc.The Series A Preferred meets the definition of mandatorily redeemable stock as it is preferred capital stock that is redeemable at the option of the holder through December 2015 and should be reported outside of equity. The Series A Preferred is accreted to its redemption value of $6.0 million. The Warrant does not qualify to be treated as equity and, accordingly, is recorded as a liability. A preferred stock anti-dilution feature is embedded within the Series A Preferred that meets the definition of a derivative.

In connection with the Financing, we filed a Certificate of Designation of Series A Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of Delaware, designating 3,879,307 shares of our preferred stock as Series A Convertible Preferred Stock. The Series A Preferred, including the Series A Preferred issuable upon exercise of the Warrant, is

convertible into shares of our common stock at a rate of 4-for-1, which conversion rate is subject to further adjustment as set forth in the Certificate of Designation. Certain rights of the holders of the Series A Preferred are senior to the rights of the holders of common stock. The Series A Preferred has a liquidation preference equal to its original price per share, plus any accrued and unpaid dividends thereon. The holders of the Series A Preferred are entitled to receive quarterly dividends, which accrue at the rate of 10.0% of the original price per share per annum, whether or not declared, shall compound annually and shall be cumulative. In any calendar quarter, we are required to pay from funds legally available a cash dividend in the amount of 50% of the distributable cash flow as defined in the Series A Purchase Agreement or the aggregate amount of dividends accrued on the Series A Preferred. During the nine months ended September 30, 2011, we recorded $0.5 million in accrued dividends.

Generally, the holders of the Series A Preferred are entitled to vote together with the holders of common stock, as a single group, on an as-converted basis. However, the Certificate of Designation provides that we shall not perform some activities, subject to certain exceptions, without the affirmative vote of a majority of the holders of the outstanding shares of Series A Preferred. The holders of the Series A Preferred also are entitled to elect or appoint, as a single group, two (2) of the five (5) directors of the Company.

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

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 during the three and nine months ended September 30, 2011. Laurus Master Fund, Ltd. exercised its warrants during the third quarter of 2011 in a cashless exercise for 60,150 shares of stock. No common stock warrants were issued or exercised during the three and nine months ended September 30, 2010. A warrant to purchase 5,172,408 shares of common stock was outstanding at September 30, 2011.

Warrant Holder	Issue Year	Expiration	Underlying Shares	Exercise Price
Affiliates of Third Security, LLC (1)	2010	December 2015	5,172,408	$0.58

(1) This Warrant was issued in connection with the Financing. The number of shares shown reflects the post-conversion shares.

I. FAIR VALUE

Financial Accounting Standards Board ("FASB") guidance on fair value measurements, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements for our financial assets and liabilities, as well as for other assets and liabilities that are carried at fair value on a recurring basis in our consolidated financial statements.

FASB guidance establishes a three-level fair value hierarchy based upon the assumptions (inputs) used to price assets or liabilities. The three levels of inputs used to measure fair value are as follows:

Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities,

Level 2—Observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets or liabilities in inactive markets, and

Level 3—Unobservable inputs reflecting our own assumptions and best estimate of what inputs market participants would use in pricing the asset or liability.

The preferred stock warrant liability and preferred stock conversion feature are recorded separately at fair value. We are

required to record these instruments at fair value at each reporting date and changes are recorded as an adjustment to earnings. The gains or losses included in earnings are reported in other income (expense) in our Statement of Operations.

The preferred stock warrant liability and preferred stock conversion feature are considered Level 3 financial instruments and are valued using the Black Scholes call option pricing formula, which approximates a binomial model for the preferred stock conversion feature. This method is among the most common and widely used valuation approaches for call options. The model relates an option's value to five variables: the current price of the underlying asset, the strike price of the option, the time to expiration or exercise of the option, a risk free interest rate, and the volatility of the underlying asset.

The following assumptions were used in the September 30, 2011valuation of the preferred stock conversion feature: the closing share price of our stock for the quarter ended September 30, 2011 discounted 15% due to the lack of marketability and liquidity, an exercise price of $0.39, expected term of 4.25 years, risk-free interest rate of 0.96% based on a 5 year U.S. Treasury and volatility of 103%.

The following assumptions were used in the September 30, 2011valuation of the preferred stock warrants: an exercise price of $2.32, expected term of 1.5 years, risk-free interest rate of 0.25% based on a 2 year U.S. Treasury and volatility of 50%.

During the three months ended September 30, 2011, the changes in the fair value of the liabilities measured using significant unobservable inputs (Level 3) were comprised of the following:

	Dollars in Thousands For the three months ended September 30, 2011		
	Preferred Stock Conversion Feature	Preferred Stock Warrant Liability	Total
Beginning balance at June 1, 2011	$7,600	$3,000	$10,600
Total gains or losses:			
Recognized in earnings	400	200	600
Balance at September 30, 2011	$8,000	$3,200	$11,200

During the nine months ended September 30, 2011, the changes in the fair value of the liabilities measured using significant unobservable inputs (Level 3) were comprised of the following:

	Dollars in Thousands For the nine months ended September 30, 2011		
	Preferred Stock Conversion Feature	Warrants	Total
Beginning balance at January 1, 2011	$1,983	$2,351	$4,334
Total gains or losses:			

Recognized in earnings	6,017	849	6,866
Balance at September 30, 2011	$8,000	$3,200	$11,200

We had no Level 3 liabilities at September 30, 2010. There were no purchases, sales, issuances or settlements of Level 3 liabilities in the three or nine months ended September 30, 2011 and 2010. The unrealized gains or losses of Level 3 liabilities are included in earnings are reported in other income (expense) in our Statement of Operations.

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J. STOCK OPTIONS

The following table summarizes stock option activity during the nine months ended September 30, 2011:

	Number of Options	Weighted Average Exercise Price
Balance at January 1, 2011	2,565,001	$ 2.11
Granted	2,335,500	1.17
Exercised	(30,000)	(0.76)
Forfeited	(334,501)	(1.66)
Cancelled	(363,000)	(6.79)
Balance at September 30, 2011	4,173,000	$ 1.20
Exercisable at September 30, 2011	2,234,712	$ 1.26

During the nine months ended September 30, 2011, we granted options exercisable to purchase 2,335,500 shares of common stock at a weighted average exercise price of $1.17 under our 2006 Equity Incentive Plan. No options were granted in the third quarter of 2011.

K. OPERATING SEGMENT AND GEOGRAPHIC INFORMATION

Our company's chief operating decision-maker is the Chief Executive Officer, who regularly evaluates our performance based on net sales and gross profit. The preparation of this segment analysis requires management to make estimates and assumptions around expenses 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 three reportable operating segments, Clinical Laboratories, Pharmacogenomic Services and Diagnostic Tools. During the third quarter of 2011, we changed the manner in which we report segment results internally. Accordingly, segment results of the prior period have been reclassified to reflect these changes. Beginning with the third quarter of 2011 our company's chief operating decision-maker is now reviewing our business as having three segments. The change in segments was driven by our corporate strategy to advance personalized medicine through proprietary molecular technologies and world-class clinical and research services. These lines of business are complementary with the Pharmacogenomics Services driving innovation and leading to kit production in our Diagnostic Tools segment and new tests in our Clinical Laboratories.

Segment information for the three months ended September 30, 2011 and 2010 is as follows:

	Dollars in Thousands			
	2011			
	Clinical Laboratories	Pharmacogenomic Services	Diagnostic Tools	Total
Net Sales	$4,085	$ 552	$3,616	$8,253
Gross Profit	2,456	241	1,748	4,445
Net Income (Loss) before Taxes	(1,472)	122	71	(1,279)
Income Tax Expense (Benefit)	(20)	—	11	(9)
Net Income (Loss)	$(1,452)	$ 122	$60	$(1,270)

Depreciation/Amortization	350	75	56	481
Restructure	2	—	3	5
Interest Income (Expense)	(238)	—	—	(238)

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	Dollars in Thousands			
	2010			
	Clinical Laboratories	Pharmacogenomic Services	Diagnostic Tools	Total
Net Sales	$918	$ 346	$3,155	$4,419
Gross Profit	248	(80)	1,849	2,017
Net Loss before Taxes	(662)	(135)	(30)	(827)
Income Tax Expense (Benefit)	—	—	71	71
Net Loss	$(662)	$ (135)	$(101)	$(898)
Depreciation/Amortization	32	45	47	124
Restructure	34	—	38	72
Interest Income (Expense)	—	—	—	—

Segment information for the nine months ended September 30, 2011 and 2010 is as follows:

	Dollars in Thousands			
	2011			
	Clinical Laboratories	Pharmacogenomic Services	Diagnostic Tools	Total
Net Sales	$11,435	$ 1,824	$10,141	$23,400
Gross Profit	6,787	764	5,601	13,152
Net Income (Loss) before Taxes	(11,331)	615	551	(10,165)
Income Tax Expense (Benefit)	—	—	(120)	(120)
Net Income (Loss)	$(11,331)	$ 615	$671	$(10,045)
Depreciation/Amortization	1,113	184	151	1,448
Restructure	28	—	12	40
Interest Income (Expense)	(720)	—	—	(720)
	9/30/2011			
Total Assets	$20,822	$ 953	$8,199	$29,974
	Dollars in Thousands			
	2010			
	Clinical Laboratories	Pharmacogenomic Services	Diagnostic Tools	Total
Net Sales	$2,790	$ 986	$11,180	$14,956
Gross Profit	1,159	(91)	6,320	7,388
Net Loss before Taxes	(1,471)	(444)	(343)	(2,258)
Income Tax Expense (Benefit)	—	—	109	109
Net Loss	$(1,471)	$ (444)	$(452)	$(2,367)
Depreciation/Amortization	98	131	151	380
Restructure	34	—	38	72
Interest Income (Expense)	—	—	1	1
	9/30/2010			
Total Assets	$5,777	$ 1,088	$7,072	$13,937

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Net sales for the three and nine months ended September 30, 2011 and 2010 by country were as follows:

	Dollars in Thousands Three Months Ended September 30,		Dollars in Thousands Nine Months Ended September 30,	
	2011	2010	2011	2010
United States	$6,034	$2,082	$16,738	$6,483
Italy	762	813	2,373	2,300
United Kingdom	193	224	451	991
France	166	209	579	812
Germany	187	194	581	1,099
United Arab Emirates	—	4	—	778
All Other Countries	911	893	2,678	2,493
Total	$8,253	$4,419	$23,400	$14,956

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

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

L. SUBSEQUENT EVENTS

Events or transactions that occur after the balance sheet date, but before the financial statements are complete, are reviewed to determine if they should be recognized.

In November 2011, we entered into a transaction with the Investors, pursuant to an Agreement Regarding Preferred Stock (the “Amendment Agreement”), in which the Investors agreed to (i) waive their rights to enforce the anti-dilution and redemption features of the Series A Preferred and (ii) at the next annual shareholder meeting, vote to amend the Certificate of Designation to remove the anti-dilution and redemption features of the Series A Preferred. In exchange, the Company issued shares of common stock to the Investors having an aggregate market value of $0.3 million.

As a result of the Amendment Agreement, the value of the Series A Preferred and Warrant, including the preferred stock conversion feature and preferred stock warrant liability, will be reclassified into shareholders equity as of the date of the Amendment Agreement. The following table sets forth a summary of the balance sheet as reported and pro-forma as if the Amendment Agreement had occurred on September 30, 2011.

	As reported Dollars in Thousands September 30, 2011	Pro-Forma September 30, 2011
Total Assets	$29,974	$29,974
Total Liabilities	29,683	18,483
Redeemable Series A convertible preferred stock	1,796	—
Total Stockholders' Equity (Deficit)	(1,505)	11,491
	$29,974	29,974

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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 sim

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, 2010. Results for the quarter ended September 30, 2011 are not necessarily indicative of results that may be attained in the future.

Overview

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

- Clinical Laboratories. Our clinical laboratories specialize in genetic testing for cardiology, neurology, mitochondrial disorders, and oncology. Located in New Haven, Connecticut and Omaha, Nebraska the molecular clinical reference laboratories are certified under the Clinical Laboratory Improvement Amendment (CLIA) as high complexity labs and our Omaha facility is accredited by CAP (College of American Pathologists).
- Pharmacogenomics Services. Pharmacogenomics research services are provided by our Contract Research Organization located in Omaha, Nebraska. This lab specializes in pharmacogenomic, biomarker and mutation discovery research serving the pharmaceutical and biomedical industries world-wide for disease research, drug and diagnostic development and clinical trial support.
- Diagnostic Tools. Our proprietary product is the WAVE® System which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. There is a worldwide installed base of over 1,500 WAVE Systems as of September 30, 2011. We also distribute bioinstruments produced by other manufacturers ("OEM Equipment") through our sales and distribution network. Service contracts to maintain installed systems are sold and supported by our technical support personnel. The installed WAVE base and some OEM Equipment platforms generate a demand for consumables that are required for the continued operation of the bioinstruments. We develop, manufacture and sell these consumable products. In addition, we manufacture and sell consumable products that can be used on multiple, independent platforms. These products include SURVEYOR® Nuclease and a range of chromatography columns.

Executive Summary

Net sales for the nine months ended September 30, 2011 increased by $8.4 million or 56% compared to the same period in

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2010. These results include the FAMILION acquisition in our Clinical Laboratories segment. During the nine months ended September 30, 2011, net sales from Clinical Laboratories increased by $8.6 million compared to the same nine month period in 2010. The Clinical Laboratories increase is a result of the revenue of $8.4 million related to the FAMILION acquisition. Net sales from Pharmacogenomics Services increased by $0.8 million for the nine months ended September 30, 2011 compared to the same period in 2010. Net sales in Diagnostic Tools were down 9% or $1.0 million for the nine months ended September 30, 2011 compared to the same period in 2010. Our gross profit margin increased from 49% for the nine months ended September 30, 2010 to 56% for the same period in 2011. Clinical Laboratories gross margin increased from 42% in the nine months ended September 30, 2010 to 59% for the same period in 2011. Loss from operations was $2.8 million for the nine months ended September 30, 2011 compared to $2.3 million for the nine months ended September 30, 2010.

As of September 30, 2011, we had cash and cash equivalents of $1.4 million.

Outlook

We anticipate continued growth in both our diagnostics and our laboratory services businesses as we commercialize new assay technologies and tests we have developed internally or in-licensed, and as we expand into other markets and regions worldwide.

Our FAMILION franchise, which we acquired in December 2010, includes eleven tests for inherited cardiac disorders. Product sales for this unit grew 12% over second quarter 2011 levels, to $2.9 million. We continue to believe that there is significant opportunity to expand this business based on increased use of existing tests and the launch of new products into the marketplace. In May, the Heart Rhythm Society issued new diagnostic guidelines supporting the use of some of our key cardiac tests, and we expect to introduce a new, competitively-positioned Plavix® response test in the near term.

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

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

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

Although the WAVE® System is a fully matured technology, and both it and its corresponding consumable sales growth in our traditional markets are shrinking, we are expanding our distribution network in Europe and introducing the systems into geographic areas, including the Middle East and Asia, to continue the revenue from our Diagnostic Tools segment. In addition, we recently announced an agreement with A. Menarini Diagnostics, one of the leading diagnostics companies in Europe, for the distribution of our new WAVE® M.C.E System and SURVEYOR® mutation detection assay kits in the European Union, which will greatly increase our footprint in key European markets and, we believe, lead to significant sales from this product line.

We also announced recently a distribution agreement with ScreenCell, a Paris-based Company, for the sale and marketing of its ScreenCell® filtration device portfolio worldwide. ScreenCell® filtration devices are devoted to

isolation of circulating rare cells, such as circulating tumor cells, which may simplify and improve non-invasive access to tumor cells. We will initially market the filtration systems to pharmaceutical and research organizations, with the goal of developing applications for screening circulating tumor cells (CTCs) combined with our sensitive mutation detection technologies including ICE COLD-PCR, BLOCker Sequencing and WAVE M.C.E and our Surveyor SCAN kits. We are targeting the use of the ScreenCell technology in combination with our technology to further develop our ultra-high sensitivity blood-based mutation detection capabilities.

We continue to advance our pipeline of cancer pathway gene mutation kits as well. We have completed development of our first ICE COLD-PCR assay kit and will commence market validation trials in the fourth quarter. Our first ICE COLD-PCR kit,

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has been designed to enrich mutations in the K-RAS gene, which are known to confer resistance to the newest treatment options in colon and lung cancer, and is the first in an expected portfolio of assay kits that can be used to test for resistance conferring mutations. Longer term, we anticipate that these ultra-sensitive mutation detection kits can become effective and efficient products for use both in earlier cancer screening in blood and to monitor treatment and disease recurrence.

Finally, we continue to look for opportunities to diversify into new markets, particularly in oncology, where the sensitivities of our technologies provide significant clinical benefit. We have also embarked on several academic collaborations to further validate our newest technologies and better determine how they can and will be used in clinical settings for patients undergoing treatment for cancer.

Uncertainties

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, 2011 we had cash and cash equivalents of $1.4 million. We believe that existing sources of liquidity are sufficient to meet expected cash needs into 2012.

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

We have translation risk that occurs when transactions are consummated in a currency other than British Pound Sterling, which is the functional currency of our foreign subsidiary These transactions, which are most often consummated in Euros, must be translated into British Pound Sterling. In addition, results of operations and the balance sheet of our foreign subsidiary are translated from British Pound Sterling to our reporting currency, which is the U.S. Dollar. As a result we are subject to exchange rate risk. Fluctuations in foreign exchange rates could impact our business.

Results of Operations

Three Months Ended September 30, 2011 and 2010

Net Sales. Net sales consisted of the following:

	Dollars in Thousands Three Months Ended September 30,		Change		
	2011	2010	$	%	
Clinical Laboratories	$4,085	$918	$3,167	345	%
Pharmacogenomics Services	552	346	206	60	%
Diagnostic Tools	3,616	3,155	461	15	%
Total Net sales	$8,253	$4,419	$3,834	87	%

Clinical Laboratories net sales increased $3.2 million during the three months ended September 30, 2011 compared to the same period in 2010. Of this increase, $3.0 million is due to revenue from the FAMILION family of genetic tests, which we acquired on December 29, 2010. In addition, our revenue increased by $0.2 million in our neurology family of tests due to the mix of tests performed and the average revenue per test.

Pharmacogenomics Services net sales of $0.6 million during the three months ended September 30, 2011 increased by $0.2 million compared to the same period of 2010 due to the volume of genetic testing performed in connection with various clinical trials at various stages by our pharmaceutical company clients. Pharmacogenomics Services net sales

have peaks due to the nature of patient enrollment patterns and the timing of clinical trials. While the revenue generated from genetic testing related to clinical trials is significant, it is usually earned over the duration of the trial. Therefore, each period for Pharmacogenomics Services should be considered on a standalone basis and is not indicative of future net sales.

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Diagnostic Tools net sales of $3.6 million increased $0.5 million, or 15%, during the three months ended September 30, 2011 as compared to the same period in 2010 due to selling more instruments in the third quarter of 2011. We sold five OEM Equipment instruments in the third quarter of 2011 compared to zero in the third quarter of 2010 and we sold four WAVE instruments in both the third quarter of 2011 and 2010. Demand for WAVE Systems has been affected by significant competitive challenges from traditional (i.e. sequencing) and evolving technologies. Net sales of bioconsumables were down $0.5 million during the three months ended September 30, 2011 compared to the same period in 2010. Bioconsumable sales volumes in both the United States and Europe were lower in the third quarter of 2011 compared to the third quarter of 2010.

Cost 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 Clinical Laboratories and Pharmacogenomics Services operations.

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

	Dollars in Thousands Three Months Ended September 30,		Margin %	
	2011	2010	2011	2010
Clinical Laboratories	$2,456	$248	60 %	27 %
Pharmacogenomics Services	241	(80)	44 %	(23)%
Diagnostic Tools	1,748	1,849	48 %	59 %
Gross Profit	$4,445	$2,017	54 %	46 %

Gross profit was $4.4 million or 54% of total net sales during the third quarter of 2011, compared to $2.0 million or 46% during the same period of 2010. During the three months ended September 30, 2011, the gross margin for Clinical Laboratories was 60% as compared to 27% in the same period of 2010. The three months ended September 30, 2011 include the gross profits from sales of the FAMILION family of genetic tests, which we acquired on December 29, 2010. Pharmacogenomics Services gross margin increased from negative 23% for the three months ended September 30, 2010 to 44% for the three months ended September 30, 2011. Pharmacogenomics Services has a relatively fixed-cost base so any increase or decrease in revenue directly impacts gross margins. Diagnostic Tools gross margin decreased from 59% in the three months ended September 30, 2010 to 48% in the same period of 2011 due to lower bioconsumables sales which also have a relatively fixed-cost base.

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, the effects of foreign currency revaluation is included here. Our selling, general and administrative costs increased $2.2 million from $2.2 million to $4.4 million during the three month period ended September 30, 2011 compared to the same period in 2010. The primary increase in our selling, general and administrative costs is due to the acquisition of the FAMILION family of genetic tests of $1.3 million. In addition, we had bad debt charges of $0.2 million and amortization of acquired intangible assets of $0.3 million. Foreign currency revaluation loss for the three months ended September 30, 2011 was $0.1 million compared to $0.2 million in revaluation gain for the three months ended September 30, 2010.

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, 2011 and 2010, these costs totaled $0.5 million and $0.6 million, respectively. Research and development expenses totaled 6% and 14% of net sales during the three months ended September 30, 2011 and 2010, respectively. The decrease as a percentage of net sales is due primarily to the consolidation of our research and development activities in Omaha, Nebraska.

Other Income (Expense). Other expense for the three months ended September 30, 2011 includes interest expense and the expense associated with the preferred stock and warrant, which is due to the change in fair value of the preferred stock conversion feature. The expense associated with the change in value of the preferred stock conversion feature is

a non-cash item.

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Income Tax Expense (Benefit). Income tax benefit for the three months ended September 30, 2011 was a benefit of less than$0.1 million. This is the result of the change in deferred tax assets and liabilities reported in the financial statements of our foreign subsidiary. This tax benefit is partially offset by tax expense related to state and franchise taxes as well as reserves for uncertain income taxes. We believe the recorded tax benefit will be offset in future periods by a tax expense, related to income reported in the financial statements of our foreign subsidiary. Income tax expense for the three months ended September 30, 2010 was $0.1 million.

Results of Operations
Nine Months Ended September 30, 2011 and 2010
Net Sales. Net sales consisted of the following:

	Dollars in Thousands Nine Months Ended September 30,		Change	
	2011	2010	$	%
Clinical Laboratories	$11,435	$2,790	$8,645	310 %
Pharmacogenomic Services	1,824	986	838	85 %
Diagnostic Tools	10,141	11,180	(1,039)	(9)%
Total Net sales	$23,400	$14,956	$8,444	56 %

Clinical Laboratories net sales increased $8.6 million during the nine months ended September 30, 2011 compared to the same period in 2010. Of this increase in revenue, $8.4 million is due to revenue from the FAMILION family of genetic tests, which we acquired on December 29, 2010.
Pharmacogenomic Services net sales of $1.8 million during the nine months ended September 30, 2011 increased $0.8 million compared to the same period in 2010. The increase is due to the completion of a significant project with a pharmaceutical company client. Pharmacogenomics Services net sales have peaks due to the nature of project-related services performed on behalf of our clients. Each period for Pharmacogenomics Services should be considered on a stand alone basis and is not indicative of future net sales.
Diagnostic Tools net sales decreased $1.0 million, or 9%, during the nine months ended September 30, 2011 as compared to the same period in 2010. The decrease was due to fewer instruments sold in the nine months ended September 30, 2011. We sold nine WAVE instruments in 2011 compared to twenty-two in 2010. Demand for WAVE Systems has been affected by significant competitive challenges from traditional (i.e. sequencing) and evolving technologies. Lower WAVE instrument sales are offset by slightly higher OEM Equipment instruments sold in 2011. We sold eight OEM Equipment instruments in the nine months ended September 30, 2011 compared to five in the same period in 2010. Bioconsumables net sales were down 10%, or $0.5 million, during the nine months ended September 30, 2011 compared to the same period in 2010.
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 Clinical Laboratories and Pharmacogenomics Services operations.
Gross Profit. Gross profit and gross margins for each of our business segments were as follows:

	Dollars in Thousands Nine Months Ended September 30,		Margin %	
	2011	2010	2011	2010
Clinical Laboratories	$6,787	$1,159	59 %	42 %
Pharmacogenomic Services	764	(91)	42 %	(9)%
Diagnostic Tools	5,601	6,320	55 %	57 %
Gross Profit	$13,152	$7,388	56 %	49 %

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Gross profit was $13.2 million or 56% of total net sales during the nine months ended September 30, 2011, compared to $7.4 million or 49% during the same period of 2010. During the nine months ended September 30, 2011, the gross margin for Clinical Laboratories was $6.8 million as compared to $1.2 million in the same period of 2010. The nine months ended September 30, 2011 include gross profit from sales of the FAMILION family of genetic tests, which we acquired on December 29,2010. Pharmacogenomics Services gross margin increased from negative 9% for the nine months ended September 30, 2010 to 42% for the nine months ended September 30, 2011. Pharmacogenomics Services have a relatively fixed-cost base so any increase or decrease in revenue directly impacts gross margins. Diagnostic Tools gross margin decreased from 57% in the nine months ended September 30, 2010 to 55% in the same period of 2011due to lower bioconsumable sales, which also have a relatively fixed-cost base.

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. Our selling, general and administrative costs increased from $7.6 million to $14.3 million during the nine month period ended September 30, 2011 compared to the same period in 2010. The primary increase in our selling, general and administrative costs is primarily due to $3.7 million in expenses related to the FAMILION family of genetic tests, which we acquired on December 29, 2010. In addition, we had $0.8 million in expense related to the vesting of the employee stock option grants, $0.9 million in amortization of the acquired intangibles and bad debt expense of $1.5 million. Foreign currency revaluation gain for the nine months ended September 30, 2011 was less than $0.1 million compared to $0.3 million in revaluation loss for the nine months ended September 30, 2010.

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. During the nine months ended September 30, 2011 and 2010 these costs totaled $1.7 million and $2.0 million, respectively. Research and development expenses totaled 7% and 13% of net sales during the nine months ended September 30, 2011 and 2010, respectively. The decrease is due primarily to the consolidation of our research and development activities in Omaha, Nebraska, the benefit which is partially offset by legal costs to defend a patent.

Other Income (Expense). Other income for the nine months ended September 30, 2011 includes an award of a federal grant under the Qualifying Therapeutic Discovery Project of $0.2 million, net of consulting fees. Other expense includes interest expense as well as the expense associated with the preferred stock and warrant, which is due to the change in fair value of the preferred stock conversion feature. The expense associated with the change in value of the preferred stock conversion feature is a non-cash item.

Income Tax Expense (Benefit). Income tax benefit for the nine months ended September 30, 2011 was a benefit of $0.1 million. This is the result of the change in deferred tax assets and liabilities reported in the financial statements of our foreign subsidiary. This tax benefit is partially offset by tax expense related to state and franchise taxes as well as reserves for uncertain income taxes. We believe the recorded tax benefit will be offset in future periods by a tax expense, related to income reported in the financial statements of our foreign subsidiary. Income tax expense for the nine months ended September 30, 2010 was $0.1 million.

Liquidity and Capital Resources

Our working capital positions at September 30, 2011 and December 31, 2010 were as follows:

	Dollars in Thousands		
	September 30, 2011	December 31, 2010	Change
Current assets (including cash and cash equivalents of $1,423 and $3,454, respectively)	$13,656	$15,034	$(1,378)
Current liabilities	10,104	8,253	1,851
Working capital	$3,552	$6,781	$(3,229)

Working capital decreased due primarily to our payment obligations related to our notes payable and capital leases, and increased accrued liabilities.

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. Historically we have been able to finance our operating losses through borrowings or from the issuance of additional equity. We currently have no plans to secure additional borrowings for this purpose, but instead are exploring alternative funding from certain existing holders of our equity securities as well as additional sources of liquidity. At September 30, 2011, we had cash and cash equivalents of $1.4 million. We believe that existing sources of liquidity are sufficient

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to meet expected cash needs into 2012, but we will need to increase our net sales and reduce our operating expenses in order to be assured of meeting our liquidity needs on a long-term basis. It may also be necessary for us to secure additional funding in the near future. However, we cannot assure you that we will be able to increase our net sales, further reduce our expenses or raise additional capital. Accordingly, we may not have sufficient sources of liquidity to continue our operations indefinitely.

Analysis of Cash Flows

Nine Months Ended September 30, 2011 and 2010

Net Change in Cash and Cash Equivalents. Cash and cash equivalents decreased by $2.0 million during the nine months ended September 30, 2011 compared to a decrease of $1.1 million during the nine months ended September 30, 2010. During the nine months ended September 30, 2011 we used cash of $0.9 million in operating activities, $0.4 million in investing activities, $0.8 million in financing activities which was offset by $0.1 million by the effect of foreign currency exchange rate changes on cash. In 2010, net cash used in operating activities was $0.9 million , $0.2 million was used in investing activities and less than $0.1 million was used in financing activities.

Cash Flows Used In Operating Activities. Cash flows used in operating activities totaled $0.9 million during both the nine months ended September 30, 2011 and 2010. The cash flows used in operating activities in 2011 include the net loss and increase in accounts receivable, offset by non-cash items including the change in fair value of the preferred stock conversion feature and warrant liability, the provision for losses on doubtful accounts and depreciation and amortization.

Cash Flows Used In Investing Activities. Cash flows used in investing activities totaled $0.4 million during the nine months ended September 30, 2011 compared to cash flows used in investing activities of $0.2 million during the same period of 2010. Cash flows used in investing activities in 2011 include purchases of property and equipment of $0.1 million and additions to our patents of $0.3 million. Cash flows used in investing activities in 2010 consisted primarily of purchases of property and equipment.

Cash Flows Used in Financing Activities. Cash flows used in financing activities were $0.8 million for the nine months ended September 30, 2011. Cash flows used in financing activities were for payments on debt and capital lease obligations and were partially offset by cash received from the issuance of common stock in connection with the exercise of stock options for 30,000 shares during the quarter. Cash flows used in financing activities were less than $0.1 million for the nine months ended September 30, 2010. Cash flows used in financing activities were for principal payments on capital leases offset by the cash received from issuance of common stock in connection with the exercise of stock options for 100,000 shares during the second quarter of 2010.

Off-Balance Sheet Arrangements

At September 30, 2011 and December 31, 2010, 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, 2010.

Recently Issued Accounting Pronouncements

Please refer to our annual report on Form 10-K for the fiscal year ended December 31, 2010. There have been no changes to those accounting pronouncements listed except as noted in note B to the financial statements contained in this report.

Impact of Inflation

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

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Management performed, with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act are recorded, processed, summarized, and reported within the time periods specified in the SEC's forms, and that such information is accumulated and communicated to our management including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosures. Based on the evaluation, the Company's Chief Executive Officer and our Chief Financial Officer concluded that, as of September 30, 2011, Transgenomic's disclosure controls and procedures were effective.

We have evaluated the changes in our internal control over financial reporting that occurred during the three months ended September 30, 2011 and concluded that there have not been any changes 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, 2010 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.

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, 2010 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.

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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)
3.3	Certificate of Designation of Series A Convertible Preferred Stock dated as of December 28, 2010 (incorporated by reference to Exhibit 3.1 to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)
4.1	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)
4.2	Series A convertible Preferred Stock Purchase Agreement, dated December 29, 2010, by and among Transgenomic, Inc., Third Security Senior Staff 2008 LLC, Third Security Staff 2010 LLC, and Third Security Incentive 2010 LLC (incorporated by reference to Exhibit 4.1 to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)
4.3	Form of Warrant (incorporated by reference to Exhibit 4.2 to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)
4.4	Registration Rights Agreement, dated December 29, 2010, by and among Transgenomic, Inc., Third Security Senior Staff 2008 LLC, Third Security Staff 2010 LLC, and Third Security Incentive 2010 LLC (incorporated by reference to Exhibit 4.3 to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)
4.5	Secured Promissory Note, issued December 29, 2010 by Transgenomic, Inc. in favor of PGxHealth, LLC (incorporated by reference to Exhibit 4.4 to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)
4.6	Secured Promissory Note, issued December 29, 2010 by Transgenomic, Inc. in favor of PGxHealth, LLC (incorporated by reference to Exhibit 4.5 to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)
10.1	Sublease Agreement, dated December 29, 2010, by and between Transgenomic, Inc. and Clinical Data, Inc. (incorporated by reference to Exhibit 10.1 to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)
10.2	Noncompetition and Nonsolicitation Agreement, dated December 29, 2010 by and among PGxHealth, LLC, Clinical Data, Inc. and Transgenomic, Inc. (incorporated by reference to Exhibit 10.2 to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)
10.3	Security Agreement, dated December 29, 2010, by and between PGxHealth, LLC and Transgenomic, Inc. (incorporated by reference to Exhibit 10.3 to Registrant's Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)

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
101.INS	XBRL Instance Document *
101.SCH	XBRL Taxonomy Extension Schema Document *
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document *
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document *
101.LAB	XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document *

* XBRL information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Act of 1934, and is not subject to liability under those sections, is not part of any registration statement or prospectus to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.

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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 10, 2011

By: /S/ CRAIG J. TUTTLE
Craig J. Tuttle
President and Chief Executive Officer