

TRANSGENOMIC INC  
Form 10-Q  
November 08, 2012  
Table of Contents

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

---

FORM 10-Q

---

(Mark One)

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

For the quarterly period ended September 30, 2012

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 000-30975

---

TRANSGENOMIC, INC.

(Exact name of registrant as specified in its charter)

---

Delaware  
(State or other jurisdiction of  
incorporation or organization)

911789357  
(I.R.S. Employer  
Identification No.)

12325 Emmet Street, Omaha, Nebraska  
(Address of principal executive offices)  
(402) 452-5400

68164  
(Zip Code)

(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 (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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.

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

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

As of November 7, 2012, the number of shares of common stock outstanding was 71,645,725.



Table of Contents

TRANSGENOMIC, INC.  
INDEX

	Page No.
PART I. <u>FINANCIAL INFORMATION</u>	<u>3</u>
Item 1. <u>Financial Statements</u>	<u>3</u>
<u>Condensed Consolidated Balance Sheets as of September 30, 2012 (Unaudited) and December 31, 2011 (Audited)</u>	<u>3</u>
<u>Unaudited Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2012 and 2011</u>	<u>4</u>
<u>Unaudited Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2012 and 2011</u>	<u>5</u>
<u>Unaudited Condensed Consolidated Statements of Stockholders' Equity for the Nine Months Ended September 30, 2012</u>	<u>6</u>
<u>Unaudited Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2012 and 2011</u>	<u>7</u>
<u>Notes to Condensed Consolidated Unaudited Financial Statements</u>	<u>8</u>
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>21</u>
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>29</u>
Item 4. <u>Controls and Procedures</u>	<u>29</u>
PART II. <u>OTHER INFORMATION</u>	<u>30</u>
Item 1. <u>Legal Proceedings</u>	<u>30</u>
Item 1A. <u>Risk Factors</u>	<u>30</u>
Item 6. <u>Exhibits</u>	<u>31</u>
<u>Signatures</u>	<u>33</u>

Table of Contents

## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

(Dollars in thousands except per share data)

	September 30, 2012 (unaudited)	December 31, 2011
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$4,747	\$4,946
Short term investments	3,998	—
Accounts receivable, net	8,157	7,573
Inventories, net	4,406	3,859
Other current assets	1,186	820
Total current assets	22,494	17,198
<b>PROPERTY AND EQUIPMENT:</b>		
Equipment	10,819	10,143
Furniture, fixtures & leasehold improvements	3,762	3,682
	14,581	13,825
Less: accumulated depreciation	(12,490)	(11,969)
	2,091	1,856
<b>OTHER ASSETS:</b>		
Goodwill	6,674	6,440
Intangibles, net	11,485	7,966
Other assets	143	102
	\$42,887	\$33,562
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$1,517	\$2,609
Accrued compensation	1,058	1,133
Short term debt	—	3,082
Current maturities of long term debt	6,957	3,703
Accrued expenses	3,627	2,782
Deferred revenue	1,279	1,377
Other liabilities	1,067	1,042
Accrued preferred stock dividend	1,095	600
Total current liabilities	16,600	16,328
<b>LONG TERM LIABILITIES:</b>		
Long term debt less current maturities	448	4,937
Common stock warrant liability	2,100	—
Other long-term liabilities	1,163	1,249
Total liabilities	20,311	22,514
<b>STOCKHOLDERS' EQUITY:</b>		
Series A preferred stock, \$.01 par value, 15,000,000 shares authorized, 2,586,205 shares issued and outstanding	26	26
Common stock, \$.01 par value, 150,000,000 shares authorized, 71,645,725 and 49,625,725 shares issued and outstanding, respectively	721	501
Additional paid-in capital	170,706	152,987

Edgar Filing: TRANSGENOMIC INC - Form 10-Q

Accumulated other comprehensive income	434	336
Accumulated deficit	(149,311	) (142,802 )
Total stockholders' equity	22,576	11,048
	\$42,887	\$33,562

See notes to unaudited condensed consolidated financial statements.

3

---

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Dollars in thousands except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
NET SALES	\$7,889	\$8,253	\$24,188	\$23,400
COST OF GOODS SOLD	4,089	3,808	12,722	10,248
Gross profit	3,800	4,445	11,466	13,152
OPERATING EXPENSES:				
Selling, general and administrative	5,559	4,364	15,832	14,272
Research and development	668	515	1,870	1,650
Restructuring charges	—	5	—	40
	6,227	4,884	17,702	15,962
LOSS FROM OPERATIONS	(2,427	) (439	) (6,236	) (2,810
OTHER INCOME (EXPENSE):				
Interest expense, net	(207	) (238	) (713	) (720
Expense on preferred stock	—	(600	) —	(6,866
Effect on warrants	—	—	1,000	—
Other, net	(6	) (2	) 23	231
	(213	) (840	) 310	(7,355
LOSS BEFORE INCOME TAXES	(2,640	) (1,279	) (5,926	) (10,165
INCOME TAX EXPENSE (BENEFIT)	114	(9	) 88	(120
NET LOSS	\$(2,754	) \$(1,270	) \$(6,014	) \$(10,045
PREFERRED STOCK DIVIDENDS AND ACCRETION	(165	) (275	) (495	) (803
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS	\$(2,919	) \$(1,545	) \$(6,509	) \$(10,848
BASIC AND DILUTED LOSS PER COMMON SHARE	\$(0.04	) \$(0.03	) \$(0.09	) \$(0.22
BASIC AND DILUTED WEIGHTED AVERAGE SHARES OF COMMON STOCK OUTSTANDING	71,645,725	49,327,527	68,669,229	49,306,861

See notes to unaudited condensed consolidated financial statements.

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Dollars in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net Loss	\$(2,754	) \$(1,270	) \$(6,014	) \$(10,045
Foreign currency translation adjustment, net of tax	88	(56	) 98	86
Other Comprehensive Income (Loss), net of tax	88	(56	) 98	86
Comprehensive Loss	\$(2,666	) \$(1,326	) \$(5,916	) \$(9,959

See notes to unaudited condensed consolidated financial statements.

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Nine Months Ended September 30, 2012

(Dollars in thousands except per share data)

	Preferred Stock		Common Stock				Accumulated	
	Outstanding	Par	Outstanding	Par	Additional	Accumulated	Other	Total
	Shares	Value	Shares	Value	Paid-in	Deficit	Comprehensive	
					Capital		Income	
Balance, January 1, 2012	2,586,205	\$26	49,625,725	\$501	\$152,987	\$ (142,802 )	\$ 336	\$11,048
Net loss			—	—	—	(6,014 )	—	(6,014 )
Foreign currency translation adjustment, net of tax			—	—	—	—	98	98
Non-cash stock-based compensation			—	—	556	—	—	556
Private Placement, net			22,000,000	220	17,153			17,373
Issuance of shares of stock for employee stock options			20,000	—	10	—	—	10
Dividends on preferred stock			—	—	—	(495 )	—	(495 )
Balance, September 30, 2012	2,586,205	\$26	71,645,725	\$721	\$170,706	\$ (149,311 )	\$ 434	\$22,576

See notes to unaudited condensed consolidated financial statements.



Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Dollars in thousands)

	Nine Months Ended September 30,	
	2012	2011
<b>CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES:</b>		
Net loss	\$(6,014	) \$(10,045 )
Adjustments to reconcile net loss to net cash flows provided by (used in) operating activities:		
Depreciation and amortization	1,570	1,506
Non-cash, stock based compensation	556	734
Provision for losses on doubtful accounts	1,649	1,432
Provision for losses on inventory obsolescence	88	47
Preferred stock revaluation	—	6,866
Warrant revaluation	(1,000	) —
Changes in operating assets and liabilities:		
Accounts receivable	(2,153	) (1,418 )
Inventories	(616	) (44 )
Prepaid expenses and other current assets	(377	) (269 )
Accounts payable	(1,113	) 137
Accrued expenses	(403	) (131 )
Other long term liabilities	3	268
Long term deferred income taxes	33	18
Net cash flows used in operating activities	(7,777	) (899 )
<b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(641	) (147 )
Purchase of short term investments	(8,994	) —
Proceeds from the sale of short term investments	4,996	—
Acquisition of intangible assets	(3,394	) —
Change in other assets	(345	) (256 )
Net cash flows used in investing activities	(8,378	) (403 )
<b>CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES:</b>		
Principal payments on capital lease obligations	(244	) (165 )
Issuance of common stock and warrants, net	17,483	23
Principal payment on note payable	(1,317	) (659 )
Net cash flows provided by (used in) financing activities	15,922	(801 )
EFFECT OF FOREIGN CURRENCY EXCHANGE RATE CHANGES ON CASH	34	72
NET CHANGE IN CASH AND CASH EQUIVALENTS	(199	) (2,031 )
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,946	3,454
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$4,747	\$1,423
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>		
Cash paid during the period for:		
Interest	\$753	\$495
Income taxes, net	2	106
<b>SUPPLEMENTAL DISCLOSURE OF NON-CASH INFORMATION</b>		
Acquisition of equipment through capital leases	\$175	\$388
Dividends accrued on preferred stock	495	450
Note Payable converted to Equity	3,000	—

Acquisition of intangible assets	1,007	—
See notes to unaudited condensed consolidated financial statements.		

7

---

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

**A. BUSINESS DESCRIPTION**

**Business Description.**

Transgenomic, Inc. is a global biotechnology company advancing personalized medicine in the detection and treatment of cancer and inherited diseases through its proprietary molecular technologies and 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 also accredited by the College of American Pathologists (CAP).

**Pharmacogenomics Services.** Our Contract Research Organization located in Omaha, Nebraska provides pharmacogenomics research services supporting Phase II and Phase III clinical trials conducted by our pharmaceutical customers. This lab specializes in pharmacogenomic, biomarker and mutation discovery research testing that serves the pharmaceutical and biomedical industries world-wide for disease research, drug and diagnostic development and clinical trial support. The lab employs a variety of genomic testing service technologies including ICE COLD-PCR technology. ICE COLD-PCR is a proprietary platform technology that can be run in any laboratory with standard PCR technology and which enables detection of mutations from virtually any sample type including tissue biopsies, blood, and circulating tumor cells (CTCs) at levels greater than 1,000-fold higher than standard DNA sequencing techniques.

**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 more than 1,550 WAVE Systems as of September 30, 2012. 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**

**Basis of Presentation.**

The condensed consolidated balance sheet as of December 31, 2011 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, 2012 and 2011 are unaudited and reflect all adjustments that are, in the opinion of management, necessary for a fair presentation of the financial position and operating results for the interim periods. These unaudited consolidated financial statements and notes should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2011 contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2012. The results of operations for the interim periods presented are not necessarily indicative of the results for the entire year.

**Principles of Consolidation.**

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

**Risks and Uncertainties.**

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

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

Use of Estimates.

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

Reclassifications.

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

Fair Value.

Unless otherwise specified, book value approximates fair market value. Short term investments and the common stock warrant liability are recorded at fair value. See Footnote H - Fair Value.

Cash and Cash Equivalents.

Cash and cash equivalents include cash and investments with original maturities at the date of acquisition of three months or less.

Concentrations of Cash.

From time to time, we may maintain a cash position with financial institutions in amounts that exceed federally insured limits. We have not experienced any losses on such accounts as of September 30, 2012.

Short term Investments.

Short term investments consist of U.S. Treasury securities with original maturities at the date of acquisition of one year or less.

Accounts Receivable.

The following is a summary of activity for the allowance for doubtful accounts during the three and nine months ended September 30, 2012 and 2011:

	Dollars in Thousands			
	Beginning Balance	Provision	Write Offs	Ending Balance
Three Months Ended September 30, 2012	\$1,236	\$679	\$(339)	) \$1,576
Three Months Ended September 30, 2011	\$1,387	\$205	\$(113)	) \$1,479
Nine Months Ended September 30, 2012	\$1,088	\$1,649	\$(1,161)	) \$1,576
Nine Months Ended September 30, 2011	\$334	\$1,432	\$(287)	) \$1,479

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.

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

**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, 2012 and 2011:

	Dollars in Thousands			
	Beginning Balance	Provision	Write Offs	Ending Balance
Three Months Ended September 30, 2012	\$559	\$35	\$(13	) \$581
Three Months Ended September 30, 2011	\$520	\$(2	) \$(4	) \$514
Nine Months Ended September 30, 2012	\$511	\$88	\$(18	) \$581
Nine Months Ended September 30, 2011	\$518	\$47	\$(51	) \$514

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

**Property and Equipment.**

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

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

Depreciation expense related to property and equipment was \$0.2 million and \$0.2 million during the three months ended September 30, 2012 and 2011, respectively. Included in depreciation for the three months ended September 30, 2012 and 2011 was \$0.1 million and less than \$0.1 million, respectively, related to equipment acquired under capital leases. Depreciation expense related to property and equipment was \$0.5 million and \$0.5 million during the nine months ended September 30, 2012 and 2011, respectively. Included in depreciation for the nine months ended September 30, 2012 and 2011 was \$0.2 million and \$0.1 million, respectively, related to equipment acquired under capital leases.

**Goodwill.**

Goodwill is the excess of the purchase price over fair value of assets acquired and is not amortized. Goodwill is tested for impairment annually. We perform this impairment analysis during the fourth quarter of each year or when a significant event occurs that may impact goodwill. Impairment occurs when the carrying value is determined to be not recoverable thereby causing the carrying value of the goodwill to exceed its fair value. If impaired, the asset's carrying value is reduced to its fair value. No events have transpired in the nine months ended September 30, 2012 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, 2012 had vesting periods of one or three years from the date of grant. None of the stock options outstanding at September 30, 2012 are subject to

performance or market-based vesting conditions.

10

---

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

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

During the nine months ended September 30, 2012, we recorded compensation expense of \$0.6 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 of September 30, 2012, there was \$0.7 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.

We granted 477,500 stock options during the quarter ended September 30, 2012. The fair value of the options granted was estimated on the grant date using the Black-Scholes option pricing model. The Black-Scholes model with the following assumptions was used to estimate the fair value of the options: risk-free interest rates of 0.7% based on the U.S. Treasury yield in effect at the time of grant; dividend yields of zero percent; expected lives of 5.00 years, based on expected exercise activity behavior; and volatility of 114% based on the historical volatility of our stock over a time that is consistent with the expected life of the option. Forfeitures of 3.88% have been assumed.

We did not grant any stock options during the quarter ended September 30, 2011.

**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 segment are recognized on an individual test basis and occur when the test report is completed, reviewed and sent to the client. Sales are recorded at our list price less a provision for insurance, Medicare and Medicaid contractual adjustments. There are no deferred net sales associated with our Clinical Laboratories segment. Adjustments to the allowances, based on actual receipts from third party payers, are recorded upon settlement.

In our Pharmacogenomics Services segment, we perform services on a project by project basis and recognize revenue when services are delivered. These projects typically do not extend beyond one year. At September 30, 2012 and December 31, 2011, deferred net sales associated with pharmacogenomics research projects for which we have received payment in advance of performing services was \$0.2 million and \$0.1 million, respectively, and are included in the balance sheet in accrued expenses.

Net sales of products in our Diagnostic Tools segment 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, for which payment is received at the time of execution, cover specific time periods and net sales associated with these contracts are deferred and recognized ratably over the service period. At September 30, 2012 and December 31, 2011, deferred net sales associated with our service contracts was \$1.1 million and \$1.3 million, respectively, and is included in the balance sheet in accrued expenses.



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.

Common Stock Warrants.

Our issued and outstanding warrants to purchase common stock do not qualify to be treated as equity, and accordingly, are recorded as a liability ("Common Stock Warrant Liability"). The Common Stock Warrant liability was initially recorded at fair value using a Monte Carlo simulation model. We are required to present these instruments at fair value at each reporting date

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

and any changes in fair values are recorded as an adjustment to earnings. The Common Stock Warrant liability is considered a level three financial instrument. See Footnote H - Fair Value.

**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 \$0.1 million is reported as other comprehensive income on the accompanying consolidated statement of comprehensive loss for the nine months September 30, 2012. A cumulative translation gain of \$0.1 million was reported as accumulated other comprehensive income for the nine months ended September 30, 2011. Revenues and expenses are translated at the average rates during the period. For transactions that are not denominated in the functional currency, we recognized \$0.1 million as foreign currency transaction loss in the determination of net loss for the nine months ending September 30, 2012 and less than \$0.1 million as foreign currency transaction gain in the determination of net loss for the nine months ending September 30, 2011.

**Loss Per Share.**

Basic loss per share is calculated based on the weighted-average number of common shares outstanding during each period. Diluted loss 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 29,269,699 and 17,751,940 shares of our common stock have been excluded from the computation of diluted loss per share at September 30, 2012 and 2011, respectively. The options, warrants and conversion rights that were exercisable in 2012 and 2011 were not included because the effect would be anti-dilutive due to the net loss.

**Recently adopted accounting pronouncements.**

In June 2011, the FASB issued guidance on the presentation of comprehensive income. The new guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. Instead, an entity will be required to present either a continuous statement of net income and other comprehensive income or in two separate but consecutive statements. The new guidance is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2011. We elected to report other comprehensive income and its components in a separate statement of comprehensive income for the three and nine months ended September 30, 2012 and 2011.

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

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

In May 2011, the FASB issued Accounting Standards Update No. 2011-04, "Fair Value Measurement" ("ASU 2011-04"). ASU 2011-04 amends ASC 820 to achieve common fair value measurement and disclosure requirements in U.S. Generally Accepted Accounting Principles (GAAP) and International Financial Reporting Standards (IFRS). The amended guidance requires information disclosure regarding transfers between Level 1 and Level 2 of the fair value

hierarchy, information disclosure regarding sensitivity of a fair value measurement categorized within Level 3 of the fair value hierarchy to changes in unobservable inputs and any interrelationships between those unobservable inputs, and the categorization by level of the fair value hierarchy for items that are not measured at fair value. The amended guidance was effective for financial periods beginning after December 15, 2011. ASU 2011-04 did not have a material effect on our consolidated financial position or results of operations.

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

## C. INVENTORIES

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

	Dollars in Thousands	
	September 30, 2012	December 31, 2011
Finished goods	\$3,333	\$2,608
Raw materials and work in process	1,563	1,485
Demonstration inventory	91	277
	\$4,987	\$4,370
Less allowance for obsolescence	(581)	(511)
Total	\$4,406	\$3,859

## D. INTANGIBLES AND OTHER ASSETS

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

	Dollars in Thousands					
	September 30, 2012			December 31, 2011		
	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Intangibles—acquired technology	\$9,100	\$1,594	\$7,506	\$6,535	\$911	\$5,624
Intangibles—assay royalties	1,434	359	1,075	1,434	205	1,229
Intangibles—third party payor relationships	367	—	367	367	—	367
Intangibles—tradenames and trademarks	842	86	756	344	49	295
Intangibles—customer relationships	695	—	695	—	—	—
Intangibles—covenants not to compete	277	—	277	—	—	—
Patents	915	266	649	703	267	436
Intellectual property	170	10	160	20	5	15
	\$13,800	\$2,315	\$11,485	\$9,403	\$1,437	\$7,966

	Estimated Useful Life
Intellectual property	10 years
Patents	life of patent
Intangibles—acquired technology	7 – 15 years
Intangibles—third party payor relationships	Indefinite
Intangibles—customer relationships	5 years
Intangibles—covenants not to compete	3 years
Intangibles—tradenames and trademarks	7 years

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

Amortization expense for intangible assets was \$0.3 million during each of the three months ended September 30, 2012 and 2011. Amortization expense for intangible assets was \$0.9 million during the nine months ended

September 30, 2012 and \$1.0 million during the nine months ended September 30, 2011. Amortization expense for

intangible assets is expected to be \$1.7 million in each of the years 2013 through 2017.

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

On September 21, 2012, we acquired certain intangible assets from Axial Biotech, Inc. ("Axial") related to the ScolioScore™ assay. In consideration for the purchase of the intangible assets, we made a cash payment of approximately \$3.4 million to Axial and certain of its creditors. In addition, following the transfer of all of the assets related to the ScolioScore™ assay and confirmation that the ScolioScore™ assay operates, within our laboratories pursuant to protocol agreed upon by us and Axial, we will pay an additional \$1.0 million to Axial and certain of its creditors, \$0.1 million which will be placed into escrow for a period of one year from the closing of the transaction to secure Axial's indemnification obligations for, among other things, any breach of, or default under, any of Axial's representations, warranties, covenants or agreements contained in the asset purchase agreement. This acquisition provides us with the ScolioScore™ assay technology and intellectual property, and an established revenue and customer base.

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

Intangibles—acquired technology	Relief from Royalty Method
Intangibles—tradenames	Relief from Royalty Method
Intangibles—customer relationships	Multi-Period Excess Earnings Method
Intangibles—covenants not to compete	With and Without Method
Patents	Relief from Royalty Method

The Income Approach uses valuation techniques to convert future amounts, cash flows or earnings, to a single, discounted amount. The fair value measure is based on the value that is indicated by market expectations about the present value of those future amounts.

The Relief from Royalty Method assumes that if the Company did not have proprietary ownership of the genetic testing processes on which its revenues depend, it might elect to lease the rights or licenses from another company. The fair value is measured as the estimated discounted cash flows of the royalty payments avoided by ownership.

The Multi Period Excess Earnings Method measures the fair value as the estimated discounted cash flows of the existing customer relationships over a period during which revenues from existing customer relationships are assumed to have been substantially replaced by revenues from future customers.

The With and Without Method measures the fair value of the non-competition agreements as the probability adjusted difference between the estimated discounted cash flows with and without the effect of competition. The model that includes competition includes lost revenues as well as increased expenses required to rebuild the lost revenues.

The assets acquired were \$4.2 million in identifiable intangible assets and \$0.2 million in goodwill. No liabilities were assumed. The acquired assets are reported as a component of our laboratory services segment.

The goodwill arising from the acquisition has been assigned to our Laboratory Services segment and is expected to be deductible for tax purposes.

The amounts we have recorded for the allocation of our indefinite intangible assets and goodwill are preliminary and amounts may change when the acquisition accounting is completed.

E.COMMITMENTS AND CONTINGENCIES

From time to time we are subject to 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 2022. The future minimum lease payments required under these leases are approximately \$0.3 million for the remainder of 2012, \$1.1 million in 2013, \$1.1 million in 2014, \$1.0 million in 2015, \$0.9 million in 2016 and \$0.8 million in 2017. Rent expense for each of the nine months ended September 30, 2012 and 2011 was \$0.7 million and \$0.7 million, respectively. At September 30, 2012, firm commitments to vendors totaled \$3.0 million.

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

F. INCOME TAXES

We file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and various foreign jurisdictions. We have statutes of limitation open for federal income tax returns related to tax years 2009 through 2011. We have state income tax returns subject to examination primarily for tax years 2009 through 2011. Open tax years related to foreign jurisdictions, primarily the United Kingdom, remain subject to examination for the tax years 2009 through 2011.

Income tax expense for the nine months ended September 30, 2012 was \$0.1 million. Income tax benefit for the nine months ended September 30, 2011 was \$0.1 million. Our effective tax rate for the nine months ended September 30, 2012 was 1.48%, which is primarily the result of valuation allowances against the net operating losses for the U.S., which results in us not recording net deferred tax assets in the U.S.

During the three and nine months ended September 30, 2012 and 2011, there were no material changes to the liability for uncertain tax positions.

G. STOCKHOLDERS' EQUITY

Common Stock.

At our Annual Meeting of Stockholders, held on May 23, 2012, our stockholders approved an amendment to our certificate of incorporation to increase the authorized number of shares of our common stock from 100,000,000 to 150,000,000. Our Board of Directors is authorized to issue up to 150,000,000 shares of common stock, from time to time, as provided in a resolution or resolutions adopted by the Board of Directors.

On February 7, 2012 we entered into definitive agreements with institutional and other accredited investors and raised approximately \$22.0 million in a private placement financing ("Private Placement"), which includes an aggregate of \$3.0 million in convertible notes issued in December 2011 to entities associated with Third Security, LLC, a related party, that automatically convert into shares of our common stock and warrants to purchase such common stock on the same terms as all investors in the Private Placement. Pursuant to the purchase agreement, we issued an aggregate of 19,000,000 shares of our common stock at a price per share of \$1.00, as well as five-year warrants to purchase up to an aggregate of 9,500,000 shares of common stock with an exercise price of \$1.25 per share. In connection with the conversion of the convertible notes issued by us to the entities associated with Third Security, LLC, the entities received an aggregate of 3,000,000 shares of common stock and 1,500,000 warrants on the same terms as all investors in the Private Placement. The costs incurred to complete the Private Placement were recorded as a reduction in equity in the amount of \$1.5 million. Net proceeds from this offering will be used for general corporate and working capital purposes, primarily to accelerate development of several of our key initiatives.

In connection with the Private Placement the investors have a Registration Rights Agreement which requires the Company to maintain an effective registration statement with the SEC. In the event that the registration statement is not effective the Company shall pay to each holder an amount in cash, as liquidated damages, equal to 1.5% of the aggregate purchase price paid by such holder and again on each 30 day anniversary that the deadline is not met. In no event shall the aggregate amount of the liquidated damages payable to a holder exceed 10% of the purchase price.

Pursuant to our equity financing completed in February 2012, we are obligated to pay PGxHealth, LLC ("PGx") an aggregate of \$5.5 million as a prepayment under the senior secured promissory note (the "Note"). We have accounted for the full prepayment amount as a current liability as of September 30, 2012. We have contacted PGx on numerous occasions to make arrangements for the prepayment to PGx in accordance with the terms of the Note, as well as to coordinate the timing of the prepayment. However, PGx has not responded to any of our outreach efforts. We made our initial payment of \$1.2 million under the Note in June 2012, and intend to continue to comply with the original terms of the Note.

Common Stock Warrants.



Common stock warrants issued during the three and nine ended September 30, 2012 were 0 and 11,000,000, respectively, and none of the issued warrants were exercised. No common stock warrants were issued or exercised during the three and nine months ended September 30, 2011. Warrants to purchase an aggregate of 16,172,408 shares of common stock were outstanding at September 30, 2012.

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

Warrant Holder	Issue Year	Expiration	Underlying Shares	Exercise Price
Affiliates of Third Security, LLC <sup>(1)</sup>	2010	December 2015	5,172,408	\$0.58
Various Institutional Holders <sup>(2)</sup>	2012	February 2017	9,500,000	\$1.25
Affiliates of Third Security, LLC <sup>(2)</sup>	2012	February 2017	1,500,000	\$1.25
			16,172,408	

(1) This Warrant was issued in connection with the issuance of warrants to purchase shares of our Series A Preferred Stock to affiliates of Third Security, LLC in December 2010. The number of underlying shares shown reflects the number of shares of common stock issuable upon conversion of the shares of Series A Preferred Stock for which this Warrant is currently exercisable.

(2) These Warrants were issued in connection with the Private Placement completed in February 2012.

**H. FAIR VALUE**

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.

U.S. Treasury securities are classified as Level 1 within the fair value hierarchy, as fair value is based on quoted prices in active markets.

	Dollars in Thousands	
	September 30, 2012	December 31, 2011
U.S. Treasury securities	\$3,998	\$—

**Common Stock Warrant Liability**

Our issued and outstanding warrants to purchase common stock do not qualify to be treated as equity, and accordingly are recorded as a liability. The Common Stock Warrant Liability represents the fair value of the 11.0 million warrants issued in February 2012. We are required to record these instruments at fair value at each reporting date and changes are recorded as a non-cash adjustment to earnings. The gains or losses included in earnings are reported in other income (expense) in our Statement of Operations. Management does not believe that this liability will be settled by a use of cash.

The Common Stock Warrant Liability is considered a Level 3 financial instrument and is valued using a Monte Carlo simulation. This method is well suited to value options with non-standard features, such as anti-dilution protection. A Monte Carlo simulation model uses repeated random sampling to simulate significant uncertainty in inputs.

Assumptions and inputs used in the valuation of the common stock warrants are broken down into four sections: Static Business Inputs; Static Technical Inputs; Simulated Business Inputs; and Simulated Technical Inputs.

Static Business Inputs include: Our equity value, which was estimated using our stock price of \$0.95 as of September 30, 2012; the amount of the down-round financing, the timing of the down-round financing, the expected exercise period of 4.35 years from the valuation date and the fact that no other potential fundamental transactions are expected during the term of the common stock warrants.

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

Static Technical Inputs include: volatility of 55% and the risk-free interest rate of 0.54% based on the 4.5-year U.S. Treasury yield interpolated from the 3 year and 5 year U.S. Treasury bonds.

Simulated Business Inputs include: the probability of down-round financing which was estimated to be 25% for simulated equity values below the down-round financing cut-off point.

Simulated Technical Inputs include: our equity value in periods 1-10 follows a geometric Brownian motion and is simulated over 10 independent six-month periods; a down-round financing event was randomly simulated in an iteration based on the 25% discrete probability of a down-round financing for those iterations where our simulated equity value at the expected timing of down-round financing was below the down-round financing cut-off point.

During the three months ended September 30, 2012, the changes in the fair value of the liability measured using significant unobservable inputs (Level 3) was comprised of the following:

	Dollars in Thousands For the Three Months Ended September 30, 2012
Beginning balance at June 30, 2012	\$2,100
Total gains or losses:	
Recognized in earnings	—
Balance at September 30, 2012	\$2,100

During the nine months ended September 30, 2012, the changes in the fair value of the liability measured using significant unobservable inputs (Level 3) was comprised of the following:

	Dollars in Thousands For the Nine Months Ended September 30, 2012
Beginning balance	\$3,100
Total gains or losses:	
Recognized in earnings	(1,000 )
Balance at September 30, 2012	\$2,100

**Preferred Stock Warrant Liability and Conversion Feature**

Prior to November 2011, we were required to record our 5.2 million of preferred stock warrants and the preferred stock's conversion feature at their respective fair values at each reporting date and changes were recorded as an adjustment to earnings. The gains or losses included in earnings were reported in other income (expense) in our Statement of Operations.

Due to a change in terms we are no longer required to recognize the preferred stock warrant and preferred stock conversion feature as liabilities. They were reclassified into stockholders' equity as of the date of the amended agreement.

The preferred stock warrant liability and preferred stock conversion feature were considered Level 3 financial instruments and were 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, 2011 valuation of the preferred stock conversion feature: the closing share price of our common 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 five year U.S. Treasury bond and volatility of 103%.

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

The following assumptions were used in the September 30, 2011 valuation 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 two 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 30, 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

The change in unrealized gains or losses of Level 3 liabilities is included in earnings and is reported in other income (expense) in our Statement of Operations.

**I. STOCK OPTIONS**

The following table summarizes stock option activity during the nine months ended September 30, 2012:

	Number of Options	Weighted Average Exercise Price
Balance at January 1, 2012	4,172,000	\$ 1.10
Granted	626,500	1.03

Edgar Filing: TRANSGENOMIC INC - Form 10-Q

Exercised	(20,000	) (0.50	)
Forfeited	(439,000	) (1.20	)
Canceled	(25,500	) (5.42	)
Balance at September 30, 2012	4,314,000	\$ 1.06	
Exercisable at September 30, 2012	2,752,471	\$ 1.02	

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

During the nine months ended September 30, 2012, we granted options exercisable to purchase 626,500 shares of common stock at a weighted average exercise price of \$1.03 per share under our 2006 Equity Incentive Plan. Options to purchase an aggregate of 2,335,500 shares of common stock were granted during the nine months ended September 30, 2011.

**J. OPERATING SEGMENT AND GEOGRAPHIC INFORMATION**

Our chief operating decision-maker is our Chief Executive Officer, who regularly evaluates our performance based on net sales and net loss before taxes. 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.

Segment information for the three months ended September 30, 2012 and 2011 is as follows:

	Dollars in Thousands				
	2012				
	Clinical Laboratories	Pharmacogenomic Services	Diagnostic Tools	Total	
Net Sales	\$4,498	\$ 220	\$3,171	\$7,889	
Gross Profit	2,385	(38	) 1,453	3,800	
Net Loss before Taxes	(1,694	) (213	) (733	) (2,640	)
Income Tax Expense	—	—	114	114	
Net Loss	\$(1,694	) \$(213	) \$(847	) \$(2,754	)
Depreciation/Amortization	\$418	\$ 24	\$53	\$495	
Interest Expense, net	\$(201	) \$—	\$(6	) \$(207	)

	September 30, 2012			
Total Assets	\$28,822	\$1,731	\$12,334	\$42,887

	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 Expense, net	\$(238	) \$ —	\$ —	\$(238	)



Edgar Filing: TRANSGENOMIC INC - Form 10-Q

	September 30, 2011			
	\$20,822	\$ 953	\$8,199	\$29,974
Total Assets				

19

---

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARIES

## NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2012 and 2011

Segment information for the nine months ended September 30, 2012 and 2011 is as follows:

	Dollars in Thousands			
	2012			
	Clinical Laboratories	Pharmacogenomic Services	Diagnostic Tools	Total
Net Sales	\$13,329	\$1,198	\$9,661	\$24,188
Gross Profit	6,693	418	4,355	11,466
Net Loss before Taxes	(4,309)	) (310)	) (1,307)	) (5,926)
Income Tax Expense	—	—	88	88
Net Loss	\$(4,309)	) \$(310)	) \$(1,395)	) \$(6,014)
Depreciation/Amortization	\$1,265	\$92	\$213	\$1,570
Restructure	\$—	\$—	\$—	\$—
Interest Expense, net	\$(665)	) \$(11)	) \$(37)	) \$(713)

	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 Benefit	—	—	(120)	) (120)
Net Income (Loss)	\$(11,331)	) \$615	\$671	\$(10,045)
Depreciation/Amortization	\$1,113	\$184	\$209	\$1,506
Restructure	\$28	\$—	\$12	\$40
Interest Expense, net	\$(720)	) \$—	\$—	\$(720)

Net sales for the three and nine months ended September 30, 2012 and 2011 by country were as follows:

	Dollars in Thousands		Dollars in Thousands	
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
United States	\$5,442	\$6,034	\$17,013	\$16,738
Italy	571	762	2,277	2,373
United Kingdom	546	193	1,113	451
France	264	166	575	579
Germany	517	187	769	581
All Other Countries	549	911	2,441	2,678
Total	\$7,889	\$8,253	\$24,188	\$23,400

Other than the countries specifically identified above, no other country individually accounted for more than 5% of total net sales.

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

## Table of Contents

### K. 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. We have no material subsequent events to disclose.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Forward-Looking Information

This report, including Management's Discussion & Analysis, contains forward-looking statements. These statements are based on management's current views, assumptions or beliefs of future events and financial performance and are subject to uncertainty and changes in circumstances. Readers of this report should understand that these statements are not guarantees of performance or results. Many factors could affect our actual financial results and cause them to vary materially from the expectations contained in the forward-looking statements. These factors include, among other things: our expected revenue, income (loss), receivables, operating expenses, supplier pricing, availability and prices of raw materials, Medicare/Medicaid/Insurance reimbursements, product pricing, foreign currency exchange rates, sources of funding operations and acquisitions, our ability to raise funds, sufficiency of available liquidity, future interest costs, future economic circumstances, industry conditions, our ability to execute our operating plans, the success of our cost savings initiatives, competitive environment and related market conditions, actions of governments and regulatory factors affecting our business and other risks as described in our reports filed with the Securities and Exchange Commission. In some cases these statements are identifiable through the use of words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "target," "can," "could," "may," "should," "will," "would" and similar. 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 and in Part I, Item 1A "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, which we filed with the Securities and Exchange Commission on March 14, 2012.

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 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, which we filed with the Securities and Exchange Commission on March 14, 2012. Results for the three and nine months ended September 30, 2012 are not necessarily indicative of results that may be attained in the future.

### Overview

We are a global biotechnology company advancing personalized medicine in the detection and treatment of cancer and inherited diseases through our proprietary molecular technologies and 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 also accredited by the College of American Pathologists (CAP).

**Pharmacogenomics Services.** Our Contract Research Organization located in Omaha, Nebraska provides pharmacogenomics research services supporting Phase II and Phase III clinical trials conducted by our pharmaceutical customers. This lab specializes in pharmacogenomic, biomarker and mutation discovery research testing that serves

the pharmaceutical and biomedical industries world-wide for disease research, drug and diagnostic development and

Table of Contents

clinical trial support. The lab employs a variety of genomic testing service technologies including ICE COLD-PCR technology. ICE COLD-PCR is a proprietary platform technology that can be run in any laboratory with standard PCR technology and which enables detection of mutations from virtually any sample type including tissue biopsies, blood, and circulating tumor cells (CTCs) at levels greater than 1,000-fold higher than standard DNA sequencing techniques. 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 more than 1,550 WAVE Systems as of September 30, 2012. 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.

In our Clinical Laboratories segment, one of our key products is our new proprietary C-GAAP (Clopidogrel Genetic Absorption Activation Panel) test. In July of 2012, we successfully secured Medicare coverage for C-GAAP, which is a simple but comprehensive saliva test that accurately predicts whether or not a patient has the appropriate genetic make up to receive a therapeutic benefit from Plavix® (clopidogrel). This innovative test analyzes markers in two important genes to identify patients who are at a genetically increased risk of major adverse cardiovascular events due to diminished effectiveness of Plavix® (clopidogrel). As a result of this coverage, the 48 million Americans currently covered by Medicare will have access to this important genetic test.

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

In September, we announced the completion of the acquisition of global rights to the ScolioScore™ Adolescent Idiopathic Scoliosis (AIS) Prognostic Test from Axial Biotech. This acquisition provides Transgenomic with the ScolioScore™ assay technology and intellectual property, an established revenue and customer base, and access to a testing market estimated at more than 400,000 patients in the United States alone. ScolioScore™ is the first clinically validated and commercially available saliva-based multi-gene test that provides a highly accurate assessment of the likelihood of spinal curve progression for individuals diagnosed with AIS, or an abnormal lateral curve of the spine. ScolioScore™ has the ability to identify patients that will not progress to a severe curvature of the spine and reduces those patients' need for repeated doctor visits, and more importantly, years of exposure to radiation from frequent X-Rays which significantly increases these patients' risk for cancer. The health economic benefits of the ScolioScore™ Test are considerable for patients, physicians, and payors, when taking into account the time and expense associated with repeated radiography and the costs related to treating AIS. ScolioScore™ is emblematic of the kind of value-added, proprietary genetic test that Transgenomic seeks to provide to patients.

In August, we announced a new commercial collaboration with the Medical College of Wisconsin Laboratories (MCW), a world-renowned institution with a robust presence in genomics and genetic testing. In addition to traditional sequencing services, MCW is the first lab to offer Transgenomic's proprietary NuclearMitome Test which employs next-generation sequencing technology to identify mutations in 448 genes and, to date, represents the most comprehensive genetic test available for mitochondrial disorders. Mitochondrial disorders are notoriously difficult to diagnose because they affect multiple organ systems, including the liver, the brain and nervous system, kidneys, and cardiovascular system. We expect that MCW will commence processing commercial tests in the 4th quarter of 2012. 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. ICE COLD-PCR enables detection of mutations from virtually any sample type including tissue biopsies, blood, and circulating tumor cells (CTCs). The broad use of this innovative technology

has the potential to benefit cancer screening, diagnosis, monitoring, and therapy selection since it has the ability to perform safer, less invasive, and more frequent assessments of a cancer and its mutations, all through a simple blood draw. In addition to our on-going study in several cancer types with MD Anderson, we have initiated two new collaborations for clinical validation of our advanced platform technology.

Collaboration with NYU Langone Medical Center to better understand molecular events that drive non-small cell lung cancer and validate the use of ICE COLD-PCR mutation detection in blood (which we refer to as a “blood biopsy”) for determining the appropriate response to existing and novel therapies in NSCLC.

Table of Contents

Collaboration with the University of Nebraska Medical Center for employing ICE COLD-PCR for the early detection of Pancreatic Cancer. Transgenomic was awarded an NIH STTR Grant to support this work.

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

Finally, in September, we announced the appointment of Mark P. Colonnese as Executive Vice President and Chief Financial Officer of Transgenomic. Mr. Colonnese has nearly 30 years of experience in leading business growth and financial strategies for life sciences companies. In this new role, Mr. Colonnese will be a key player in Transgenomic's expansion through strategic corporate development, new collaborations, and future acquisitions. He will also lead our financial and capital markets strategy and advise on business development and transactional activities.

**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. We have been able to historically finance our operating losses through borrowings or from the issuance of additional equity. At September 30, 2012 we had cash, cash equivalents and short term investments of \$8.7 million. We believe that existing sources of liquidity are sufficient to meet expected cash needs for at least the next 12 months.

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 and financial results.



## Table of Contents

### Results of Operations

Net sales for the nine months ended September 30, 2012 increased by \$0.8 million, or 3% compared to the same period in 2011. During the nine months ended September 30, 2012, net sales from our Clinical Laboratories segment increased by \$1.9 million compared to the same nine month period in 2011. Net sales from our Pharmacogenomics Services segment decreased by \$0.6 million for the nine months ended September 30, 2012 compared to the same period in 2011. Net sales in our Diagnostic Tools segment decreased \$0.5 million for the nine months ended September 30, 2012 compared to the same period in 2011. Our gross profit margin decreased to 47% for the nine months ended September 30, 2012 from 56% for the nine months ended September 30, 2011. Loss from operations was \$6.2 million for the nine months ended September 30, 2012 compared to \$10.0 million for the nine months ended September 30, 2011.

### Three Months Ended September 30, 2012 and 2011

Net Sales. Net sales for the three months ended September 30, 2012 decreased by \$0.4 million, or 4% compared to the same period of 2011. Net sales performance in each of the segments was as follows:

	Dollars in Thousands				
	Three Months Ended				
	September 30,		Change		
	2012	2011	\$	%	
Clinical Laboratories	\$4,498	\$4,085	\$413	10	%
Pharmacogenomics Services	220	552	(332)	(60)	)%
Diagnostic Tools	3,171	3,616	(445)	(12)	)%
Total Net Sales	\$7,889	\$8,253	\$(364)	(4)	)%

Clinical Laboratories net sales of \$4.5 million increased \$0.4 million, or 10% during the three months ended September 30, 2012 compared to the same period in 2011. Revenue increased compared to last year due to higher test volumes, largely reflecting the introduction of our C-GAAP diagnostic test, and a modest shift towards higher priced tests.

Pharmacogenomics Services net sales of \$0.2 million during the three months ended September 30, 2012 decreased by \$0.3 million compared to the same period of 2011 due to a decrease in the volume of genetic testing performed in connection with various clinical trials by our pharmaceutical company clients. Pharmacogenomics Services net sales trends are more volatile than our other segments 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 can be 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.

Diagnostic Tools net sales of \$3.2 million decreased \$0.4 million, or 12%, during the three months ended September 30, 2012 as compared to the same period in 2011. We sold more instruments in the third quarter of 2012 than in the third quarter of 2011, but there was a shift this quarter to lower priced instruments.

Cost of Goods Sold. Cost of goods sold includes 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.

Table of Contents

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 %		
	2012	2011	2012	2011	
Clinical Laboratories	\$2,385	\$2,456	53	%	60
Pharmacogenomics Services	(38	) 241	(17	)%	44
Diagnostic Tools	1,453	1,748	46	%	48
Gross Profit	\$3,800	\$4,445	48	%	54

Gross profit was \$3.8 million, or 48% of total net sales during the third quarter of 2012, compared to \$4.4 million, or 54% of total net sales during the same period of 2011. During the three months ended September 30, 2012, the gross margin for Clinical Laboratories was 53% as compared to 60% in the same period of 2011. The change in Clinical Laboratories gross margin is attributable to a change in the mix of tests performed and higher operating supplies, wages and software costs, which we are investing in a project to improve the efficiency of our lab operations. Pharmacogenomics Services gross margin decreased from 44% for the three months ended September 30, 2011 to (17)% for the three months ended September 30, 2012. Pharmacogenomics Services has a relatively fixed-cost base and any increase or decrease in revenue directly impacts gross margins. Diagnostic Tools gross margin decreased to 46% for the three months ended September 30, 2012 from 48% in the same period of 2011 due to the mix of instruments sold.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses primarily consist of personnel costs, marketing, travel costs, professional fees, and facility costs. In addition, the effects of foreign currency revaluation are included in selling, general and administrative expenses. Our selling, general and administrative costs increased \$1.2 million to \$5.6 million from \$4.4 million during the three month period ended September 30, 2012 compared to the same period in 2011. We had higher bad debt expenses and stock compensation costs during the three months ended September 30, 2012. We also had higher recruiting fees, which were incurred to increase the size of our sales force to support C-GAAP and the launch of ScoliScore™, and higher marketing materials expenses. Included in our selling, general and administrative expenses for the three month period ended September 30, 2012 were \$0.1 million in costs related to our acquisition of the ScoliScore™ test from Axial.

**Research and Development Expenses.** Research and development expenses primarily include personnel costs, intellectual property 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, 2012 and 2011, these costs totaled \$0.7 million and \$0.5 million, respectively. Research and development expenses totaled 8% and 6% of net sales during the three months ended September 30, 2012 and 2011, respectively.

**Other Income (Expense).** Other expense for the three months ended September 30, 2012 and 2011 includes interest expense of \$0.2 million.

**Income Tax Expense (Benefit).** Income tax expense for the three months ended September 30, 2012 was \$0.1 million, primarily related to income reported in the financial statements of our foreign subsidiary. Income tax benefit for the three months ended September 30, 2011 was nominal.

Table of Contents

## Nine Months Ended September 30, 2012 and 2011

Net Sales. Net sales for the nine months ended September 30, 2012 increased by \$0.8 million, or 3%., compared to the same period of 2011. Net sales performance in each of the segments was as follows:

	Dollars in Thousands		Change		
	Nine Months Ended				
	September 30,				
	2012	2011	\$	%	%
Clinical Laboratories	\$13,329	\$11,435	\$1,894	17	%
Pharmacogenomics Services	1,198	1,824	(626)	(34)	)%
Diagnostic Tools	9,661	10,141	(480)	(5)	)%
Total Net sales	\$24,188	\$23,400	\$788	3	%

Clinical Laboratories net sales of \$13.3 million increased \$1.9 million, or 17% during the nine months ended September 30, 2012 compared to the same period in 2011 due to a higher volume of tests, including new tests such as our NuclearMitome test and our C-GAAP test as well as the mix of tests performed.

Pharmacogenomics Services net sales of \$1.2 million during the nine months ended September 30, 2012 decreased by \$0.6 million compared to the same period of 2011 due to the lower volume of genetic testing performed in connection with various clinical trials by our pharmaceutical company clients. Pharmacogenomics Services net sales trends are more volatile than our other segments 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 can be 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.

Diagnostic Tools net sales of \$9.7 million decreased \$0.5 million during the nine months ended September 30, 2012 as compared to the same period in 2011. We sold more instruments at a lower average sales price per instrument during the nine months ended September 30, 2012 compared to 2011.

Cost of Goods Sold. Cost of goods sold includes 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		Margin %		
	Nine Months Ended				
	September 30,				
	2012	2011	2012	2011	%
Clinical Laboratories	\$6,693	\$6,787	50	% 59	%
Pharmacogenomics Services	418	764	35	% 42	%
Diagnostic Tools	4,355	5,601	45	% 55	%
Gross Profit	\$11,466	\$13,152	47	% 56	%

Gross profit was \$11.5 million or 47% of total net sales during the nine months ended September 30, 2012, compared to \$13.2 million, or 56% of total net sales during the same period of 2011.

During the nine months ended September 30, 2012, the gross margin for Clinical Laboratories was 50% as compared to 59% in the same period of 2011 due to the mix of tests performed and higher operating supplies, wages and software costs incurred both in connection with repairing and improving the Laboratory Information Management System (LIMS) at our New Haven facility following its software failure in the first quarter of 2012, including processing our sample backlog, and in connection with an important project to improve the efficiency of our lab operations.



Table of Contents

Pharmacogenomics Services gross margin decreased from 42% for the nine months ended September 30, 2011 to 35% for the nine months ended September 30, 2012. Pharmacogenomics Services has a relatively fixed-cost base and any increase or decrease in revenue directly impacts gross margins.

Diagnostic Tools gross margin decreased to 45% in the nine months ended September 30, 2012 from 55% in the nine months ended September 30, 2011 due to the mix of instruments sold.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses primarily consist of personnel costs, marketing, travel costs, professional fees, and facility costs. In addition, the effects of foreign currency revaluation are included in selling, general and administrative expenses. Our selling, general and administrative costs increased \$1.6 million from \$14.3 million to \$15.8 million during the nine month period ended September 30, 2012 compared to the same period in 2011. We had higher bad debt expense, marketing materials and employment fees, partially offset by lower stock compensation costs for the nine months ended September 30, 2012 as compared to the same period of 2011. Included in our higher outside services for the nine month period ended September 30, 2012 were the costs related to our acquisition of the ScoliScore™ test of \$0.1 million.

**Research and Development Expenses.** Research and development expenses primarily include personnel costs, legal fees, outside services, collaboration expenses, supplies, and facility costs and are expensed in the period in which they are incurred. For the nine months ended September 30, 2012 and 2011, these costs totaled \$1.9 million and \$1.7 million, respectively. Research and development expenses totaled 8% of net sales during the nine months ended September 30, 2012 and 7% during the same period in 2011.

**Other Income (Expense).** Other expense for the nine months ended September 30, 2012 and 2011 includes interest expense of \$0.7 million and the income associated with the change in fair value of our Common Stock Warrant Liability of \$1.0 million. Other expense in 2011 also includes the expense associated with the change in fair value of the Preferred Stock conversion feature and warrants of 6.9 million. The income or expense associated with the change in fair values of our Common Stock Warrant Liability and the preferred stock conversion feature and warrants are non-cash items.

**Income Tax Expense (Benefit).** Income tax expense for the nine months ended September 30, 2012 was \$0.1 million. This is primarily comprised of taxes on income earned by our foreign subsidiary. Income tax benefit for the nine months ended September 30, 2011 was \$0.1 million.

### Liquidity and Capital Resources

Our working capital positions at September 30, 2012 and December 31, 2011 were as follows:

	Dollars in Thousands		
	September 30, 2012	December 31, 2011	Change
Current assets (including cash, cash equivalents and short term investments of \$8,745 and \$4,946, respectively)	\$22,494	\$17,198	\$5,296
Current liabilities	16,600	16,328	272
Working capital	\$5,894	\$870	\$5,024

On February 7, 2012, we entered into a definitive agreement with institutional and other accredited investors and raised approximately \$22.0 million in a private placement financing which included \$3.0 million in convertible notes issued in December 2011 that were converted into shares of our common stock as part of the private placement financing. Net proceeds of the private placement financing were \$17.4 million.

Pursuant to our equity financing completed in February 2012, we are obligated to pay PGxHealth, LLC ("PGx") an aggregate of \$5.5 million as a prepayment under the senior secured promissory note (the "Note"). We have accounted for the full prepayment amount as a current liability as of September 30, 2012. We have contacted PGx on numerous occasions to make arrangements for the prepayment to PGx in accordance with the terms of the Note, as well as to coordinate the timing of the prepayment. However, PGx has not responded to any of our outreach efforts. We made our initial payment of \$1.2 million under the Note in June 2012, and intend to continue to comply with the original

terms of the Note.

On September 21, 2012, we acquired certain intangible assets from Axial Biotech, Inc (Axial) related to the Scoliscore™ assay. In consideration for the purchase of the intangible assets, we made a cash payment of approximately \$3.4 million to Axial and certain of its creditors. In addition, within ten days following the transfer of all of the assets related to the Scoliscore™ assay and confirmation that the Scoliscore™ assay operates, within our laboratories pursuant to protocol agreed upon by us and Axial,

## Table of Contents

we will pay an additional \$1.0 million to Axial and certain of its creditors, \$0.1 million of which will be placed into escrow for a period of one year from the closing of the transaction to secure Axial's indemnification obligations for, among other things, any breach of, or default under, any of Axial's representations, warranties, covenants or agreements contained in the asset purchase agreement.

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. At September 30, 2012, we had cash, cash equivalents and short term investments of \$8.7 million. We believe that existing sources of liquidity are sufficient to meet expected cash needs for at least the next 12 months. However, we cannot be certain 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, 2012 and 2011

**Net Change in Cash and Cash Equivalents.** Cash and cash equivalents decreased by \$0.2 million during the nine months ended September 30, 2012 compared to a decrease of \$2.0 million during the nine months ended September 30, 2011. During the nine months ended September 30, 2012 we used cash of \$7.8 million in operating activities, \$8.4 million in investing activities, which was offset by cash provided by financing activities of \$15.9 million. In the nine months ended September 30, 2011, net cash used in operating activities was \$0.9 million, \$0.4 million was used in investing activities and \$0.8 million was used in financing activities.

**Cash Flows Used In Operating Activities.** Cash flows used in operating activities totaled \$7.8 million during the nine months ended September 30, 2012 compared to cash flows used in operating activities of \$0.9 million during the nine months ended September 30, 2011. The cash flows used in operating activities in 2012 include the net loss, increase in accounts receivable of \$2.2 million and decrease in accounts payable of \$1.1 million, offset by non-cash items including the warrant revaluation of \$1.0 million, provision for losses on doubtful accounts of \$1.6 million, stock option expense of \$0.6 million and depreciation and amortization of \$1.6 million. The cash flows used in operating activities in 2011 include the net loss and increase in accounts receivable of \$1.4 million, offset by the non-cash items, which include revaluation of the preferred stock conversion feature and warrant liability of \$6.9 million, provision for losses on doubtful accounts of \$1.4 million and depreciation and amortization of \$1.5 million.

**Cash Flows Used In Investing Activities.** Cash flows used in investing activities totaled \$8.4 million during the nine months ended September 30, 2012 compared to cash flows used in investing activities of \$0.4 million during the same period of 2011. Cash flows used in investing activities in 2012 included purchases of short term investments of \$9.0 million, acquisition of ScoliScore™ assets of \$3.4 million, purchases of property and equipment of \$0.6 million and additions to our patents of \$0.3 million, offset by proceeds from the sale of short term investments of \$5.0 million. 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 Provided by or Used in Financing Activities.** Cash flows provided by financing activities were \$15.9 million for the nine months ended September 30, 2012. Cash provided by financing activities during the nine months ended September 30, 2012 included the proceeds from the issuance of 19.0 million shares of our common stock and from the issuance of our common stock in connection with the exercise of stock options for 20,000 shares. Cash flows used in financing activities were for payments on debt and capital lease obligations. 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 offset by the cash received from issuance of common stock in connection with the exercise of stock options for 10,000 shares during the first nine months of 2011.

### Off-Balance Sheet Arrangements

At September 30, 2012 and December 31, 2011, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

#### Critical Accounting Policies 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



## Table of Contents

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, 2011 filed with the Securities and Exchange Commission on March 14, 2012.

### Recently Issued Accounting Pronouncements

Please refer to our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 filed with the Securities and Exchange Commission on March 14, 2012. There have been no changes to those accounting pronouncements listed except as noted in Footnote B - Summary of Significant Accounting Policies to the notes to unaudited condensed consolidated financial statements contained in this report.

### Impact of Inflation

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

## Item 3. Quantitative and Qualitative Disclosures About Market Risk

### Foreign Currency Translation Risk

Sales of products in foreign countries are mainly completed in either the Euro or the British Pounds Sterling. Additionally, the British Pound Sterling is the functional currency of our wholly owned subsidiary, Transgenomic Limited. Results of operations and the balance sheet are translated from the functional currency of the subsidiary to our reporting currency of the U.S. Dollar. Results of operations for our foreign subsidiary are translated using the average exchange rate during the period. Assets and liabilities are translated at the exchange rate in effect at the balance sheet date. In addition, we have revaluation risk, which occurs when the transaction is consummated in a currency other than the British Pound Sterling. This transaction must be revalued by Transgenomic Limited, whose functional currency is the British Pound Sterling. The majority of the transactions consummated by Transgenomic Limited are in Euro. As a result, we are subject to exchange rate risk and we do not currently engage in foreign currency hedging activities.

## Item 4. Controls and Procedures

**Evaluation of Disclosure Controls and Procedures.** Management performed, with the participation of our Chief Executive Officer and our 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 Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our disclosure controls and procedures are designed to ensure 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 Securities and Exchange Commission's rules and 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, our Chief Executive Officer and our Chief Financial Officer concluded that, as of September 30, 2012, our 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, 2012 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.



Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are subject to a number of claims of various amounts that 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

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

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

Except as set forth above, there have been no material changes in our risk factors from those previously disclosed in Part 1, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2011 that was filed with the Securities and Exchange Commission on March 14, 2012.

Table of Contents

Item 6. Exhibits

(a) Exhibits

- |       |  |
|-------|--|
| 2.1** | Asset Purchase Agreement among the Registrant, Scoli Acquisition sUb, Inc. and Axial Biotech, Inc. dated August 27, 2012   |
| 3.1   | Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly 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 Exhibit 3(ii) to the Registrant's Current 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 the Registrant's Current Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)   |
| 3.4   | Certificate of Amendment of Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (Registration No. 000-30975) filed on May 29, 2012)   |
| 3.5   | Certificate of Amendment of Certificate of Designation of Series A Convertible Preferred Stock of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (Registration No. 000-30975) filed on May 29, 2012)  |
| 4.1   | Form of Certificate of the Registrant's Common Stock (incorporated by reference to Exhibit 4 to the Registrant's Registration Statement on Form S-1 (Registration No. 333-32174) filed on March 10, 2000)  |
| 4.2   | Common Stock Purchase Warrant by and between the Registrant and Laurus Master Fund, Ltd., dated December 3, 2003 (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-3 (Registration No. 333-111442) filed on December 22, 2003)                             |
| 4.3   | Registration Rights Agreement by and between the Registrant and Laurus Master Fund, Ltd., dated December 3, 2003 (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-3 (Registration No. 333-111442) filed on December 22, 2003)                             |
| 4.4   | Common Stock Purchase Warrant by and between the Registrant and Laurus Master Fund, Ltd., dated February 19, 2004, as amended on April 15, 2004 (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-3 (Registration No. 333-114661) filed on April 21, 2004) |
| 4.5   | Registration Rights Agreement by and between the Registrant and Laurus Master Fund, Ltd., dated February 19, 2004 (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-3 (Registration No. 333-114661) filed on April 21, 2004)                               |
| 4.6   | Common Stock Purchase Warrant by and between the Registrant and Laurus Master Fund, Ltd., dated August 31, 2004 (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-3 (Registration No. 333-118970) filed on September 14, 2004)                             |

- 4.7 Common Stock Purchase Warrant by and between the Registrant and Oppenheimer & Co., Inc. dated October 27, 2005 (incorporated by reference to Exhibit 10.34 to the Registrant's Annual Report on Form 10-K filed on March 31, 2006)
- 4.8 Form of Series A Convertible Preferred Stock Warrant issued to Third Security Senior Staff 2008 LLC, Third Security Staff 2010 LLC, and Third Security Incentive 2010 LLC (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)
- 4.9 Registration Rights Agreement, dated December 29, 2010, by and among the Registrant, 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 the Registrant's Current Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)
- 4.10 First Amendment to Registration Rights Agreement dated November 8, 2011 (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on November 14, 2011)
- 4.11 Secured Promissory Note, issued December 29, 2010 by the Registrant in favor of PGxHealth, LLC (incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)
- 4.12 Secured Promissory Note, issued December 29, 2010 by the Registrant in favor of PGxHealth, LLC (incorporated by reference to Exhibit 4.5 to the Registrant's Current Report on Form 8-K (Registration No. 000-30975) filed on January 4, 2011)

Table of Contents

4.13	Convertible Promissory Note by and between the Registrant and Third Security Senior Staff 2008 LLC dated December 30, 2011 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on January 6, 2012)
4.14	Convertible Promissory Note by and between the Registrant and Third Security Staff 2010 LLC dated December 30, 2011 (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on January 6, 2012)
4.15	Convertible Promissory Note by and between the Registrant and Third Security Incentive 2010 LLC dated December 30, 2011 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on January 6, 2012)
4.16	Form of Warrant issued by the Registrant to the Third Security Entities on February 7, 2012 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on February 7, 2012)
4.17	Form of Warrant issued by the Registrant to the Investors on February 7, 2012 (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on February 7, 2012)
4.18	Form of Registration Rights Agreement entered into by and among the Registrant, the Third Security Entities and the Investors dated February 2, 2012 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on February 7, 2012)
10.1#	Employment Agreement between Registrant and Mark P. Colonnese (incorporated by reference Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 17, 2012)
31.1	Certification of Craig J. Tuttle, President and Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended
31.2	Certification of Mark P. Colonnese, Executive Vice President and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended
32.1	Certification of Craig J. Tuttle, President and Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended
32.2	Certification of Mark P. Colonnese, Executive Vice President Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended
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 *

Pursuant to Item 601(b)(2) of Regulation S-K, the schedules to this agreement have been omitted. The Registrant agrees to furnish supplementally a copy of any omitted schedule to the Securities and Exchange Commission upon request.

\*\*

# Indicates management contract or compensatory plan.

\*

Attached as Exhibit 101 to this report are documents formatted in XBRL (Extensible Business Reporting Language). Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, the interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is otherwise not subject to liability under these sections.

32

---

Table of Contents

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 8, 2012

By: /S/ CRAIG J. TUTTLE

Craig J. Tuttle

President and Chief Executive Officer