

TRANSGENOMIC INC  
Form 10-Q  
November 14, 2013  
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, 2013

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

Commission File Number: 000-30975

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

Delaware  
(State or other jurisdiction of incorporation or organization)

91-1789357  
(I.R.S. Employer Identification No.)

12325 Emmet Street, Omaha, Nebraska  
(Address of principal executive offices)  
(402) 452-5400  
(Registrant's telephone number, including area code)

68164  
(Zip 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  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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 13, 2013, the number of shares of common stock outstanding was 88,245,725.



Table of ContentsTRANSGENOMIC, 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, 2013 (Unaudited) and December 31, 2012 (Audited)</u>	<u>3</u>
<u>Unaudited Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2013 and 2012</u>	<u>4</u>
<u>Unaudited Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2013 and 2012</u>	<u>5</u>
<u>Unaudited Condensed Consolidated Statements of Stockholders' Equity for the Nine Months Ended September 30, 2013</u>	<u>6</u>
<u>Unaudited Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2013 and 2012</u>	<u>7</u>
<u>Notes to Unaudited Condensed Consolidated 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>28</u>
Item 4. <u>Controls and Procedures</u>	<u>28</u>
PART II. <u>OTHER INFORMATION</u>	<u>29</u>
Item 1. <u>Legal Proceedings</u>	<u>29</u>
Item 1A. <u>Risk Factors</u>	<u>29</u>
Item 5. <u>Other Information</u>	<u>29</u>
Item 6. <u>Exhibits</u>	<u>30</u>
<u>Signatures</u>	<u>32</u>

Table of Contents

## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

TRANSGENOMIC, INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(Dollars in thousands except per share data)

	September 30, 2013 (unaudited)	December 31, 2012
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$4,016	\$4,497
Accounts receivable, net	4,414	8,081
Inventories, net	4,454	5,092
Other current assets	1,290	1,047
Total current assets	14,174	18,717
<b>PROPERTY AND EQUIPMENT:</b>		
Equipment	11,164	10,682
Furniture, fixtures & leasehold improvements	3,863	3,848
	15,027	14,530
Less: accumulated depreciation	(12,907)	(12,340)
	2,120	2,190
<b>OTHER ASSETS:</b>		
Goodwill	6,918	6,918
Intangibles, net	9,563	10,764
Other assets	405	202
	\$33,180	\$38,791
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Current maturities of long term debt	\$1,091	\$6,171
Accounts payable	1,907	2,052
Accrued compensation	1,386	1,121
Accrued expenses	2,393	3,686
Deferred revenue	1,147	1,171
Other liabilities	1,067	1,067
Total current liabilities	8,991	15,268
<b>LONG TERM LIABILITIES:</b>		
Long term debt, less current maturities	5,469	—
Common stock warrant liability	300	900
Accrued preferred stock dividend	1,805	1,260
Other long-term liabilities	1,221	1,089
Total liabilities	17,786	18,517
<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, 88,245,725 and 71,645,725 shares issued and outstanding, respectively	882	721
Additional paid-in capital	178,458	170,881
Accumulated other comprehensive income	365	435
Accumulated deficit	(164,337)	(151,789)

Edgar Filing: TRANSGENOMIC INC - Form 10-Q

Total stockholders' equity	15,394	20,274
	\$33,180	\$38,791

See notes to unaudited condensed consolidated financial statements.

3

---

Table of Contents

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
NET SALES	\$6,646	\$7,889	\$21,326	\$24,188
COST OF GOODS SOLD:	3,795	4,089	11,384	12,722
Gross profit	2,851	3,800	9,942	11,466
OPERATING EXPENSES:				
Selling, general and administrative	7,627	5,559	19,783	15,832
Research and development	630	668	2,307	1,870
	8,257	6,227	22,090	17,702
LOSS FROM OPERATIONS	(5,406	) (2,427	) (12,148	) (6,236
OTHER INCOME (EXPENSE):				
Interest expense, net	(155	) (207	) (459	) (713
Effect on warrants	—	—	600	1,000
Other, net	1	(6	) 54	23
	(154	) (213	) 195	310
LOSS BEFORE INCOME TAXES	(5,560	) (2,640	) (11,953	) (5,926
INCOME TAX EXPENSE	(8	) 114	52	88
NET LOSS	\$(5,552	) \$(2,754	) \$(12,005	) \$(6,014
PREFERRED STOCK DIVIDENDS	(181	) (165	) (544	) (495
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS	\$(5,733	) \$(2,919	) \$(12,549	) \$(6,509
BASIC AND DILUTED LOSS PER COMMON SHARE	\$(0.06	) \$(0.04	) \$(0.14	) \$(0.09
BASIC AND DILUTED WEIGHTED AVERAGE SHARES OF COMMON STOCK OUTSTANDING	88,245,725	71,645,725	86,847,190	68,669,229

See notes to unaudited condensed consolidated financial statements.

Table of Contents

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Net Loss	\$ (5,552	) \$ (2,754	) \$ (12,005	) \$ (6,014
Other comprehensive income (loss) - foreign currency translation adjustment, net of tax	104	88	(69	) 98
Comprehensive Loss	\$ (5,448	) \$ (2,666	) \$ (12,074	) \$ (5,916

See notes to unaudited condensed consolidated financial statements.

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY  
 UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
 Nine Months Ended September 30, 2013  
 (Dollars in thousands except per share data)

	Preferred Stock		Common Stock			Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Outstanding Shares	Par Value	Outstanding Shares	Par Value	Additional Paid-in Capital			
Balance, January 1, 2012	2,586,205	\$26	49,625,725	\$501	\$152,987	\$(142,802 )	\$336	\$11,048
Net loss	—	—	—	—	—	(8,327 )	—	(8,327 )
Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	99	99
Stock-based compensation	—	—	—	—	731	—	—	731
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	—	—	—	—	—	(660 )	—	(660 )
Balance, December 31, 2012	2,586,205	\$26	71,645,725	\$721	\$170,881	\$(151,789 )	\$435	\$20,274
Net loss	—	—	—	—	—	(12,005 )	—	(12,005 )
Foreign currency translation adjustment, net of tax	—	—	—	—	—	—	(69 )	(69 )
Stock-based compensation	—	—	—	—	167	—	—	167
Private placement, net	—	—	16,600,000	166	7,405	—	—	7,571
Other	—	—	—	(5 )	5	—	—	—
Dividends on preferred stock	—	—	—	—	—	(544 )	—	(544 )
Balance, September 30, 2013	2,586,205	\$26	88,245,725	\$882	\$178,458	\$(164,338 )	\$366	\$15,394

See notes to unaudited condensed consolidated financial statements.



Table of Contents

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

	Nine Months Ended September 30,	
	2013	2012
<b>CASH FLOWS USED IN OPERATING ACTIVITIES:</b>		
Net loss	\$(12,005	) \$(6,014
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation and amortization	2,102	1,570
Stock based compensation	168	556
Provision for losses on doubtful accounts	5,205	1,649
Provision for losses on inventory obsolescence	19	88
Warrant revaluation	(600	) (1,000
Loss on sale of fixed assets	9	—
Gain on foreign currency settlement	(62	) —
Changes in operating assets and liabilities:		
Accounts receivable	(1,539	) (2,153
Inventories	589	(616
Other current assets	(268	) (377
Accounts payable	(145	) (1,113
Accrued expenses	32	(403
Other liabilities	163	3
Deferred income taxes	—	33
Net cash flows used in operating activities	(6,332	) (7,777
<b>CASH FLOWS USED IN INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(510	) (641
Purchases of short term investments	—	(8,994
Acquisition	(849	) (3,394
Other assets	(238	) (345
Net cash flows used in investing activities	(1,597	) (8,378
<b>CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES:</b>		
Principal payments on capital lease obligations	(264	) (244
Issuance of common stock, net of issuance costs	7,570	17,483
Payment of deferred financing costs	(241	) —
Proceeds from borrowings	6,560	—
Principal payment on note payable	(6,171	) (1,317
Net cash flows provided by financing activities	7,454	15,922
EFFECT OF FOREIGN CURRENCY EXCHANGE RATE CHANGES ON CASH	(6	) 34
NET CHANGE IN CASH AND CASH EQUIVALENTS	(481	) (199
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,497	4,946
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$4,016	\$4,747
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>		
Cash paid during the period for:		
Interest	\$615	\$753
Income taxes, net	—	2
<b>SUPPLEMENTAL DISCLOSURE OF NON-CASH INFORMATION</b>		
Acquisition of equipment through capital leases	\$—	\$175
Dividends accrued on preferred stock	544	495

Edgar Filing: TRANSGENOMIC INC - Form 10-Q

Note payable converted to equity	—	3,000
Deferred financing costs in accounts payable	—	—
See notes to unaudited condensed consolidated financial statements.		

7

---

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY  
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
Three and Nine Months Ended September 30, 2013 and 2012

1. 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 two complementary business segments:

**Laboratory Services.** Our clinical laboratories specialize in genetic testing for cardiology, neurology, mitochondrial disorders and oncology. Our clinical laboratories located in New Haven, Connecticut and Omaha, Nebraska 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”). Our laboratory located in Omaha, Nebraska also provides pharmacogenomics research services supporting Phase II and Phase III clinical trials conducted by pharmaceutical companies. Our laboratories employ 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 that 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<sup>®</sup> System, which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. 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<sup>®</sup> Nuclease and a range of chromatography columns.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation.

The condensed consolidated balance sheet as of December 31, 2012 was derived from our audited balance sheet as of that date. The accompanying condensed consolidated financial statements as of and for the three and nine months ended September 30, 2013 and 2012 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 condensed 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, 2012 contained in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 14, 2013. 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 subsidiary. 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 unaudited condensed consolidated financial statements.

Use of Estimates.

The preparation of condensed 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.

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARY

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

Three and Nine Months Ended September 30, 2013 and 2012

**Reclassifications.**

Certain prior year amounts have been reclassified in order to conform to the current year presentation regarding segment reporting. In the second quarter of 2013, we modified the presentation of our accrued preferred stock dividend payable from current liabilities to long term liabilities. As a result, we have revised the balance sheet presentation as of December 31, 2012. This revision from current liabilities to long term liabilities has no effect on total assets, liabilities or equity.

**Fair Value.**

Unless otherwise specified, book value approximates fair market value. The common stock warrant liability is recorded at fair value. See Note 9 - "Fair Value" to the notes to our accompanying unaudited condensed consolidated financial statements for additional information.

**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, 2013.

**Accounts Receivable.**

The following is a summary of activity for the allowance for doubtful accounts during the three and nine months ended September 30, 2013 and 2012:

	Dollars in Thousands			
	Beginning Balance	Provision	Write Offs	Ending Balance
Three Months Ended September 30, 2013	\$2,362	\$2,769	\$(1,086)	) \$4,045
Three Months Ended September 30, 2012	\$1,236	\$679	\$(339)	) \$1,576
Nine Months Ended September 30, 2013	\$2,171	\$4,966	\$(3,092)	) \$4,045
Nine Months Ended September 30, 2012	\$1,088	\$1,649	\$(1,161)	) \$1,576

While payment terms are generally 30 days, we have also provided extended payment terms in certain cases. In addition, we operate globally and the payment terms for some of our international customers 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 by assigning a consistent reserve percentage to each accounts receivable aging category and contractual allowances by regularly evaluating individual customer payment history. Accounts receivable are written off when deemed uncollectible and all collection efforts have been exhausted. During the nine months ended September 30, 2013, in accordance with our stated policy, we wrote-off approximately \$3.1 million of accounts receivable, related to services rendered in prior year periods, determined to be uncollectible.

**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.



Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARY

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

Three and Nine Months Ended September 30, 2013 and 2012

The following is a summary of activity for the allowance for obsolete inventory during the three and nine months ended September 30, 2013 and 2012:

	Dollars in Thousands			
	Beginning Balance	Provision	Write Offs	Ending Balance
Three Months Ended September 30, 2013	\$593	\$19	\$(3)	) \$609
Three Months Ended September 30, 2012	\$559	\$35	\$(13)	) \$581
Nine Months Ended September 30, 2013	\$616	\$19	\$(26)	) \$609
Nine Months Ended September 30, 2012	\$511	\$88	\$(18)	) \$581

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 using 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 during each of the three months ended September 30, 2013 and 2012. Included in depreciation for each of the three months ended September 30, 2013 and 2012 was \$0.1 million related to equipment acquired under capital leases. Depreciation expense related to property and equipment was \$0.5 million during each of the nine months ended September 30, 2013 and 2012. Included in depreciation for the nine months ended September 30, 2013 and 2012 was \$0.2 million related to equipment acquired under capital leases.

**Goodwill.**

Goodwill is the excess of the purchase price over fair value of assets acquired and is not amortized. Goodwill is tested for impairment annually. We perform this impairment analysis during the fourth quarter of each year or when a significant event occurs that may impact goodwill. Impairment occurs when the carrying value is determined to be not recoverable, thereby causing the carrying value of the goodwill to exceed its fair value. If impaired, the asset's carrying value is reduced to its fair value. No events have transpired in the nine months ended September 30, 2013 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, 2013 had vesting periods of one or three years from the date of grant. None of the stock options outstanding at September 30, 2013 are subject to performance or market-based vesting conditions.

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

During the nine months ended September 30, 2013, we recorded compensation expense of \$0.2 million within selling, general and administrative expense. As of September 30, 2013, there was \$1.6 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.

10

---



Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2013 and 2012

We granted 4,020,500 stock options during the quarter ended September 30, 2013. The fair value of the options granted was estimated on the grant date using the Black-Scholes option pricing model with the following assumptions: risk-free interest rates of 1.39% based on the U.S. Treasury yield in effect at the time of grant; dividend yields of zero percent; expected lives of 4.51 years, based on expected exercise activity behavior; and volatility of 105% based on the historical volatility of our common stock over a time that is consistent with the expected life of the option. Forfeitures of 11.06% were also assumed.

Included in the stock options granted during the quarter ended September 30, 2013, were stock appreciation rights of 1,000,000 and 660,000 shares of common stock for the Chief Executive Officer and Chief Financial Officer, respectively. These rights will vest over three years, with an exercise price equal to the fair value of one share of Transgenomic's common stock on the date of grant, which was September 30, 2013.

During the nine months ended September 30, 2012, we recorded compensation expense of \$0.5 million within selling, general and administrative expense. As of September 30, 2012, there was \$0.6 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 with the following assumptions: 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 common stock over a time that is consistent with the expected life of the option. Forfeitures of 3.88% were also assumed.

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 Laboratory Services segment are recognized on samples collected from patients of health care providers and individuals who take part in clinical trials. Revenue is recognized from patients of health care providers on an individual test basis and occurs when the test report is completed, reviewed and sent to the client. Sales are recorded at our list price less a provision for insurance and Medicare and Medicaid contractual adjustments. There are no deferred net sales associated with these tests. Adjustments to the allowances, based on actual receipts from third party payors, are recorded upon settlement. For clinical trials, 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 each of September 30, 2013 and December 31, 2012, deferred revenue associated with clinical trials for which we received payment in advance of performing services was \$0.2 million and was included in the balance sheet in deferred revenue.

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, 2013 and December 31, 2012, deferred net revenue associated with our service contracts was \$0.9 million and \$1.0 million, respectively, and was included in the balance sheet in deferred revenue.

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

Common Stock Warrants.

Certain of 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

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2013 and 2012

recorded at fair value using a Monte Carlo simulation model. We are required to present these instruments at fair value at each reporting date 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 for purposes of fair value measurement. See Note 9 - "Fair Value" to the notes to our accompanying unaudited condensed consolidated financial statements for additional information.

Translation of Foreign Currency.

Our foreign subsidiary uses the local currency of the country in which it is located, British Pound Sterling, 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 loss of \$0.1 million was reported as other comprehensive income on the accompanying unaudited condensed consolidated statement of comprehensive loss for the nine months ended September 30, 2013. A cumulative translation gain of \$0.1 million was reported as accumulated other comprehensive income for the nine months ended September 30, 2012. Revenues and expenses are translated at the average rates during the period. For transactions that are not denominated in the functional currency, we recognized less than \$0.1 million as foreign currency transaction expense in the determination of net loss for the nine months ended September 30, 2013 and \$0.1 million as foreign currency transaction loss in the determination of net loss for the nine months ended September 30, 2012.

Loss Per Share.

Basic loss per share is calculated based on the weighted-average number of common shares outstanding during each of September 30, 2013 and 2012. Diluted loss per share includes 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 44,730,497 and 30,836,894 shares of our common stock have been excluded from the computation of diluted loss per share at September 30, 2013 and 2012, respectively. The options, warrants and conversion rights that were exercisable during the nine months ended September 30, 2013 and 2012 were not included because the effect would be anti-dilutive due to the net loss.

Recent accounting pronouncements.

In February 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2013-02, Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income ("ASU 2013-02"), which requires the presentation of significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount being reclassified is required under generally accepted accounting principles in the United States ("GAAP") to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under GAAP to be reclassified in their entirety to net income, cross-reference to other disclosures that provide additional detail about these amounts is required. ASU 2013-02 is effective for fiscal years beginning after December 15, 2012. The adoption of this new guidance had no impact on our consolidated financial position, results of operations or cash flows.

In February 2013 FASB issued ASU No. 2013-04, Obligations Resulting from Joint and Several Liability Arrangements for Which the Total Amount of the Obligation Is Fixed at the Reporting Date ("ASU 2013-04"). ASU 2013-04 requires reporting and disclosure of obligations resulting from joint and several liability arrangements within the scope of Subtopic 405-40 for which the total amount of the obligation is fixed at the reporting date. For public companies, ASU 2013-04 is effective for fiscal years and interim periods within those years beginning after December 15, 2013. The guidance in ASU 2013-04 is to be applied retrospectively for those obligations resulting from joint and several liability arrangements within the scope of Subtopic 405-40 that exist at the beginning of an entity's fiscal year of adoption. Earlier application is permitted. When adopted, ASU 2013-04 is not expected to materially impact our accompanying unaudited condensed consolidated financial statements.

In March 2013, the FASB released ASU No. 2013-05, Foreign Currency Matters (Topic 830): Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity (a consensus of the FASB Emerging Issues Task Force) (“ASU 2013-05”). ASU 2013-05 provides that, when a reporting entity (parent) ceases to have a controlling financial interest in a subsidiary or group of assets that is a nonprofit activity or a business within a foreign entity, the parent is required to release any related cumulative translation adjustment into net income. The provisions of ASU 2013-05 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. When adopted, ASU 2013-05 is not expected to materially impact our accompanying unaudited condensed consolidated financial statements.

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARY

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

Three and Nine Months Ended September 30, 2013 and 2012

In April 2013, FASB issued ASU No. 2013-07, Liquidation Basis of Accounting (“ASU 2013-07”). ASU 2013-07 requires an entity to prepare its financial statements using the liquidation basis of accounting when liquidation is imminent. The amendments are effective for entities that determine liquidation is imminent during annual reporting periods beginning after December 15, 2013, and interim reporting periods therein. Entities are to apply the requirements prospectively from the day that liquidation becomes imminent. Early application is permitted. Entities that are using the liquidation basis of accounting as of the effective date in accordance with other Topics (for example, terminating employee benefit plans) are not required to apply the amendments. Instead, those entities are to continue to apply the guidance in those other Topics until they have completed liquidation. When adopted, ASU 2013-07 is not expected to materially impact our accompanying unaudited condensed consolidated financial statements.

**3. INVENTORIES**

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

	Dollars in Thousands	
	September 30, 2013	December 31, 2012
Finished goods	\$3,183	\$4,057
Raw materials and work in process	1,638	1,547
Demonstration inventory	242	104
	\$5,063	\$5,708
Less allowance for obsolescence	(609	) (616
Total	\$4,454	\$5,092

**4. INTANGIBLES AND OTHER ASSETS**

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

	Dollars in Thousands			Dollars in Thousands		
	September 30, 2013			December 31, 2012		
	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Intangibles—technology	\$9,009	\$2,858	\$6,151	\$9,009	\$1,910	\$7,099
Intangibles—assay royalties	1,434	563	871	1,434	410	1,024
Intangibles—third party payor relationships	367	67	300	367	49	318
Intangibles—tradenames and trademarks	834	204	620	824	115	709
Intangibles—customer relationships	652	43	609	652	11	641
Intangibles—covenants not to compete	84	61	123	184	15	169
Patents	1,071	321	750	929	280	649
Intellectual property	170	31	139	170	15	155
	\$13,711	\$4,148	\$9,563	\$13,569	\$2,805	\$10,764

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARY

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

Three and Nine Months Ended September 30, 2013 and 2012

	Estimated Useful Life
Technology	7-8 years
Assay royalties	7 years
Third party payor relationships	15 years
Tradenames and trademarks	7 years
Customer relationships	15 years
Covenants not to compete	3 years
Patents	Life of the patent
Intellectual property	7 years

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

Amortization expense for intangible assets was \$0.5 million and \$0.3 million during the three months ended September 30, 2013 and 2012, respectively. Amortization expense for intangible assets was \$1.4 million and \$0.9 million during the nine months ended September 30, 2013 and 2012, respectively. Amortization expense for intangible assets is expected to be \$1.7 million in each of the years 2013 through 2017.

## 5. DEBT

	Dollars in Thousands	
	September 30, 2013	December 31, 2012
Revolving Line of Credit <sup>(1)</sup>	\$2,560	\$—
Term Loan <sup>(2)</sup>	4,000	—
PGxHealth note payable (the “First Note” <sup>(3)</sup> )	—	6,171
Total debt, including short term debt	6,560	6,171
Current maturities of long term debt	(1,091	) (6,171
Long-term debt, net of current maturities	\$5,469	\$—

On March 13, 2013 (the “Effective Date”), we entered into a Loan and Security Agreement with affiliates of Third Security, LLC (the “Lenders”) for (a) a revolving line of credit (the “Revolving Line”) with borrowing availability of up to \$4.0 million, subject to reduction based on our eligible accounts receivable, and (b) a term loan (the “Term Loan”) of \$4.0 million (the “Loan Agreement”). Proceeds were used to pay off the First Note and for general corporate and working capital purposes.

On August 2, 2013, we entered into an amendment to the Loan and Security Agreement, the (“Amendment”). The Amendment, which became effective as of June 30, 2013, reduces our future minimum revenue covenants under the Loan Agreement and modifies the interest rates applicable to the amounts advanced under the Revolving Line. As of September 30, 2013, we were in compliance with the amended financial covenants.

On November 14, 2013, we entered into a second amendment to the Loan and Security Agreement, the (“Second Amendment”). The Second Amendment, which is effective as of October 31, 2013, reduces our future minimum revenue covenant under the Loan Agreement.

(1) Revolving Line of Credit. Amounts advanced under the Revolving Line bear interest at an annual rate equal to the greater of (a) 4.25% or (b) the Wall Street Journal prime rate plus 1%. Interest is payable on a monthly basis, with the balance payable at the maturity of the Revolving Line. The current interest rate is 4.25%. Under the Amendment, amounts advanced under the Revolving Line bear interest at an annual rate equal to the greater of (x) 6.25% or (y) the Wall Street Journal prime rate plus 3%. Under the Loan Agreement, we paid the Lenders an

Edgar Filing: TRANSGENOMIC INC - Form 10-Q

upfront fee of \$20,000, and will pay the Lenders an additional commitment fee of \$20,000 on each one year anniversary of the Effective Date during the term of the Revolving Line. In addition, a fee of 0.5% per annum is payable quarterly on the unused portion of the Revolving Line. The Revolving Line matures on September 1, 2016.

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2013 and 2012

Term Loan. We received \$4.0 million under the Term Loan on the Effective Date. We are required to make interest-only payments under the Term Loan through December 31, 2013 and principal and interest payments on a (2) monthly basis thereafter, beginning on January 1, 2014, over 33 months using a straight-line amortization rate. Interest under the Term Loan will accrue at the annual rate of one month LIBOR plus 6.1%, subject to a LIBOR floor of 3%. The current interest rate is 9.1%.

We paid the Lenders an upfront fee of \$40,000 for the Term Loan, and will pay the Lenders an additional final payment of \$120,000 at maturity or prepayment of the Term Loan. In addition, if we repay the Term Loan prior to maturity, we will pay the Lenders a prepayment penalty of 5% of the total outstanding balance under the Term Loan if the prepayment occurs within one year after the Effective Date, 2.5% of the total outstanding balance under the Term Loan if the prepayment occurs between one and two years after the Effective Date, and 1% of the total outstanding balance under the Term Loan if the prepayment occurs thereafter.

Additional Terms

The Loan Agreement contains affirmative and negative covenants. Under the Term Loan, we are required to maintain a minimum liquidity ratio and achieve a minimum amount of revenue, and we also agreed not to (i) pledge or otherwise encumber our assets other than to the Lenders, (ii) enter into additional borrowings or guarantees, (iii) repurchase our capital stock, or (iv) enter into certain mergers or acquisitions without the Lenders' consent. Additionally, the Loan Agreement contains a subjective acceleration clause at the discretion of the Lenders.

To secure the repayment of any amounts borrowed under the Revolving Line and the Term Loan, we granted the Lenders a security interest in all of our assets. The occurrence of an event of default under the Loan Agreement could result in the acceleration of our obligations under the Loan Agreement and would increase the applicable interest rate under the Revolving Line or Term Loan (or both) by 5%, and permit the Lenders to exercise remedies with respect to the collateral under the Loan Agreement.

First Note. The First Note was a three year senior secured promissory note payable to PGxHealth, LLC which was entered into on December 29, 2010 in conjunction with our acquisition of the FAMILION family of genetic tests. (3) Interest was payable at 10% per year with quarterly interest payments through March 29, 2012. Thereafter, quarterly installments included both principal and interest through December 30, 2013. The First Note was paid in full on March 13, 2013.

6. 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 \$0.4 million for the remainder of 2013, \$1.1 million in 2014, \$1.0 million in 2015, \$0.9 million in 2016, \$0.8 million in 2017 and \$1.3 million thereafter. Rent expense for each of the nine months ended September 30, 2013 and 2012 was \$0.8 million and \$0.7 million, respectively. At September 30, 2013, firm commitments to vendors totaled \$1.4 million.

7. 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 2010 through 2012. We have state income tax returns subject to examination primarily for tax years 2010 through 2012. Open tax years related to foreign jurisdictions, primarily the United Kingdom, remain subject to examination for the tax years 2010 through 2012.

Income tax expense for the nine months ended September 30, 2013 was \$0.1 million. Income tax expense for the nine months ended September 30, 2012 was zero. Our effective tax rate for the nine months ended September 30, 2013 was 0.1%, 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 each of the three and nine months ended September 30, 2013 and 2012, there were no material changes to the liability for uncertain tax positions.

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARY

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

Three and Nine Months Ended September 30, 2013 and 2012

## 8. STOCKHOLDERS' EQUITY

## Common Stock.

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 our stockholders.

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 (the "Private Placement"), which included an aggregate of \$3.0 million in convertible notes issued in December 2011 to entities affiliated with Third Security, LLC, a related party, that automatically converted 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 11,435,158 shares of common stock with an exercise price of \$1.08 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 1,736,110 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 are being used for general corporate and working capital purposes, primarily to accelerate development of several of our key initiatives.

On January 24, 2013, we entered into a Securities Purchase Agreement with certain institutional and other accredited investors pursuant to which we: (i) sold to the investors an aggregate of 16,600,000 shares of our common stock at a price per share of \$0.50 for aggregate gross proceeds of approximately \$8.3 million; and (ii) issued to the investors warrants to purchase up to an aggregate of 8,300,000 shares of our common stock with an exercise price of \$0.75 per share (the "Offering"). The warrants may be exercised, in whole or in part, at any time from January 30, 2013 until January 30, 2018 and contain both cash and "cashless exercise" features. Affiliates of Third Security, LLC, a related party, purchased an aggregate of 6,000,000 shares of common stock and warrants to purchase an aggregate of 3,000,000 shares of common stock in the Offering on the same terms as the other investors. We are using the net proceeds from the Offering for general corporate and working capital purposes, primarily to accelerate development of several of our key initiatives.

In connection with the Offering, we entered into a registration rights agreement with the investors (the "Registration Rights Agreement"). The Registration Rights Agreement required that we file with the Securities and Exchange Commission a registration statement to register for resale the shares of common stock sold and the shares of common stock issuable upon exercise of the warrants (the "Warrant Shares") by March 16, 2013. The registration statement was filed with the Securities and Exchange Commission on March 15, 2013 and was declared effective by the Securities and Exchange Commission on March 29, 2013.

## Common Stock Warrants.

During the nine months ended September 30, 2013 and 2012, we issued warrants to purchase 10,091,268 and 13,171,268, shares of common stock, respectively. None of the issued warrants were exercised during such periods. Included in the warrants issued in 2013 were 8,300,000 warrants issued in connection with the Offering and 1,791,268 warrants issued due to repricing requirements contained in the warrants issued in the Private Placement. Warrants to purchase an aggregate of 26,643,676 shares of common stock were outstanding at September 30, 2013.

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	11,435,158	\$1.08
Affiliates of Third Security, LLC <sup>(2)</sup>	2012	February 2017	1,736,110	\$1.08

Edgar Filing: TRANSGENOMIC INC - Form 10-Q

Various Institutional Holders <sup>(3)</sup>	2013	January 2018	5,300,000	\$0.75
Affiliates of Third Security, LLC <sup>(3)</sup>	2013	January 2018	3,000,000	\$0.75
			26,643,676	

This warrant was issued in connection with the issuance of warrants to purchase shares of our Series A Preferred (1) Stock to affiliates of Third Security, LLC in December 2010. The number of underlying shares shown reflects the number of

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Nine Months Ended September 30, 2013 and 2012

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, which was completed in February 2012.

(2) Warrants were repriced and additional warrants were issued in connection with the warrants issued in the Offering.

(3) These warrants were issued in connection with the Offering, which was completed in January 2013.

## 9. 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.

### Debt

Our long term debt is considered a Level 2 liability for which book value approximates fair market value.

### Common Stock Warrant Liability

Certain of 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 13.2 million warrants issued in the Private Placement. 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 \$0.38 as of September 30, 2013; the amount of the down-round financing; the timing of the down-round financing; the expected exercise period of 3.36 years from the valuation date; and the fact that no other potential fundamental transactions are expected during the term of the common stock warrants.

Static Technical Inputs include: volatility of 50% and the risk-free interest rate of 0.82% based on the 3.5-year U.S. Treasury yield interpolated from the three-year and five-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, which in periods 1-10 follows a geometric Brownian motion and is simulated over 10 independent six-month periods; and a down-round financing event which 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.

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARY

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

Three and Nine Months Ended September 30, 2013 and 2012

During 2013 we noted an error in the calculation of the warrant liability as of December 31, 2012 causing the liability to be understated by \$0.3 million. This has been corrected in 2013.

During the three months ended September 30, 2013, 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, 2013	September 30, 2012
Beginning balance at July 1	\$ 300	\$ 2,100
Total gains or losses:		
Recognized in earnings	—	—
Balance at September 30	\$ 300	\$ 2,100

During the nine months ended September 30, 2013, 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, 2013	September 30, 2012
Beginning balance at January 1	\$ 900	\$ 3,100
Additions	—	—
Total gains or losses:		
Recognized in earnings	(600	) (1,000
Balance at September 30	\$ 300	\$ 2,100

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

## 10. STOCK OPTIONS

The following table summarizes stock option activity during the nine months ended September 30, 2013:

	Number of Options	Weighted Average Exercise Price
Balance at January 1, 2013	4,353,167	\$ 1.05
Granted	5,933,000	0.37
Exercised	—	—
Forfeited	(962,500	) (1.01
Expired	(188,333	) (1.66
Balance at September 30, 2013	9,135,334	\$ 0.62
Exercisable at September 30, 2013	3,151,511	\$ 1.01

Edgar Filing: TRANSGENOMIC INC - Form 10-Q

During the nine months ended September 30, 2013, we granted options exercisable to purchase 5,933,000 shares of common stock at a weighted average exercise price of \$0.37 per share under our 2006 Equity Incentive Plan. Options to purchase an aggregate of 626,500 shares of common stock were granted during the nine months ended September 30, 2012.

18

---

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARY

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

Three and Nine Months Ended September 30, 2013 and 2012

## 11. 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 Note 2 – “Summary of Significant Accounting Policies” to the notes to our accompanying unaudited condensed consolidated financial statements. In the first quarter of 2013, we consolidated our Clinical Laboratories and Pharmacogenomic Services business segments into a single segment and, going forward, the combined segment will be referred to as our Laboratory Services segment. We now have two reportable operating segments, Laboratory Services and Diagnostic Tools. Accordingly, segment results for the three and nine months ended September 30, 2012 have been reclassified to reflect these changes.

Segment information for the three months ended September 30, 2013 and 2012 is as follows:

	Dollars in Thousands		
	September 30, 2013		
	Laboratory Services	Diagnostic Tools	Total
Net Sales	\$4,112	\$2,534	\$6,646
Gross Profit	1,776	1,075	2,851
Net Loss before Taxes	(4,375	) (1,185	) (5,560
Income Tax Benefit	—	(8	) (8
Net Loss	\$(4,375	) \$(1,177	) \$(5,552
Depreciation/Amortization	\$606	\$65	\$671
Interest Expense, net	\$(96	) \$(59	) \$(155

	September 30, 2013		
Total Assets	\$23,648	\$9,532	\$33,180

	Dollars in Thousands		
	September 30, 2012		
	Laboratory Services	Diagnostic Tools	Total
Net Sales	\$4,718	\$3,171	\$7,889
Gross Profit	2,347	1,453	3,800
Net Income (Loss) before Taxes	(1,907	) (733	) (2,640
Income Tax Benefit	—	114	114
Net Income (Loss)	\$(1,907	) \$(847	) \$(2,754
Depreciation/Amortization	\$442	\$53	\$495
Interest Expense, net	\$(201	) \$(6	) \$(207

September 30, 2012



Edgar Filing: TRANSGENOMIC INC - Form 10-Q

Total Assets	\$30,553	\$12,334	\$42,887
--------------	----------	----------	----------

Segment information for the nine months ended September 30, 2013 and 2012 is as follows:

19

---

Table of Contents

## TRANSGENOMIC, INC. AND SUBSIDIARY

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

Three and Nine Months Ended September 30, 2013 and 2012

	Dollars in Thousands		
	September 30, 2013		
	Laboratory Services	Diagnostic Tools	Total
Net Sales	\$12,551	\$8,775	\$21,326
Gross Profit	5,822	4,120	9,942
Net Loss before Taxes	(9,641	) (2,312	) (11,953
Income Tax Expense	—	52	52
Net Loss	\$(9,641	) \$(2,364	) \$(12,005
Depreciation/Amortization	\$1,815	\$287	\$2,102
Interest Expense, net	\$(314	) \$(145	) \$(459

	Dollars in Thousands		
	September 30, 2012		
	Laboratory Services	Diagnostic Tools	Total
Net Sales	\$14,527	\$9,661	\$24,188
Gross Profit	7,111	4,355	11,466
Net Income (Loss) before Taxes	(4,619	) (1,307	) (5,926
Income Tax Benefit	—	88	88
Net Income (Loss)	\$(4,619	) \$(1,395	) \$(6,014
Depreciation/Amortization	\$1,357	\$213	\$1,570
Interest Expense, net	\$(676	) \$(37	) \$(713

Net sales for the three and nine months ended September 30, 2013 and 2012 by country were as follows:

	Dollars in Thousands		Dollars in Thousands	
	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
United States	\$5,095	\$5,442	\$16,241	\$17,013
Italy	398	571	1,225	2,277
All Other Countries	1,153	1,876	3,860	4,898
Total	\$6,646	\$7,889	\$21,326	\$24,188

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

Approximately 99% of our long-lived assets are located within the United States.

## 12. SUBSEQUENT EVENTS

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

On November 14, 2013, we entered into a second amendment to the Loan and Security Agreement, the (“Second Amendment”). The Second Amendment, is effective as of October 31, 2013, reduces our future minimum revenue covenant under the Loan Agreement.

Table of Contents

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

Forward-Looking Information

This report, including this Management's Discussion and 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," "will," "would" or the negative versions of these terms and other similar expressions.

You are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements we make are not guarantees of future performance and are subject to various assumptions, risks and other factors that could cause actual results to differ materially from those suggested by these forward-looking statements. Actual results may differ materially from those suggested by the forward-looking statements that we make for a number of reasons including those described in Part II, Item 1A, "Risk Factors," of this report and in Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, which we filed with the Securities and Exchange Commission on March 14, 2013.

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 and Analysis included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, which we filed with the Securities and Exchange Commission on March 14, 2013. Results for the three and nine months ended September 30, 2013 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 two complementary business segments:

**Laboratory Services.** Our clinical laboratories specialize in genetic testing for cardiology, neurology, mitochondrial disorders and oncology. Our clinical laboratories located in New Haven, Connecticut and Omaha, Nebraska 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"). Our laboratory located in Omaha, Nebraska also provides pharmacogenomics research services supporting Phase II and Phase III clinical trials conducted by pharmaceutical companies. Our laboratories employ 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 that 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<sup>®</sup> System, which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. 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.

Table of Contents

Third Quarter 2013 Overview

We are advancing personalized medicine in cardiology, oncology, neurology and inherited diseases through our proprietary molecular diagnostic technologies and world-class clinical research services. Today, we are a global leader in molecular diagnostic testing with a family of innovative products.

In 2013, we consolidated our Clinical Laboratories and Pharmacogenomic Services business segments into a single segment, which we now refer to as our Laboratory Services segment. We continue to anticipate growth in both our Laboratory Services and Diagnostic Tools segments, as we commercialize new technologies and tests we have developed internally, in-licensed, or acquired, and as we expand into other markets and regions worldwide.

We recently announced two strategic commercialization agreements. In October 2013, we announced the signing of a U.S. collaboration agreement with PDI, Inc. (Nasdaq: PDII) to commercialize CardioPredict™, a new 10-gene assay panel that identifies specific genes that influence the effectiveness and safety of many commonly used cardiovascular drugs including the platelet inhibitor, clopidogrel; several cholesterol-lowering drugs, known as “statins”; the blood thinner, warfarin; and certain blood pressure lowering drugs, known as beta blockers; among others. This type of test panel has become a preferred tool for cardiologists to personalize therapy selection for their patients with heart disease. Developed by Transgenomic, CardioPredict™ is the most comprehensive assay of its kind currently on the market and can assist physicians with drug selection and dosing decisions.

Under the terms of the strategic collaboration agreement, PDI will be responsible for all U.S.-based marketing and promotion of CardioPredict™, while Transgenomic will be responsible for processing CardioPredict™ in its CLIA lab and all customer support. We believe that strategic partnerships such as this one will allow Transgenomic to globally commercialize our novel assays and clinical tests in order to more effectively address the expanding genetics market.

In early November 2013, we announced an agreement with PerkinElmer, Inc. (NYSE: PKI) to market and distribute our oncology diagnostic test portfolio of products in territories outside the United States. Under the terms of the agreement, effective January 1, 2014, PerkinElmer will have the non-exclusive right to begin sales, marketing, distribution and field service activities for our line of molecular diagnostic oncology products, including CRC RAScan™ and ACE™ kits, for use on its Caliper LabChip™ platform. Europe will be the initial focus of PerkinElmer’s launch.

These collaborations highlight our strategy, which aims to optimize, through channel partnerships, the commercial potential of our assets aimed at large genetic testing markets. Doing so allows us to focus resources on our areas of strength, including sales of our instrument lines, marketing tests for rare genetic disorders in the U.S., where we are a market leader, and developing tests and companion diagnostics using proprietary technology that is unequalled in the identification and detection of low-level mutations.

In August 2013, Quest Diagnostics (Nasdaq: DGX) introduced a new, comprehensive genetic test to aid the delivery of personalized opioid pain-relieving treatment. The opioid therapy genetic test is based in part on gene variants owned by Transgenomic and was developed as a result of a non-exclusive licensing agreement between the two companies. It is believed to be the first clinical test to identify four important variants in all CYP450 genes known to influence the CYP450 enzyme system, which affects metabolism of opioids and other medications.

According to Quest, more than 100 million Americans suffer from chronic pain. Opioids, which include oxycodone and methadone, are widely used in the management of moderate to severe pain. While opioids are the most widely prescribed class of medications in the U.S., they are also implicated in high rates of drug addiction and overdose. Research demonstrates that genetic testing to identify gene variants that mediate the CYP450 enzyme system can help

physicians predict the rate of opioid drug metabolism. With this information, physicians can decide to adjust doses or administer other therapies in order to improve the prospect for effective pain relief and reduce the likelihood of drug toxicity, drug interactions and other adverse outcomes.

In May 2013, we announced our entry into a collaboration with Amgen, Inc. for the development and launch of CRC RAScan™, a CE-IVD test to screen patients with metastatic colorectal cancer (mCRC) for KRAS and NRAS mutations (collectively referred to as “RAS mutations”). In June 2013, Amgen presented results of a predefined-retrospective subset analysis of a global, multicenter, randomized Phase 3 study at the American Society of Clinical Oncology (ASCO) 2013 Annual Meeting. The RAS mutations outlined in the study, identified using our CE-IVD CRC RAScan™ kits in conjunction with our Surveyor®-Wave® technology, provide physicians with important tumor mutation information that is highly relevant when considering administration of select EGFR inhibitor therapies for metastatic colorectal cancer. The CRC RAScan™ kit provides a single kit solution with superior sensitivity versus any other kit or sequencing method currently available. Our CLIA-certified laboratory in the U.S. is validated

## Table of Contents

to receive patient samples for testing. In Europe, CE-IVD registered test kits are now available for purchase, and as of January 2014, kits will also be available from PerkinElmer.

CRC RAScan™ utilizes the DNA mismatch-cutting enzyme SURVEYOR Nuclease assay, developed exclusively by us. The SURVEYOR Nuclease assay can detect mutations at higher levels of sensitivity than stand-alone Sanger sequencing. CRC RAScan™ results can also be used to inform marginal or difficult to resolve sequencing results. Additionally, in gene regions where mutations exist at low frequencies, prescreening with CRC RAScan™ affords a cost and time-efficient workflow, as only CRC RAScan™ positive samples are advanced to the more complex and expensive Sanger sequencing analysis.

We continue to progress our commercial collaboration with the Medical College of Wisconsin, a world-renowned institution with a robust presence in genomics and genetic testing. As a result of this collaboration, we have recently launched a number of new offerings addressing neurological and mitochondrial disorders, including whole exome testing, using a next generation sequencing platform.

We continue to advance our ICE-COLD PCR technology to broaden its commercial applications. The ICE COLD-PCR technology, exclusively licensed by us 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 and PCR techniques.

In October 2013, we announced the results from an interim analysis of a research collaboration with the MD Anderson Cancer Center. Using Transgenomic's ultrasensitive ICE COLD-PCR technology, investigators analyzed blood plasma samples collected from 60 patients with colorectal cancer, melanoma, non-small cell lung cancer and several other cancers, and compared them to corresponding samples taken from tumor tissue. The results demonstrated that in a high percentage of patients, the same KRAS and BRAF genetic mutations were detected in cell-free (cf) DNA present in the blood as were originally found in primary tumors. These findings demonstrate the clinical relevance and utility of analyzing cfDNA in blood to detect low level mutations as an alternative to the far more invasive and difficult-to-conduct tissue biopsy.

In June 2013, in a joint announcement with ApoCell, Inc., we announced the results of a research collaboration with the University of Texas MD Anderson Cancer Center that coupled ApoCell's ApoStream™ platform for isolating circulating tumor cells (CTCs) with our ICE COLD-PCR technology to detect signature mutations in CTCs isolated from the blood of lung cancer patients. This small pilot study demonstrated that ICE COLD-PCR technology was able to detect a number of the mutations in CTCs that were found in matched tumors from the same patient. The results were presented at the ASCO 2013 Annual Meeting.

These studies, along with other collaborations currently ongoing at leading research institutes, continue to explore concordance rates between tumor tissue, cfDNA and CTCs isolated from patients using ICE COLD-PCR. The broad use of this innovative technology has the potential to revolutionize 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. We are also completing a review of future diagnostic applications and utility of the ICE COLD-PCR technology and products for commercial applications.

## 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, 2013 we had cash and cash equivalents of \$4.0 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. Our Laboratory Services business is dependent upon reimbursement from government and private payors that continually look for ways to reduce costs, including by unilaterally reducing reimbursement for services such as those that we provide. The government issued new reimbursement codes in 2013, which were set at pricing levels that were generally lower than the levels for identical tests in 2012. Certain private payors also used the issuance of the new codes as an opportunity to unilaterally lower their reimbursement rates. There are no assurances that reimbursements from certain of these providers will remain at levels that will allow us to be profitable.

Table of Contents

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.

## Results of Operations

Net sales for the three months ended September 30, 2013 decreased by \$1.2 million, or 16%, compared to the same period in 2012. During the three months ended September 30, 2013, net sales from our Laboratory Services segment decreased by \$0.6 million compared to the same three month period in 2012. Net sales in our Diagnostic Tools segment decreased \$0.6 million for the three months ended September 30, 2013 compared to the same period in 2012. Our gross profit margin decreased to 43% for the three months ended September 30, 2013 from 48% for the three months ended September 30, 2012. Loss from operations was \$5.4 million for the three months ended September 30, 2013 compared to \$2.4 million for the three months ended September 30, 2012.

## Three Months Ended September 30, 2013 and 2012

Net Sales. Net sales for the three months ended September 30, 2013 decreased by \$1.2 million, or 16%, compared to the same period in 2012. Net sales performance in each of the segments was as follows:

	Dollars in Thousands		Change		
	Three Months Ended				
	September 30,				
	2013	2012	\$	%	
Laboratory Services	\$4,112	\$4,718	\$(606)	(13)	)%
Diagnostic Tools	2,534	3,171	(637)	(20)	)%
Total Net Sales	\$6,646	\$7,889	\$(1,243)	(16)	)%

Laboratory Services net sales decreased \$0.6 million, or 13%, during the three months ended September 30, 2013 as compared to the same period in 2012. Laboratory Services net sales decreased in the three months ended September 30, 2013 due to lower test volumes, partially offset by a change in the mix of higher priced tests and completion of contract work associated with a collaboration agreement.

Diagnostic Tools net sales were \$2.5 million for the three months ended September 30, 2013, which represented a decrease of \$0.6 million as compared to the same period in 2012. The decrease in net sales was due to lower instrument sales.

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 Laboratory Services operations.

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

	Dollars in Thousands		Margin %		
	Three Months Ended				
	September 30,				
	2013	2012	2013	2012	
Laboratory Services	\$1,776	\$2,347	43	% 50	%
Diagnostic Tools	1,075	1,453	42	% 46	%
Gross Profit	\$2,851	\$3,800	43	% 48	%

Gross profit was \$2.9 million, or 43% of total net sales, during the third quarter of 2013, compared to \$3.8 million, or 48% of total net sales, during the same period of 2012. During the three months ended September 30, 2013, the gross

margin for Laboratory Services was 43% as compared to 50% in the same period of 2012. In 2013, the lower margins largely resulted from

Table of Contents

lower test volumes. The gross margin for Diagnostic Tools decreased to 42% for the three months ended September 30, 2013 from 46% in the same period of 2012, 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, facility costs and bad debt provisions. Our selling, general and administrative costs increased \$2.1 million to \$7.6 million from \$5.6 million during the three month period ended September 30, 2013 as compared to the same period in 2012. The increase is due to establishing an additional reserve for potentially uncollectible accounts receivable.

**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, 2013 and 2012, these costs totaled \$0.6 million and \$0.7 million, respectively. The research and development costs in 2013 related in part to the conversion of a number of our tests to a more efficient Next Generation Sequencing instrument platform. Research and development expenses totaled 9% and 8% of net sales during the three months ended September 30, 2013 and 2012, respectively.

**Other Income (Expense).** Other expense for each of the three months ended September 30, 2013 and 2012 includes interest expense of \$0.2 million. Interest expense was slightly lower than last year due to a lower interest rate on our outstanding debt.

**Income Tax Expense/(Benefit).** Income tax benefit for the three months ended September 30, 2013 and income tax expense for the same period in 2012 were each less than \$0.1 million, respectively.

Nine Months Ended September 30, 2013 and 2012

**Net Sales.** Net sales for the nine months ended September 30, 2013 decreased by \$2.9 million, or 12%, compared to the same period in 2012. Net sales performance in each of the segments was as follows:

	Dollars in Thousands				
	Nine Months Ended		Change		
	September 30, 2013	2012	\$	%	
Laboratory Services	\$12,551	\$14,527	\$(1,976)	(14)	)%
Diagnostic Tools	8,775	9,661	(886)	(9)	)%
Total Net Sales	\$21,326	\$24,188	\$(2,862)	(12)	)%

Laboratory Services net sales decreased \$2.0 million, or 14%, during the nine months ended September 30, 2013 as compared to the same period in 2012. Laboratory Services net sales decreased compared to last year due to lower test volumes, offset by a change in the mix of higher priced tests and completion of contract work associated with a collaboration agreement, compared to last year.

Diagnostic Tools net sales of \$8.8 million represented a decrease of \$0.9 million, or 9%, during the nine months ended September 30, 2013 compared to the same period in 2012. This decrease resulted from the fact that we sold fewer instruments in 2013 than in 2012.

**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 Laboratory Services operations.

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

	Dollars in Thousands				
	Nine Months Ended		Margin %		
	September 30, 2013	2012	2013	2012	
Laboratory Services	\$5,822	\$7,111	46	% 49	%
Diagnostic Tools	4,120	4,355	47	% 45	%
Gross Profit	\$9,942	\$11,466	47	% 47	%

Gross profit was \$9.9 million, or 47% of total net sales, during the third quarter of 2013, compared to \$11.5 million, or 47% of total net sales, during the same period of 2012. During the nine months ended September 30, 2013, the gross

margin for

25

---

Table of Contents

Laboratory Services was 46% as compared to 49% in the same period of 2012. In 2013, the lower margins were due to lower test volumes. The gross margin for Diagnostic Tools increased to 47% for the nine months ended September 30, 2013 from 45% in the same period of 2012 due to the mix of instruments sold. In 2012, there were more instruments sold to distributors, which carry lower margins.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses primarily consist of personnel costs, marketing, travel costs, professional fees, facility costs and bad debt provisions. Our selling, general and administrative costs increased \$4.0 million to \$19.8 million from \$15.8 million during the nine month period ended September 30, 2013 compared to the same period in 2012. We had higher sales costs due to the increase in the size of our sales force in the first half of 2013 to support the launch of new products. In addition, we also recorded a higher bad debt provision during the nine months ended September 30, 2013 compared to 2012.

**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 nine months ended September 30, 2013 and 2012, these costs totaled \$2.3 million and \$1.9 million, respectively. The increase in research and development costs is due in part to activities related to converting a number of our tests to a more efficient Next Generation Sequencing instrument platform.

Research and development expenses totaled 11% and 8% of net sales during the nine months ended September 30, 2013 and 2012, respectively.

**Other Income (Expense).** Other expense for the nine months ended September 30, 2013 and 2012 includes interest expense of \$0.5 million and \$0.7 million, respectively. In addition, other income includes the revaluation of common stock warrants, which was due to the change in fair value. The income associated with the change in fair value of the warrants is a non-cash item.

**Income Tax Expense.** Income tax expense for the nine months ended September 30, 2013 was less than \$0.1 million, compared to less than \$0.1 million income tax benefit for the nine months ended September 30, 2012.

**Liquidity and Capital Resources**

Our working capital positions at September 30, 2013 and December 31, 2012 were as follows:

	Dollars in Thousands		
	September 30, 2013	December 31, 2012	Change
Current assets (including cash and cash equivalents of \$4,016 and \$4,497, respectively)	\$14,174	\$18,717	\$(4,543)
Current liabilities	8,991	15,268	(6,277)
Working capital	\$5,183	\$3,449	\$1,734

Historically, we have 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 finance our operating losses through borrowings or from the issuance of additional equity. At September 30, 2013, we had cash on hand of \$4.0 million. We believe that existing sources of liquidity are sufficient to meet expected cash needs for the next 12 months. On January 30, 2013, we issued 16,600,000 shares of common stock at a price per share of \$0.50, as well as five year warrants to purchase up to an aggregate of 8,300,000 shares of common stock with an exercise price of \$0.75 per share. On March 13, 2013, we entered into a loan and security agreement with affiliates of Third Security, LLC for a revolving line of credit with borrowing availability of up to \$4.0 million, subject to reduction based on our eligible accounts receivable, and a term loan of \$4.0 million. Proceeds were used to extinguish the debt with PGxHealth and for working capital purposes. 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.

Please see Note 5 - "Debt" and Note 6 - "Commitments and Contingencies" to the notes to our accompanying unaudited condensed consolidated financial statements for additional information regarding our outstanding debt and debt servicing obligations.



## Table of Contents

### Analysis of Cash Flows

#### Nine Months Ended September 30, 2013 and 2012

Net Change in Cash and Cash Equivalents. Cash and cash equivalents decreased by \$0.5 million during the nine months ended September 30, 2013 compared to a decrease of \$0.2 million during the nine months ended September 30, 2012. During the nine months ended September 30, 2013, we used cash of \$6.3 million in operating activities and \$1.6 million in investing activities, which was offset by cash provided by financing activities of \$7.5 million. In the nine months ended September 30, 2012, net cash used in operating activities was \$7.8 million, and net cash used in investing activities was \$8.4 million, which was offset by cash provided by financing activities of \$15.9 million.

Cash Flows Used In Operating Activities. Cash flows used in operating activities totaled \$6.3 million during the nine months ended September 30, 2013 compared to cash flows used in operating activities of \$7.8 million during the nine months ended September 30, 2012. The cash flows used in operating activities in the first nine months of 2013 included a net loss of \$12.0 million and an increase in accounts receivable of \$1.5 million, offset by non-cash items, including the provision for losses on doubtful accounts of \$5.2 million, stock option expense of \$0.2 million and depreciation and amortization of \$2.1 million. The cash flows used in operating activities in the first nine months of 2012 included a net loss of \$6.0 million, an increase in accounts receivable of \$2.0 million, a decrease in accounts payable of \$1.1 million and a non-cash warrant revaluation gain of \$1.0 million, offset by non-cash items, which include the 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.

Cash Flows Used In Investing Activities. Cash flows used in investing activities totaled \$1.6 million during the nine months ended September 30, 2013 compared to cash flows used in investing activities of \$8.4 million during the same period of 2012. Cash flows used in investing activities in the first nine months of 2013 included payments made in connection with the acquisition of Scoliscore™ assets of \$0.8 million, purchases of property and equipment of \$0.5 million and additions to our patents of \$0.2 million. Cash flows used in investing activities in the first nine months of 2012 included the purchase of short term investments of \$9.0 million, purchases of property and equipment of \$0.6 million and additions to our patents of \$0.3 million.

Cash Flows Provided by Financing Activities. Cash flows provided by financing activities were \$7.5 million for the nine months ended September 30, 2013. Cash provided by financing activities during the nine months ended September 30, 2013 included the proceeds from the issuance of 16.6 million shares of our common stock and the refinancing of our debt. Cash flows used in financing activities consisted of the pay off of our note with PGxHealth and capital lease obligations. 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, offset by payments on debt and capital lease obligations.

### Off-Balance Sheet Arrangements

At each of September 30, 2013 and December 31, 2012, 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.

### Contractual Obligations and Commitments

There have been no material changes to our contractual obligations outside the normal course of business as compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

### Critical Accounting Policies and Estimates

Accounting policies used in the preparation of the consolidated financial statements may involve the use of management judgments and estimates. Certain of our accounting policies are considered critical as they are both important to the portrayal of our financial statements and they require significant or complex judgments on the part of



management. Our judgments and estimates are based on experience and assumptions that we believe are reasonable under the circumstances. Further, we evaluate our judgments and estimates from time to time as circumstances change. Actual financial results based on judgments or estimates may vary under different assumptions or circumstances. Our critical accounting policies are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the Securities and Exchange Commission on March 14, 2013.

## Table of Contents

### Recently Issued Accounting Pronouncements

Please refer to our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed with the Securities and Exchange Commission on March 14, 2013. There have been no changes to those accounting pronouncements listed except as noted in Note 2 - "Summary of Significant Accounting Policies" to the notes to our accompanying 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 Pound 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 a transaction is consummated in a currency other than the British Pound Sterling. As Transgenomic Limited's functional currency is the British Pound Sterling but a majority of the transactions consummated are in Euros, these transactions must be revalued by Transgenomic Limited. As a result, we are subject to exchange rate risk. We do not currently engage in foreign currency hedging activities.

Based on our overall foreign currency exchange rate exposures at September 30, 2013, we believe that a 10% change in foreign currency exchange rates would not be expected to have a material effect on our future operating results or cash flows, depending on which foreign currency exchange rates change and depending on the directional change (either a strengthening or weakening against the U.S. Dollar). If our foreign operations grow, our exposure to foreign currency exchange rate risk may become more significant.

#### 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 is 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, 2013, our disclosure controls and procedures were effective at the reasonable assurance level.

We have evaluated the changes in our internal control over financial reporting that occurred during the three months ended September 30, 2013 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

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, 2012 that was filed with the Securities and Exchange Commission on March 14, 2013, except that the following supersedes the corresponding risk factor described in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013.

Failure to comply with covenants in our loan agreements with affiliates of Third Security, LLC could adversely affect us.

Our revolving line of credit and term loan with affiliates of Third Security, LLC (the “Lenders”) are governed by a Loan and Security Agreement, which contains affirmative and negative covenants. Under the term loan, we are required to maintain a minimum liquidity ratio and achieve a minimum amount of revenue, and we also agreed not to (i) pledge or otherwise encumber our assets other than to the Lenders, (ii) enter into additional borrowings or guarantees, (iii) repurchase our capital stock, or (iv) enter into certain mergers or acquisitions without the Lenders' consent. To secure the repayment of amounts borrowed under the revolving line of credit and term loan, we granted the Lenders a security interest in all of our assets. Failure to comply with the covenants under the loan agreement would be an event of default under the loan agreement that, if not cured or waived, would give the Lenders the right to cease making additional advances, accelerate repayment of all sums due and take action to collect the amounts owed to them, including foreclosing on their security interest, which would have a material adverse effect on the Company's financial condition and results of operations.

Item 5. Other Information

On November 14, 2013, Transgenomic, Inc. (“Transgenomic”) entered into a second amendment (the “Second Amendment”) to its Loan and Security Agreement, dated March 13, 2013, with Third Security, LLC and its affiliates (the “Lenders”) for a revolving line of credit and a term loan (the “Loan Agreement”). The Second Amendment, which became effective as of October 31, 2013, reduces Transgenomic’s future minimum revenue covenant under the Loan Agreement.

The foregoing description of the Amendment does not purport to be a complete description of all terms of the Amendment and is qualified in its entirety by reference to the full text of the Amendment, a copy of which is filed as an exhibit to this Quarterly Report on Form 10-Q.

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 (incorporated by reference to Exhibit 2.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 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 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 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 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 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 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 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 filed on January 4, 2011)
- 4.3 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 filed on January 4, 2011)
- 4.4 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)
- 4.5 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)
- 4.6 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)
- 4.7 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

Edgar Filing: TRANSGENOMIC INC - Form 10-Q

Registrant's Current Report on Form 8-K filed on February 7, 2012)

- 10.1 First Amendment to Loan and Security Agreement among the Registrant, Third Security Senior Staff 2008 LLC, as administrative agent and a lender, and the other lenders party thereto, dated August 2, 2013 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 6, 2013)
- \*10.2 Employment Agreement between the Registrant and Paul Kinnon, effective September 30, 2013 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 30, 2013)
- \*10.3 Form of Incentive Stock Option Agreement between the Registrant and Paul Kinnon, effective September 30, 2013
- \*10.4 Form of Stock Appreciation Rights Agreement between the Registrant and Paul Kinnon, effective September 30, 2013
- \*10.5 Form of Stock Appreciation Rights Agreement between the Registrant and Mark Colonnese, effective September 30, 2013
- \*10.6 Form of Stock Appreciation Rights Agreement under the 2006 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on September 30, 2013)
- 10.7 Second Amendment to Loan and Security Agreement among the Registrant, Third Security Senior Staff 2008 LLC, as administrative agent and a lender, and the other lenders party thereto, effective October 31, 2013

Table of Contents

31.1	Certification of Paul Kinnon, 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 Paul Kinnon, 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 and 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
*	Denotes exhibit that constitutes a management contract, or compensatory plan or arrangement. 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.
**	

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 14, 2013

By: /S/ PAUL KINNON  
Paul Kinnon  
President and Chief Executive Officer

Date: November 14, 2013

By: /S/ MARK P. COLONNESE  
Mark P. Colonnese Executive Vice President and  
Chief Financial Officer(Principal Financial  
Officer and Principal Accounting Officer)