TRANSGENOMIC INC Form 10-Q November 08, 2012 <u>Table of Contents</u>

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

Or

0 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)

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

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

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 x No o Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. Large accelerated filer o Accelerated filer х Non-accelerated filer o (Do not check if a smaller reporting company) Smaller reporting company o Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange

Act). Yes o No x

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

# TRANSGENOMIC, INC. INDEX

PART I.	FINANCIAL INFORMATION	<u>3</u>
Item 1.	Financial Statements	<u>3</u>
	Condensed Consolidated Balance Sheets as of September 30, 2012 (Unaudited) and December 31, 2011 (Audited)	<u><sup>r</sup>3</u>
	Unaudited Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2012 and 2011	<u>4</u>
	Unaudited Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2012 and 2011	<u>5</u>
	Unaudited Condensed Consolidated Statements of Stockholders' Equity for the Nine Months Ended September 30, 2012	<u>6</u>
	Unaudited Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2012 and 2011	7
	Notes to Condensed Consolidated Unaudited Financial Statements	<u>8</u>
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>21</u>
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	<u>29</u>
Item 4.	Controls and Procedures	<u>29</u>
PART II.	OTHER INFORMATION	<u>30</u>
Item 1.	Legal Proceedings	<u>30</u>
Item 1A.	Risk Factors	<u>30</u>
Item 6.	Exhibits	<u>31</u>
<u>Signatures</u>		<u>33</u>
2		

Page No.

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

(Donars in mousands except per snare data)		
	September 30, 2012	December 31,
	(unaudited)	2011
ASSETS	(unaudited)	2011
CURRENT ASSETS:		
Cash and cash equivalents	\$4,747	\$4,946
Short term investments	3,998	
Accounts receivable, net	8,157	7,573
Inventories, net	4,406	3,859
Other current assets	1,186	820
Total current assets	22,494	17,198
PROPERTY AND EQUIPMENT:		
Equipment	10,819	10,143
Furniture, fixtures & leasehold improvements	3,762	3,682
	14,581	13,825
Less: accumulated depreciation	(12,490)	(11,969)
	2,091	1,856
OTHER ASSETS:		
Goodwill	6,674	6,440
Intangibles, net	11,485	7,966
Other assets	143	102
	\$42,887	\$33,562
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$1,517	\$2,609
Accrued compensation	1,058	1,133
Short term debt	—	3,082
Current maturities of long term debt	6,957	3,703
Accrued expenses	3,627	2,782
Deferred revenue	1,279	1,377
Other liabilities	1,067	1,042
Accrued preferred stock dividend	1,095	600
Total current liabilities	16,600	16,328
LONG TERM LIABILITIES:	1.10	4.007
Long term debt less current maturities	448	4,937
Common stock warrant liability	2,100	
Other long-term liabilities	1,163	1,249
Total liabilities	20,311	22,514
STOCKHOLDERS' EQUITY:		
Series A preferred stock, \$.01 par value, 15,000,000 shares authorized, 2,586,205	26	26
shares issued and outstanding		
Common stock, \$.01 par value, 150,000,000 shares authorized, 71,645,725 and 40,625,725 abarea isound and autotanding respectively.	721	501
49,625,725 shares issued and outstanding, respectively	170 706	152 007
Additional paid-in capital	170,706	152,987

)

Accumulated other comprehensive income	434	336	
Accumulated deficit	(149,311	) (142,802	)
Total stockholders' equity	22,576	11,048	
	\$42,887	\$33,562	
See notes to unaudited condensed consolidated financial statements.			

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

	Three Months Ended September 30,		Nine Months September 3	nded				
	2012	0,	2011		2012	υ,	2011	
NET SALES	\$7,889		\$8,253		\$24,188		\$23,400	
COST OF GOODS SOLD	4,089		\$8,235 3,808		\$24,188 12,722		\$23,400 10,248	
Gross profit	3,800		3,808 4,445		12,722		13,152	
OPERATING EXPENSES:	3,800		4,445		11,400		13,132	
	5 550		1 261		15.922		14 272	
Selling, general and administrative	5,559		4,364		15,832		14,272	
Research and development	668		515		1,870		1,650	
Restructuring charges			5				40	
	6,227		4,884	,	17,702	,	15,962	
LOSS FROM OPERATIONS	(2,427	)	(439	)	(6,236	)	(2,810	)
OTHER INCOME (EXPENSE):								
Interest expense, net	(207	)	(238	)	(713	)	(720	)
Expense on preferred stock			(600	)			(6,866	)
Effect on warrants					1,000			
Other, net	(6	)	(2	)	23		231	
	(213	)	(840	)	310		(7,355	)
LOSS BEFORE INCOME TAXES	(2,640	)	(1,279	)	(5,926	)	(10,165	)
INCOME TAX EXPENSE (BENEFIT)	114	-	(9	)	88	-	(120	)
NET LOSS	\$(2,754	)	\$(1,270	)	\$(6,014	)	\$(10,045	)
PREFERRED STOCK DIVIDENDS AND		ĺ.	<b>x</b> .	Í		ĺ.		ĺ.
ACCRETION	(165	)	(275	)	(495	)	(803	)
NET LOSS AVAILABLE TO COMMON								
STOCKHOLDERS	\$(2,919	)	\$(1,545	)	\$(6,509	)	\$(10,848	)
BASIC AND DILUTED LOSS PER COMMON								
SHARE	\$(0.04	)	\$(0.03	)	\$(0.09	)	\$(0.22	)
BASIC AND DILUTED WEIGHTED AVERAGE								
	71 645 725		40 227 527		(9 ((0 220		40 206 961	
SHARES OF COMMON STOCK	71,645,725		49,327,527		68,669,229		49,306,861	
OUTSTANDING								
See notes to unaudited condensed consolidated final	ncial statemer	nts						

See notes to unaudited condensed consolidated financial statements.

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

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

See notes to unaudited condensed consolidated financial statements.

#### TRANSGENOMIC, INC. AND SUBSIDIARIES UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY Nine Months Ended September 30, 2012 (Dollars in thousands except per share data)

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

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

(Dollars in thousands)	Nine Months E	Ended	
	September 30,		
CASH ELOWS DROVIDED DV (LISED IN) ODED ATING ACTIVITIES.	2012	2011	
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES: Net loss	\$(6,014	\$(10,045)	)
Adjustments to reconcile net loss to net cash flows provided by (used in) operating	\$(0,014	\$(10,045	)
activities:			
Depreciation and amortization	1,570	1,506	
Non-cash, stock based compensation	556	734	
Provision for losses on doubtful accounts	1,649	1,432	
Provision for losses on inventory obsolescence	88	47	
Preferred stock revaluation	_	6,866	
Warrant revaluation	(1,000	) —	
Changes in operating assets and liabilities:	(-,,	,	
Accounts receivable	(2,153	) (1,418	)
Inventories	(616	) (44	Ś
Prepaid expenses and other current assets	(377	(269	Ś
Accounts payable	· · · · · · · · · · · · · · · · · · ·	) 137	/
Accrued expenses		) (131	)
Other long term liabilities	3	268	,
Long term deferred income taxes	33	18	
Net cash flows used in operating activities	(7,777	) (899	)
CASH FLOWS USED IN INVESTING ACTIVITIES:		-	
Purchases of property and equipment	(641	) (147	)
Purchase of short term investments	(8,994	) —	
Proceeds from the sale of short term investments	4,996		
Acquisition of intangible assets	(3,394	) —	
Change in other assets	(345	) (256	)
Net cash flows used in investing activities	(8,378	) (403	)
CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES:			
Principal payments on capital lease obligations	(244	) (165	)
Issuance of common stock and warrants, net	17,483	23	
Principal payment on note payable	(1,317	) (659	)
Net cash flows provided by (used in) financing activities	15,922	(801	)
EFFECT OF FOREIGN CURRENCY EXCHANGE RATE CHANGES ON CASH	34	72	
NET CHANGE IN CASH AND CASH EQUIVALENTS	(199	) (2,031	)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,946	3,454	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$4,747	\$1,423	
SUPPLEMENTAL CASH FLOW INFORMATION			
Cash paid during the period for:			
Interest	\$753	\$495	
Income taxes, net	2	106	
SUPPLEMENTAL DISCLOSURE OF NON-CASH INFORMATION			
Acquisition of equipment through capital leases	\$175	\$388	
Dividends accrued on preferred stock	495	450	
Note Payable converted to Equity	3,000	—	

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

Table of Contents TRANSGENOMIC, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued) Three and Nine Months Ended September 30, 2012 and 2011

#### A. BUSINESS DESCRIPTION

#### **Business Description.**

Transgenomic, Inc. is a global biotechnology company advancing personalized medicine in the detection and treatment of cancer and inherited diseases through its proprietary molecular technologies and clinical and research services. We have three complementary business segments:

Clinical Laboratories. Our clinical laboratories specialize in genetic testing for cardiology, neurology, mitochondrial disorders, and oncology. Located in New Haven, Connecticut and Omaha, Nebraska, the molecular clinical reference laboratories are certified under the Clinical Laboratory Improvement Amendment (CLIA) as high complexity labs and our Omaha facility is also accredited by the College of American Pathologists (CAP).

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

Diagnostic Tools. Our proprietary product is the WAVE® System, which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. There is a worldwide installed base of more than 1,550 WAVE Systems as of September 30, 2012. We also distribute bioinstruments produced by other manufacturers ("OEM Equipment") through our sales and distribution network. Service contracts to maintain installed systems are sold and supported by our technical support personnel. The installed WAVE base and some OEM Equipment platforms generate a demand for consumables that are required for the continued operation of the bioinstruments. We develop, manufacture and sell these consumable products. In addition, we manufacture and sell consumable products that can be used on multiple, independent platforms. These products include SURVEYOR® Nuclease and a range of chromatography columns.

#### **B.SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

#### Basis of Presentation.

The condensed consolidated balance sheet as of December 31, 2011 was derived from our audited balance sheet as of that date. The accompanying consolidated financial statements as of and for the three and nine months ended September 30, 2012 and 2011 are unaudited and reflect all adjustments that are, in the opinion of management, necessary for a fair presentation of the financial position and operating results for the interim periods. These unaudited consolidated financial statements and notes should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2011 contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2012. The results of operations for the interim periods presented are not necessarily indicative of the results for the entire year. Principles of Consolidation.

The consolidated financial statements include the accounts of Transgenomic, Inc. and its wholly owned subsidiaries. All inter-company balances and transactions have been eliminated in consolidation. Risks and Uncertainties. Certain risks and uncertainties are inherent in our day-to-day operations and to the process of preparing our financial statements. The more significant of those risks are presented below and throughout the notes to the consolidated financial statements.

Table of Contents

TRANSGENOMIC, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued) Three and Nine Months Ended September 30, 2012 and 2011

Use of Estimates.

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

Reclassifications.

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

Fair Value.

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

Cash and Cash Equivalents.

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

Concentrations of Cash.

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

Short term Investments.

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

Accounts Receivable.

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

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

While payment terms are generally 30 days, we have also provided extended payment terms of up to 90 days in certain cases. We operate globally and some of the international payment terms may be greater than 90 days. Accounts receivable are carried at original invoice amount and shown net of allowance for doubtful accounts and contractual allowances. The estimate made for doubtful accounts is based on a review of all outstanding amounts on a quarterly basis. We determine the allowance for doubtful accounts and contractual allowances by regularly evaluating individual customer receivables and considering a customer's financial condition, credit history and current economic conditions. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

#### Table of Contents TRANSGENOMIC, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued) Three and Nine Months Ended September 30, 2012 and 2011

#### Inventories.

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

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

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

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

Property and Equipment.

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

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

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

Goodwill.

Goodwill is the excess of the purchase price over fair value of assets acquired and is not amortized. Goodwill is tested for impairment annually. We perform this impairment analysis during the fourth quarter of each year or when a significant event occurs that may impact goodwill. Impairment occurs when the carrying value is determined to be not recoverable thereby causing the carrying value of the goodwill to exceed its fair value. If impaired, the asset's carrying value is reduced to its fair value. No events have transpired in the nine months ended September 30, 2012 that would require an impairment analysis prior to our scheduled review.

Stock Based Compensation.

All stock options awarded to date have exercise prices equal to the market price of our common stock on the date of grant and have ten-year contractual terms. Unvested options as of September 30, 2012 had vesting periods of one or three years from the date of grant. None of the stock options outstanding at September 30, 2012 are subject to

performance or market-based vesting conditions.

#### Table of Contents TRANSGENOMIC, INC. AND SUBSIDIARIES NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued) Three and Nine Months Ended September 30, 2012 and 2011

We measure and recognize compensation expense for all stock-based awards made to employees and directors, including stock options. Compensation expense is based on the calculated fair value of the awards as measured at the grant date and is expensed ratably over the service period of the awards (generally the vesting period). During the nine months ended September 30, 2012, we recorded compensation expense of \$0.6 million within selling, general and administrative expense. During the nine months ended September 30, 2012, we recorded September 30, 2011, we recorded compensation expense of \$0.7 million within selling, general and administrative expense. As of September 30, 2012, there was \$0.7 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of nearly three years.

We granted 477,500 stock options during the quarter ended September 30, 2012. The fair value of the options granted was estimated on the grant date using the Black-Scholes option pricing model. The Black-Scholes model with