TRANSGENOMIC INC Form 10-Q August 14, 2015 Table of Contents

SEC	TED STATES FURITIES AND EXCHANGE COMI SHINGTON, D.C. 20549	SSION
FOI	RM 10-Q	
(Ma	rk One)	
X	QUARTERLY REPORT PURSUA OF 1934	TT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT
	For the quarterly period ended Jun	0, 2015
OR		
o	TRANSITION REPORT PURSUA OF 1934	TT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT
Con	For the transition period fromnmission File Number: 000-30975	to
TRA	ANSGENOMIC, INC.	
(Exa	act name of registrant as specified in i	charter)
Dela	ware	91-1789357
(Stat	te or other jurisdiction of	(I.R.S. Employer
	rporation or organization)	Identification No.)
1232	25 Emmet Street, Omaha, Nebraska	68164
	dress of principal executive offices) 452-5400	(Zip Code)
•	gistrant's telephone number, including	rea code)
		et (1) has filed all remonts required to be filed by Section 12 on 15(d) of the

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 Acce

Accelerated filer

0

Non-accelerated filer o (Do not check if a smaller reporting company)

Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange

Act). Yes o No x

As of July 31, 2015, the number of shares of common stock outstanding was 13,872,510.

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TRANSGENOMIC, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

TRANSGENOMIC, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

(Dollars in thousands, except per share data)

(Donars in thousands, except per share data)		
	June 30, 2015	December 31,
	(unaudited)	2014
ASSETS	,	
CURRENT ASSETS:		
Cash and cash equivalents	\$2,309	\$1,609
Accounts receivable, net	9,719	7,627
Inventories, net	2,619	3,005
Other current assets	826	1,191
Total current assets	15,473	13,432
PROPERTY AND EQUIPMENT:		
Equipment	11,519	11,369
Furniture, fixtures & leasehold improvements	3,877	3,877
•	15,396	15,246
Less: accumulated depreciation	(14,076) (13,764
	1,320	1,482
OTHER ASSETS:	,	,
Goodwill	6,918	6,918
Intangibles, net	7,549	7,964
Other assets	149	210
	\$31,409	\$30,006
LIABILITIES AND STOCKHOLDERS' EQUITY	+,	+
CURRENT LIABILITIES:		
Current maturities of long-term debt	\$2,825	\$462
Accounts payable	4,743	4,871
Accrued compensation	1,028	1,129
Accrued expenses	2,698	2,550
Deferred revenue	952	1,035
Other liabilities	1,067	1,068
Total current liabilities	13,313	11,115
LONG TERM LIABILITIES:	13,313	11,113
Long-term debt, less current maturities	4,850	7,375
Common stock warrant liability	560	145
Accrued preferred stock dividend	_	3,130
Other long-term liabilities	1,762	1,688
Total liabilities	20,485	23,453
STOCKHOLDERS' EQUITY:	20,403	23,433
Preferred stock, \$0.01 par value, 15,000,000 shares authorized, 4,029,502 shares		
issued and outstanding	40	40
Common stock, \$0.01 par value, 150,000,000 shares authorized, 12,328,918 and		
•	123	81
8,084,471 shares issued and outstanding, respectively (1) Additional paid-in capital (1)	107 107	190.690
Accumulated other comprehensive income	197,187 348	189,680 340
Accumulated other comprehensive income Accumulated deficit		
Accumulated deficit	(186,774) (183,588)

Total stockholders' equity 10,924 6,553 \$31,409 \$30,006

(1) The shares of common stock and additional paid-in capital for all periods presented reflect the one-for-twelve reverse stock split that took effect on January 27, 2014.

See notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended			Six Months Ended				
	June 30,				June 30,			
	2015		2014		2015		2014	
NET SALES	\$7,040		\$6,764		\$13,553		\$13,015	
COST OF GOODS SOLD:	4,168		4,371		7,707		8,128	
Gross profit	2,872		2,393		5,846		4,887	
OPERATING EXPENSES:								
Selling, general and administrative	5,073		5,563		10,127		10,851	
Research and development	576		785		1,143		1,530	
	5,649		6,348		11,270		12,381	
LOSS FROM OPERATIONS	(2,777)	(3,955)	(5,424)	(7,494)
OTHER INCOME (EXPENSE):								
Interest expense, net	(186)	(146)	(376)	(328)
Warrant revaluation	(270)	200		(415)	250	
Other, net					(13)		
	(456)	54		(804)	(78)
LOSS BEFORE INCOME TAXES	(3,233)	(3,901)	(6,228)	(7,572)
INCOME TAX EXPENSE (BENEFIT)	42		(8)	88		497	
NET LOSS	\$(3,275)	\$(3,893)	\$(6,316)	\$(8,069)
PREFERRED STOCK DIVIDENDS	(331)	(305)	(662)	(535)
NET LOSS AVAILABLE TO COMMON	\$(3,606	`	\$(4,198	`	\$(6,978	`	\$(8,604)
STOCKHOLDERS	\$(3,000	,	\$(4,190	,	\$(0,976	,	\$(0,004	,
BASIC AND DILUTED LOSS PER COMMON SHARE (1)	\$(0.30)	\$(0.57)	\$(0.65)	\$(1.17)
BASIC AND DILUTED WEIGHTED-AVERAGE								
SHARES OF COMMON STOCK OUTSTANDING (1)	12,149,632		7,353,695		10,778,857		7,353,695	

⁽¹⁾ Net loss per share and the number of shares used in the per share calculations for all periods presented reflect the one-for-twelve reverse stock split that took effect on January 27, 2014.

See notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,				
	2015	2014		2015		2014	
Net Loss	\$(3,275) \$(3,893)	\$(6,316)	\$(8,069)
Other comprehensive income (loss) - foreign currency translation adjustment	42	22		8		34	
Comprehensive Loss	\$(3,233) \$(3,871)	\$(6,308)	\$(8,035)

See notes to unaudited condensed consolidated financial statements.

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TRANSGENOMIC, INC. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Six Months Ended
June 30, 2015

(Dollars in thousands, except per share data)

	Preferred St	ock	Common Stock (1)						
	Outstanding Shares		Outstanding Shares	Par Value	Additional Paid-in Capital (1)	Accumulated Deficit	Accumulated Other Comprehensiv Income	Total e	
Balance, January 1, 2014 Net loss	2,586,205 —	\$26 —	7,353,695 —	\$73 —	\$179,459 —	\$ (168,502) (13,942)	\$ 390 —	\$11,446 (13,942)	
Foreign currency translation adjustment	_		_		_	_	(50)	(50)	
Non-cash stock-based compensation	_				977	_	_	977	
Private placement, net	_	_	730,776	8	2,353	_	_	2,361	
Preferred stock agreement	1,443,297	14	_	_	6,891	_	_	6,905	
Dividends on preferred stock	_	_	_	_	_	(1,144)	_	(1,144)	
Balance, December 31, 2014	4,029,502	\$40	8,084,471	\$81	\$189,680	\$ (183,588)	\$ 340	\$6,553	
Net loss			_			(6,316)		(6,316)	
Foreign currency translation adjustment	_		_		_	_	8	8	
Stock-based compensation	_		_		328	_	_	328	
Private placement, net	_	_	3,573,899	36	6,173	_	_	6,209	
Conversion of convertible promissory notes	e	_	670,548	6	1,006	_	_	1,012	
Reversal of dividends on preferred stock			_		_	3,130	_	3,130	
Balance, June 30, 2015	4,029,502	\$40	12,328,918	\$123	\$197,187	\$ (186,774)		\$10,924	
(1) The shares of common stock and additional paid-in capital for all periods presented reflect the one-for-twelve									

⁽¹⁾ The shares of common stock and additional paid-in capital for all periods presented reflect the one-for-twelve reverse stock split that took effect on January 27, 2014.

See notes to unaudited condensed consolidated financial statements.

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

	Six Months E	nd	ed	
	June 30,			
	2015		2014	
CASH FLOWS USED IN OPERATING ACTIVITIES:				
Net loss	\$(6,316)	\$(8,069)
Adjustments to reconcile net loss to net cash flows used in operating activities:				
Depreciation and amortization	1,111		981	
Stock-based compensation	322		637	
Provision for losses on doubtful accounts	1,909		1,523	
Provision for losses on inventory obsolescence	328		55	
Warrant revaluation	415		(250)
Loss on sale of fixed assets	14			
Deferred interest	61		145	
Deferred tax provision	81		550	
Changes in operating assets and liabilities:				
Accounts receivable	(3,994)	(3,479)
Inventories	42		(88))
Other current assets	146		5	
Accounts payable	(131)	667	
Accrued expenses and other liabilities			66	
Net cash flows used in operating activities	(6,012)	(7,257)
CASH FLOWS USED IN INVESTING ACTIVITIES:				
Purchases of property and equipment	(194)	(110)
Other assets	(46)	(62)
Net cash flows used in investing activities	(240)	(172)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:				
Principal payments on capital lease obligations	(34)	(82)
Issuance of preferred stock, net			6,906	
Issuance of common stock, net	6,209		_	
Proceeds from borrowings	923		4,440	
Principal payment on note payable	(148)	(4,283)
Net cash flows provided by financing activities	6,950		6,981	
EFFECT OF FOREIGN CURRENCY EXCHANGE RATE CHANGES ON CASH	2		13	
NET CHANGE IN CASH AND CASH EQUIVALENTS	700		(435)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	1,609		1,626	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$2,309		\$1,191	
SUPPLEMENTAL CASH FLOW INFORMATION				
Cash paid during the period for:				
Interest	\$222		\$147	
SUPPLEMENTAL DISCLOSURE OF NON-CASH INFORMATION				
Conversion of convertible promissory notes	1,012		_	
See notes to unaudited condensed consolidated financial statements.				

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TRANSGENOMIC, INC. AND SUBSIDIARY NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS Three and Six Months Ended June 30, 2015 and 2014

1. BUSINESS DESCRIPTION

Business Description.

Transgenomic, Inc. ("we", "us", "our", the "Company" or "Transgenomic") is a global biotechnology company advancing personalized medicine for the detection and treatment of cancer and inherited diseases through our proprietary molecular technologies and world-class clinical and research services. A key goal is to bring our Multiplexed ICE COLD-PCR ("MX-ICP") product to the clinical market through strategic licensing agreements, enabling the use of blood and other bodily fluids for more effective and patient-friendly diagnosis, monitoring and treatment of cancer.

MX-ICP is a simple, proprietary technology that amplifies the ability to detect genetic mutations by 100 - 400 fold. This technology has been validated internally on all currently available sequencing platforms, including Sanger, Next Gen Sequencing and Digital PCR. By enhancing the level of detection of genetic mutations and suppressing the normal, "wild-type" DNA, several benefits are provided. It is generally understood that most current technologies are unable to consistently identify mutations that occur in less than approximately 5% of a sample. However, many mutations found at much lower levels, even down to 0.01%, are known to be clinically relevant and can have significant consequences to a patient: both in terms of how they will respond to a given drug or treatment and how a given tumor is likely to change over time. More importantly, in our view, significantly improving the level of detection while using blood, saliva and even urine as a source for DNA, rather than depending on painful, expensive and potentially dangerous tumor biopsies, is an important advancement in patient care with respect to cancer detection, treatment and monitoring of the disease and can result in significant cost savings for the healthcare system by replacing invasive procedures with the simple collection of blood or other bodily fluid. By broadening the types of samples that can be used for testing and allowing all sequencing platforms to provide improved identification of low level mutations, MX-ICP has the potential to make testing more patient friendly, enable genetic monitoring of disease progression, effectively guide treatment protocols, and reduce the overall cost of diagnosis and monitoring while improving patient outcomes.

Currently, our operations are organized and reviewed by management along our major product lines and presented in the following two business segments;

Laboratory Services. Our laboratories specialize in genetic testing for cardiology, neurology and mitochondrial disorders, and for oncology. Our Patient Testing laboratories located in New Haven, Connecticut and Omaha, Nebraska are certified under the Clinical Laboratory Improvement Amendment ("CLIA") as high complexity laboratories and our Omaha facility is accredited by the College of American Pathologists. Our Biomarker Identification laboratory located in Omaha provides pharmacogenomics research services supporting Phase II and Phase III clinical trials conducted by pharmaceutical and biotechnology companies. Our laboratories employ a variety of genomic testing service technologies, including our new, high performance MX-ICP technology. ICE COLD-PCR is a proprietary ultra-high sensitivity platform technology with breakthrough potential to enable wide adoption of personalized, precision medicine in cancer and other diseases. It can be run in any laboratory that contains standard PCR systems. MX-ICP enables detection of multiple known and unknown mutations from virtually any sample type, including tissue biopsies, blood, urine, saliva, cell-free DNA ("cfDNA") and circulating tumor cells ("CTCs") at levels greater than 1,000-fold higher than standard DNA sequencing techniques. It is easy to implement and use within existing workflows.

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Genetic Assays and Platforms. Our proprietary product in this business segment is the WAVE® System, which has broad applicability to genetic variation detection in both molecular genetic research and molecular diagnostics. We also distribute bio-instruments 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 bio-instruments. 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 a range of chromatography columns. Going Concern

The condensed consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America applicable for a going concern, which assume that we will realize our assets and discharge our liabilities in the ordinary course of business. We have incurred substantial operating losses and have used cash in our operating activities for the

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TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Six Months Ended June 30, 2015 and 2014

past few years. As of June 30, 2015, we had working capital of approximately \$2.2 million. Our ability to continue as a going concern is dependent upon a combination of generating additional revenue, improving cash collections, potentially selling underutilized assets and, if necessary, raising additional financing to meet our obligations and pay our liabilities arising from normal business operations when they come due. The outcome of these matters cannot be predicted with any certainty at this time and raises substantial doubt that we will be able to continue as a going concern. These condensed consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. We cannot be certain that additional financing will be available on acceptable terms, or at all, and our failure to raise capital when needed could limit our ability to continue our operations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation.

The condensed consolidated balance sheet as of December 31, 2014 was derived from our audited balance sheet as of that date. The accompanying condensed consolidated financial statements as of and for the three and six months ended June 30, 2015 and 2014 are unaudited and reflect all adjustments (consisting of only normal recurring 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, 2014 contained in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on April 15, 2015. The results of operations for the interim periods presented are not necessarily indicative of the results for fiscal year 2015.

Following approval of our stockholders, on January 15, 2014, our Board of Directors approved a reverse split of our common stock, par value \$0.01, at a ratio of one-for-twelve. This reverse stock split became effective on January 27, 2014 and, unless otherwise indicated, all share amounts, per share data, share prices, exercise prices and conversion rates set forth in these notes and the accompanying condensed consolidated financial statements have, where applicable, been adjusted retroactively to reflect this reverse stock split.

Principles of Consolidation.

The condensed consolidated financial statements include the accounts of Transgenomic, Inc. and our 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 in 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 condensed consolidated financial statements.

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" 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.

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TRANSGENOMIC, INC. AND SUBSIDIARY

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Three and Six Months Ended June 30, 2015 and 2014

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 June 30, 2015. Accounts Receivable.

The following is a summary of activity for the allowance for doubtful accounts during the three and six months ended June 30, 2015 and 2014:

	Dollars in Thousands				
	Beginning	Additions	Deductions		Ending
	Balance	Additions	Deductions		Balance
Three Months Ended June 30, 2015	\$9,193	\$1,198	\$(1,965)	\$8,426
Three Months Ended June 30, 2014	\$3,540	\$850	\$(349)	\$4,041
Six Months Ended June 30, 2015	\$7,947	\$2,730	\$(2,251)	\$8,426
Six Months Ended June 30, 2014	\$3,838	\$1,523	\$(1,320)	\$4,041

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. The estimate for contractual allowances is based on contractual terms or historical reimbursement rates and is recorded when revenue is recorded. We determine the allowance for doubtful accounts and contractual allowances by regularly evaluating individual payor receivables and considering a payor's financial condition, credit history, reimbursement rates and current economic conditions. Accounts receivable are written off when deemed uncollectible and after all collection efforts have been exhausted. Recoveries of accounts receivable previously written off are recorded as a reduction in bad debt expense when received.

Inventories.

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

The following is a summary of activity for the allowance for obsolete inventory during the three and six months ended June 30, 2015 and 2014:

	Dollars in Thousands				
	Beginning Balance	Additions	Deductions	Ending Balance	
Three Months Ended June 30, 2015	\$601	\$328	\$(8)	