

ORASURE TECHNOLOGIES INC
Form 10-Q
November 08, 2016
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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, 2016.

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 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of

36-4370966
(IRS Employer

Incorporation or Organization)

Identification No.)

220 East First Street, Bethlehem, Pennsylvania
(Address of Principal Executive Offices)

18015
(Zip code)

(610) 882-1820

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Number of shares of Common Stock, par value \$.000001 per share, outstanding as of November 3, 2016: 55,730,629 shares.

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Table of Contents**Item 1. FINANCIAL STATEMENTS****ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****(Unaudited)****(in thousands, except per share amounts)**

	September 30, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 111,726	\$ 94,094
Restricted cash	1,810	
Short-term investments	7,618	7,225
Accounts receivable, net of allowance for doubtful accounts of \$633 and \$798	15,471	19,265
Inventories	12,070	13,242
Prepaid expenses	1,364	1,533
Other current assets	660	1,355
Total current assets	150,719	136,714
PROPERTY AND EQUIPMENT, net	20,069	20,083
INTANGIBLE ASSETS, net	11,205	12,591
GOODWILL	19,243	18,250
OTHER ASSETS	2,322	1,683
	\$ 203,558	\$ 189,321

LIABILITIES AND STOCKHOLDERS EQUITY**CURRENT LIABILITIES:**

Accounts payable	\$ 4,422	\$ 5,087
Deferred revenue	7,911	9,735
Accrued expenses	9,618	10,412

Total current liabilities	21,951	25,234
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OTHER LIABILITIES	2,289	1,768
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DEFERRED INCOME TAXES	2,836	2,883
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COMMITMENTS AND CONTINGENCIES (Note 7)**STOCKHOLDERS EQUITY**

Preferred stock, par value \$.000001, 25,000 shares authorized,
none issued

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Common stock, par value \$.000001, 120,000 shares authorized, 55,723 and 55,705 shares issued and outstanding			
Additional paid-in capital	347,274		345,253
Accumulated other comprehensive loss	(13,138)		(15,639)
Accumulated deficit	(157,654)		(170,178)
Total stockholders' equity	176,482		159,436
	\$	203,558	\$
			189,321

See accompanying notes to the consolidated financial statements.

Table of Contents**ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF INCOME****(Unaudited)****(in thousands, except per share amounts)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
NET REVENUES:				
Product	\$ 25,460	\$ 25,714	\$ 78,286	\$ 75,792
Other	6,791	4,147	14,413	11,545
	32,251	29,861	92,699	87,337
COST OF PRODUCTS SOLD	9,576	9,192	28,626	28,974
Gross profit	22,675	20,669	64,073	58,363
OPERATING EXPENSES:				
Research and development	3,196	2,525	8,547	8,961
Sales and marketing	6,428	9,677	22,531	26,465
General and administrative	6,907	6,931	19,803	18,971
	16,531	19,133	50,881	54,397
Operating income	6,144	1,536	13,192	3,966
OTHER INCOME (EXPENSE)	498	81	(34)	395
Income before income taxes	6,642	1,617	13,158	4,361
INCOME TAX EXPENSE	400	147	634	810
NET INCOME	\$ 6,242	\$ 1,470	\$ 12,524	\$ 3,551
EARNINGS PER SHARE:				
BASIC	\$ 0.11	\$ 0.03	\$ 0.23	\$ 0.06
DILUTED	\$ 0.11	\$ 0.03	\$ 0.22	\$ 0.06
SHARES USED IN COMPUTING EARNINGS PER SHARE:				
BASIC	55,653	56,482	55,549	56,427
DILUTED	56,530	56,692	56,273	56,900

See accompanying notes to the consolidated financial statements.

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited)

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
NET INCOME	\$ 6,242	\$ 1,470	\$ 12,524	\$ 3,551
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	(729)	(2,858)	2,501	(6,036)
COMPREHENSIVE INCOME (LOSS)	\$ 5,513	\$ (1,388)	\$ 15,025	\$ (2,485)

See accompanying notes to the consolidated financial statements.

Table of Contents**ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)****(in thousands)**

	Nine Months Ended September 30,	
	2016	2015
OPERATING ACTIVITIES:		
Net income	\$ 12,524	\$ 3,551
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	4,438	4,543
Depreciation and amortization	4,212	4,259
Amortization of lease incentives	(60)	
Unrealized foreign currency loss	75	450
Deferred income taxes	(205)	198
Changes in assets and liabilities		
Restricted cash	(1,810)	
Accounts receivable	3,818	(1,572)
Inventories	1,236	633
Prepaid expenses and other assets	1,186	(614)
Accounts payable	(125)	(72)
Deferred revenue	(1,829)	5,269
Accrued expenses and other liabilities	(90)	(1,540)
Net cash provided by operating activities	23,370	15,105
INVESTING ACTIVITIES:		
Purchases of short-term investments	(22,966)	(19,411)
Proceeds from maturities of short-term investments	22,966	16,450
Purchases of property and equipment	(3,512)	(1,885)
Net cash used in investing activities	(3,512)	(4,846)
FINANCING ACTIVITIES:		
Payments for debt issue costs	(367)	
Proceeds from exercise of stock options	894	124
Repurchase of common stock	(3,311)	(883)
Net cash used in financing activities	(2,784)	(759)
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	558	(1,690)
NET INCREASE IN CASH AND CASH EQUIVALENTS	17,632	7,810
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	94,094	92,867

CASH AND CASH EQUIVALENTS, END OF PERIOD	\$	111,726	\$	100,677
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:				
Cash paid for income taxes	\$	812	\$	230
Noncash investing activities (accrued property and equipment purchases)	\$	241	\$	76

See accompanying notes to the consolidated financial statements.

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

(Unaudited)

(in thousands, except per share amounts, unless otherwise indicated)

1. The Company

We develop, manufacture, market and sell diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products, including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. Our diagnostic products include tests that are performed on a rapid basis at the point-of-care, tests that are processed in a laboratory, and a rapid point-of-care HIV test approved for use in the domestic consumer retail or over-the-counter (OTC) market. We also manufacture and sell devices used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomic, personalized medicine, microbiome and animal genetic markets. Lastly, we manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, commercial and industrial entities, retail pharmacies and mass merchandisers, and to consumers over the internet.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation. The consolidated financial statements include the accounts of OraSure Technologies, Inc. (OraSure) and its wholly-owned subsidiary, DNA Genotek, Inc. (DNAG). All intercompany transactions and balances have been eliminated. References herein to we, us, our, or the Company mean OraSure and its consolidated subsidiary, unless otherwise indicated.

The accompanying consolidated financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015. Results of operations for the three and nine months ended September 30, 2016 are not necessarily indicative of the results of operations expected for the full year.

Use of Estimates. The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the valuation of accounts receivable and inventories and assumptions utilized in impairment testing for intangible assets and goodwill, as well as calculations related to contingencies and accruals, among others. These estimates and assumptions are based on management's best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors, which management believes to be reasonable under the circumstances, including the current economic environment. We adjust such

estimates and assumptions when facts and circumstances dictate. Illiquid credit markets, volatile equity and foreign currency markets, reductions in government funding, and declines in consumer spending have combined to increase the uncertainty inherent in such estimates and assumptions. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in those estimates resulting from continuing changes in the economic environment and other factors will be reflected in the financial statements in those future periods.

Short-Term Investments. We consider all short-term investments to be available-for-sale securities. These securities are comprised of guaranteed investment certificates with purchased maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses, if any, reported in stockholders' equity as a component of accumulated other comprehensive loss.

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Our available-for-sale securities as of September 30, 2016 and December 31, 2015 consisted of guaranteed investment certificates with amortized cost and fair value of \$7,618 and \$7,225, respectively.

Fair Value of Financial Instruments. As of September 30, 2016 and December 31, 2015, the carrying values of cash and cash equivalents, accounts receivable, and accounts payable approximate their respective fair values based on their short-term nature.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Included in cash and cash equivalents at September 30, 2016 and December 31, 2015, was \$98,056 and \$65,509 invested in money market funds. These funds are Level 1 instruments.

We offer a nonqualified deferred compensation plan for certain eligible employees and members of our Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds and Company stock. The fair value of the plan assets as of September 30, 2016 and December 31, 2015 was \$1,888 and \$1,324, respectively, and was calculated using the quoted market prices of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 instruments. The fair value of plan assets is included in Other Assets with the same amount included in Other Liabilities in the accompanying consolidated balance sheets.

All of our available-for-sale securities are measured as Level 1 instruments as of September 30, 2016 and December 31, 2015.

In February 2016, we purchased certificates of deposit (CD) from a commercial bank in the amount of \$1,810. The CDs bear interest at an annual rate ranging from 0.17% to 0.25% and mature monthly through February 28, 2018. The carrying values of the CDs approximate their fair value. These CDs serve as collateral for certain standby letters of credit and are reported as restricted cash on the accompanying consolidated balance sheets. Also see Note 7 Commitments and Contingencies.