

ORASURE TECHNOLOGIES INC
Form 10-Q
May 09, 2018

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 March 31, 2018.

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 36-4370966
(State or Other Jurisdiction of (IRS Employer Identification No.)

Incorporation or Organization)

220 East First Street, Bethlehem, Pennsylvania 18015
(Address of Principal Executive Offices) (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, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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

Emerging growth company

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 May 2, 2018: 61,063,828 shares.

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Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except per share amounts)

	March 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$64,042	\$71,029
Restricted cash	23	1,840
Short-term investments	79,446	83,028
Accounts receivable, net of allowance for doubtful accounts of \$351 and \$471	28,197	42,521
Inventories	20,907	19,343
Prepaid expenses	2,213	1,658
Other current assets	1,926	2,486
Total current assets	196,754	221,905
PROPERTY AND EQUIPMENT, net	22,975	21,372
INTANGIBLE ASSETS, net	7,390	8,223
GOODWILL	19,584	20,083
LONG TERM INVESTMENTS	34,880	20,690
OTHER ASSETS	4,340	3,928
	\$285,923	\$296,201
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$9,622	\$10,228
Deferred revenue	1,799	1,314
Accrued expenses	9,765	20,695
Total current liabilities	21,186	32,237
OTHER LIABILITIES	4,258	3,932
DEFERRED INCOME TAXES	1,761	1,951
COMMITMENTS AND CONTINGENCIES (Note 8)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value \$.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value \$.000001, 120,000 shares authorized, 61,053 and 60,662 shares		
issued and outstanding	—	—
Additional paid-in capital	393,429	387,931
Accumulated other comprehensive loss	(13,006)	(10,340)
Accumulated deficit	(121,705)	(119,510)
Total stockholders' equity	258,718	258,081
	\$285,923	\$296,201

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2018	2017
NET REVENUES:		
Product	\$38,318	\$31,482
Other	3,669	1,064
	41,987	32,546
COST OF PRODUCTS SOLD	17,520	12,236
Gross profit	24,467	20,310
OPERATING EXPENSES:		
Research and development	4,075	2,970
Sales and marketing	7,499	6,877
General and administrative	13,391	7,092
Gain on litigation settlement	-	(12,500)
	24,965	4,439
Operating income (loss)	(498)	15,871
OTHER INCOME	412	467
Income (loss) before income taxes	(86)	16,338
INCOME TAX EXPENSE	2,033	3,897
NET INCOME (LOSS)	\$(2,119)	\$12,441
EARNINGS (LOSS) PER SHARE:		
BASIC	\$(0.03)	\$0.22
DILUTED	\$(0.03)	\$0.21
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:		
BASIC	60,865	56,929
DILUTED	60,865	58,772

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(Unaudited)

(in thousands)

	Three Months Ended March 31,	
	2018	2017
NET INCOME (LOSS)	\$(2,119)	\$12,441
OTHER COMPREHENSIVE INCOME (LOSS)		
Currency translation adjustments	(2,154)	450
Unrealized loss on marketable securities	(512)	—
COMPREHENSIVE INCOME (LOSS)	\$(4,785)	\$12,891

See accompanying notes to the consolidated financial statements.

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)

	Three Months Ended March 31,	
	2018	2017
OPERATING ACTIVITIES:		
Net income (loss)	\$(2,119)	\$12,441
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	7,483	1,518
Depreciation and amortization	1,868	1,419
Unrealized foreign currency gain	(298)	(1)
Deferred income taxes	(141)	(139)
Changes in assets and liabilities		
Accounts receivable	14,206	(4,143)
Inventories	(1,661)	(893)
Prepaid expenses and other assets	2	1,505
Accounts payable	(1,115)	2,619
Deferred revenue	421	(84)
Accrued expenses and other liabilities	(11,010)	(1,623)
Net cash provided by operating activities	7,636	12,619
INVESTING ACTIVITIES:		
Purchases of investments	(57,765)	(7,514)
Proceeds from maturities and redemptions of investments	45,893	—
Purchases of property and equipment	(1,897)	(878)
Net cash (used in) investing activities	(13,769)	(8,392)
FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	954	9,417
Repurchase of common stock	(2,959)	(851)
Net cash (used in) provided by financing activities	(2,005)	8,566
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(666)	99
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(8,804)	12,892
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, BEGINNING OF PERIOD	72,869	107,959
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, END OF PERIOD	\$64,065	\$120,851
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	\$8,886	\$1,949
Noncash investing activities (accrued property and equipment purchases)	\$1,157	\$297
Noncash unrealized losses on marketable securities	\$(512)	\$—

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

(Unaudited)

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

1. The Company

Our business is comprised of two segments: Our “OSUR” business consists of the development, manufacture, marketing and sale of oral fluid 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 molecular collections systems or “DNAG” business consists of the manufacture and sale of specimen collection kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic, academic research, pharmacogenomics, personalized medicine, microbiome and animal genetics markets.

Our OSUR diagnostic products include tests that are performed on a rapid basis at the point of care and tests that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians’ offices, and commercial and industrial entities. We also manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery or freezing. These cryosurgical products are sold in both professional and over-the-counter (“OTC”) markets in North America, Europe, Central and South America, and Australia.

Our “DNAG” or molecular collection systems business is operated by our subsidiary, DNA Genotek Inc., a company based in Ottawa, Canada. DNAG’s Oragen[®] DNA sample collection kit provides an all-in-one system for the collection, stabilization, transportation and storage of DNA from human saliva. We also sell research use only sample collection products into the microbiome and tuberculosis markets and we offer our customers a suite of genomics and microbiome services called “GenoFIND[™]”, which range from package customization and study design optimization to extraction, analysis and reporting services. We serve customers worldwide, including many leading research universities and hospitals.

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, 2017. Results of operations for the three months ended March 31, 2018 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 accruals, taxes, and performance-based compensation expense, 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. 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.

Investments. We consider all investments to be available-for-sale securities. These securities are comprised of guaranteed investment certificates and corporate bonds 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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The following is a summary of our available-for-sale securities as of March 31, 2018 and December 31, 2017:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2018				
Guaranteed investment certificates	\$ 21,708	\$ —	\$ —	\$21,708
Corporate bonds	93,683	1	(1,066)	92,618
Total available-for-sale securities	\$ 115,391	\$ 1	\$ (1,066)	\$114,326
December 31, 2017				
Guaranteed investment certificates	\$ 22,261	\$ —	\$ —	\$22,261
Corporate bonds	82,010	—	(553)	81,457
Total available-for-sale securities	\$ 104,271	\$ —	\$ (553)	\$103,718
At March 31, 2018 maturities of our available-for-sale securities were as follows:				
Less than one year	\$ 80,158	\$ 1	\$ (713)	\$79,446
Greater than one year	\$ 35,233	\$ —	\$ (353)	\$34,880

Fair Value of Financial Instruments. As of March 31, 2018 and December 31, 2017, the carrying values of cash and cash equivalents, restricted cash, 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).

All of our available-for-sale securities are measured as Level 1 instruments as of March 31, 2018 and December 31, 2017.

Included in cash and cash equivalents at March 31, 2018 and December 31, 2017, was \$28,831 and \$40,760 invested in government money market funds and certificates of deposit. Both are measured as 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 March 31, 2018 and December 31, 2017 was \$3,972 and \$3,514, 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.

In 2018, we purchased a certificate of deposit (“CD”) from a commercial bank as collateral for a standby letter of credit. The CD bears an interest rate of 1.28% and matures on May 20, 2018. The carrying value of the CD approximates its fair value and is reported as restricted cash on the accompanying consolidated balance sheets. Also see Note 8 – Commitments and Contingencies.

Inventories. Inventories are stated at the lower of cost or net realizable value with cost determined on a first-in, first-out basis, and are comprised of the following:

	March 31,	December 31,
	2018	2017
Raw materials	\$ 10,990	\$ 10,299
Work in process	388	199
Finished goods	9,529	8,845
	\$	