
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): May 2, 2018

OraSure Technologies, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16537
(Commission
File Number)

36-4370966
(I.R.S. Employer
Identification No.)

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

18015-1360
(Zip Code)

Registrant's telephone number, including area code: 610-882-1820

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by a check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 – Results of Operations and Financial Condition.

On May 2, 2018, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended March 31, 2018 and financial guidance for the second quarter of 2018. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

The information in this Item and attached Exhibit shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

Item 7.01 – Regulation FD Disclosure.

On May 2, 2018, the Company held a webcast conference call with analysts and investors, during which Stephen S. Tang, Ph.D., the Company’s President and Chief Executive Officer, and Ronald H. Spair, the Company’s Chief Financial Officer and Chief Operating Officer, discussed the Company’s consolidated financial results for the quarter ended March 31, 2018, provided financial guidance for the second quarter of 2018 and described certain business developments. A copy of the prepared remarks of Dr. Tang and Mr. Spair is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

The information in this Item and attached Exhibit shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

Item 9.01 – Financial Statements and Exhibits.**(d) Exhibits**

Exhibit Number	Description
99.1	<u>Press Release, dated May 2, 2018, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2018 and financial guidance for the second quarter of 2018.</u>
99.2	<u>Prepared Remarks of Stephen S. Tang, Ph.D. and Ronald H. Spair for OraSure Technologies, Inc. First Quarter 2018 Analyst/ Investor Conference Call Held May 2, 2018.</u>

Signatures

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ORASURE TECHNOLOGIES, INC .

Date: May 2, 2018

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary



OraSure Technologies, Inc.

Company Contact:

Ronald H. Spair
 Chief Financial Officer
 610-882-1820
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OraSure Announces 2018 First Quarter Financial Results

BETHLEHEM, PA – May 2, 2018 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its consolidated financial results for the quarter ended March 31, 2018.

Financial Highlights

- Consolidated net revenues for the first quarter of 2018 were \$42.0 million, a 29% increase from the first quarter of 2017. Consolidated net product revenues were \$38.3 million, representing a 22% increase over the first quarter of 2017.
- Net molecular collection systems revenues were \$18.4 million during the first quarter of 2018, which represents a 72% increase over the first quarter of 2017.
- International sales of the Company's OraQuick® HIV products of \$5.7 million increased 117% compared to the first quarter of 2017. This increase was primarily the result of higher sales of the Company's HIV self-test.
- International sales of the Company's OraQuick® HCV product of \$665,000 for the first quarter of 2018 decreased 85% compared to the first quarter of 2017 as a result of the non-renewal of a foreign government supply contract in support of a countrywide HCV eradication program at the end of 2017. This program contributed \$2.8 million of sales during the first quarter of 2017.
- Consolidated net loss for the first quarter of 2018 was \$2.1 million, or \$0.03 per share, which compares to consolidated net income of \$12.4 million, or \$0.21 per share on a fully diluted basis, for the first quarter of 2017. Consolidated net loss for the current quarter included \$6.4 million of transition costs associated the retirement of the Company's Chief Executive Officer and Chief Financial Officer and the hiring of their successors. These transition costs approximated \$0.10 per share and primarily consist of non-cash stock compensation charges. Consolidated net income for the three months ended March 31, 2017 included a \$12.5 million gain related to the settlement of litigation against Ancestry.com DNA and its contract manufacturer. This gain was accounted for as a reduction of operating expenses and approximated \$0.16 per share on an after-tax and fully diluted basis in that period.
- Cash and investments totaled \$178.4 million and working capital amounted to \$175.6 million at March 31, 2018.

"We are pleased to see that our growth strategy is delivering the expected results and 2018 is off to a strong start," said Stephen S. Tang, Ph.D., President and Chief Executive Officer of OraSure Technologies. "Our first quarter benefitted from robust growth in sales of our molecular collections and international HIV products. Importantly, we expect to see continued growth from those businesses for the remainder of the year. Our years of planning and investment are paying off and OraSure has never been financially stronger than it is now. We see significant opportunity in our existing markets and we will look to expand our addressable markets where possible."

Financial Results

Consolidated net product revenues for the first quarter of 2018 increased 22% over the comparable period of 2017, primarily as a result of higher sales of the Company's molecular collections products and higher international sales of the OraQuick® HIV self-test, partially offset by lower international sales of the OraQuick® HCV test. First quarter 2018 sales of the OraQuick® HIV self-test included \$985,000 of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation").

Consolidated other revenues were \$3.7 million and \$1.1 million for the first quarter of 2018 and 2017, respectively. Other revenues in the first quarter of 2018 included royalty income of \$1.6 million associated with a litigation settlement agreement, Ebola and Zika-related funding received from the U.S. Biomedical Advanced Research Development Authority ("BARDA") of \$1.5 million and cost reimbursement under the Company's charitable support agreement with the Gates Foundation of \$529,000, which is separate from the support payments mentioned above. Other revenues in the first quarter of 2017 consisted only of BARDA funding.

Consolidated gross margin was 58% and 62% for the three months ended March 31, 2018 and 2017, respectively. Gross margin was lower for the current quarter primarily due to an increase in lower margin product sales and a decrease in the absorption of fixed costs as a result of lower production levels in the first quarter of 2018, partially offset by an increase in other revenues and lower scrap and spoilage costs as compared to the first quarter of 2017.

Consolidated operating expenses increased to \$25.0 million during the first quarter of 2018 compared to \$4.4 million in the first quarter of 2017. This increase was largely due to the inclusion in the current quarter of \$6.4 million of transition costs as discussed above and the absence of the \$12.5 million litigation gain associated with the settlement of litigation against Ancestry.com DNA that was included in the first quarter of 2017. There was no similar gain recorded during the first quarter of 2018. The first quarter of 2018 also included higher spending on the Company's Ebola and Zika products and higher staffing and consulting costs, partially offset by a reduction in legal expenses.

The Company reported an operating loss of \$498,000 in the first quarter of 2018, compared to operating income of \$15.9 million in the first quarter of 2017.

Income tax expense was \$2.0 million during the first quarter of 2018 compared to \$3.9 million recorded in the first quarter of 2017. Income tax expense in the first quarter of 2017 included the additional taxes due as a result of the \$12.5 million litigation settlement gain. Income tax expense in the first quarter of 2018 reflects the higher pre-tax income generated by the Company's Canadian subsidiary.

The Company's cash and investment balance totaled \$178.4 million at March 31, 2018, compared to \$176.6 million at December 31, 2017. Working capital was \$175.6 million at March 31, 2018, compared to \$189.7 million at December 31, 2017. For the three months ended March 31, 2018, the Company generated \$7.6 million in cash from operations.

Second Quarter 2018 Outlook

The Company expects consolidated net revenues to range from \$42.0 million to \$42.5 million and is projecting consolidated net income of approximately \$0.03 per share for the second quarter of 2018. These results include approximately \$1.7 million in final management transition costs projected for the quarter.

Financial Data
**Condensed Consolidated Financial Data
(In thousands, except per-share data)**
Unaudited

	Three months ended March 31,	
	2018	2017
Results of Operations		
Net revenues	\$ 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)
Total operating expenses	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
Weighted average shares:		
Basic	60,865	56,929
Diluted	60,865	58,772

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended March 31,				
	Dollars		%	Percentage of Total Net Revenues	
	2018	2017		Change	2018
Market					
Infectious disease testing	\$ 14,170	\$ 14,583	(3) %	34 %	45 %
Risk assessment testing	3,002	3,130	(4)	7	10
Cryosurgical systems	2,785	3,063	(9)	6	9
Molecular collection systems	18,361	10,706	72	44	33
Net product revenues	38,318	31,482	22	91	97
Other	3,669	1,064	245	9	3
Net revenues	\$ 41,987	\$ 32,546	29 %	100 %	100 %

	Three Months Ended March 31,		
	2018	2017	% Change
OraQuick® Revenues			
Domestic HIV	\$ 3,344	\$ 3,812	(12) %
International HIV	5,737	2,644	117
Domestic OTC HIV	1,632	1,542	6
Net HIV revenues	10,713	7,998	34
Domestic HCV	1,627	1,709	(5)
International HCV	665	4,402	(85)
Net HCV revenues	2,292	6,111	(62)
Net product revenues	\$ 13,005	\$ 14,109	(8) %

	Three Months Ended March 31,		
	2018	2017	% Change
Cryosurgical Systems Revenues			
Domestic professional	\$ 875	\$ 1,496	(42) %
International professional	150	130	15
Domestic OTC	289	285	1
International OTC	1,471	1,152	28
Net product revenues	\$ 2,785	\$ 3,063	(9) %

	Three Months Ended March 31,		
	2018	2017	% Change
Molecular Collection Systems Revenues			
Commercial Genomics	\$ 14,256	\$ 7,254	97 %
Academic Genomics	2,832	2,685	5
Microbiome	1,273	767	66
Net product revenues	\$ 18,361	\$ 10,706	72 %

	Three Months Ended March 31,		
	2018	2017	% Change
Other Revenues			
Royalty income	\$ 1,602	\$ -	N/A
BARDA funding	1,538	1,064	45 %
Charitable support reimbursement	529	-	N/A
Other revenues	\$ 3,669	\$ 1,064	245 %

Condensed Consolidated Balance Sheets (Unaudited)

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
<u>Assets</u>		
Cash and cash equivalents	\$ 64,065	\$ 72,869
Short-term investments	79,446	83,028
Accounts receivable, net	28,197	42,521
Inventories	20,907	19,343
Other current assets	4,139	4,144
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 non-current assets	4,340	3,928
Total assets	<u>\$ 285,923</u>	<u>\$ 296,201</u>
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 9,622	\$ 10,228
Deferred revenue	1,799	1,314
Other current liabilities	9,765	20,695
Other non-current liabilities	4,258	3,932
Deferred income taxes	1,761	1,951
Stockholders' equity	258,718	258,081
Total liabilities and stockholders' equity	<u>\$ 285,923</u>	<u>\$ 296,201</u>

Additional Financial Data (Unaudited)	Three Months Ended	
	March 31,	
	<u>2018</u>	<u>2017</u>
Capital expenditures	\$ 1,897	\$ 878
Depreciation and amortization	\$ 1,868	\$ 1,419
Stock-based compensation	\$ 7,483	\$ 1,518
Cash provided by operating activities	\$ 7,636	\$ 12,619

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2018 first quarter financial results, certain business developments and financial guidance for the second quarter of 2018, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Stephen S. Tang, President and Chief Executive Officer, and Ronald H. Spair, Chief Financial Officer and Chief Operating Officer. The call will include prepared remarks by management and a question and answer session.

In order to listen to the conference call, please either dial 844-831-3030 (Domestic) or 315-625-6887 (International) and reference Conference ID #4298046 or go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Relations page. Please click on the webcast link and follow the prompts for registration and access 10 minutes prior to the call. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until midnight, May 9, 2018, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #4298046.

About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of point-of-care diagnostic and collection devices and other technologies designed to detect or diagnose critical medical conditions. Its first-to-market, innovative products include rapid tests for the detection of antibodies to HIV and HCV on the OraQuick® platform, oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications, and oral fluid laboratory tests for detecting various drugs of abuse. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, commercial and industrial entities and consumers. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health.

Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration (“FDA”) or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company’s products; impact of significant customer concentration in the genomics business; impact of increased reliance on U.S. government contracts; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing, collection or other products; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention (“CDC”) or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company’s stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in credit agreements; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could affect our results are discussed more fully in the Company’s Securities and Exchange Commission (“SEC”) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2017, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

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OraSure Technologies, Inc.
2018 First Quarter
Analyst/Investor Conference Call
May 2, 2018

Prepared Remarks of Stephen S. Tang, Ph.D. and Ronald H. Spair

Please see “Important Information” at the conclusion of the following prepared remarks

Introduction – Steve Tang

Thank you Joni. Good afternoon everyone and welcome to our call.

It is a pleasure to be hosting my first earnings call as CEO of OraSure Technologies. Later on in the call, I will share with you my thoughts since becoming CEO and update you on my initial impressions. I would like to thank all those on the OraSure team that have assisted with my transition and helped make my job a bit easier today as we had a very strong start to 2018. As a result of years of planning, investment and execution, OraSure now operates two key businesses -- Molecular Collections and Infectious Disease Testing -- that are driving solid results.

Overall, our business is well positioned to continue future growth. Our path forward is clear. We see opportunities to expand through the growth of our existing products and the deployment of our strong balance sheet to further maximize the value of our Company. Innovation is critical to the success of any company and is one of my top priorities. We all know that companies that do not innovate are destined to be left behind. Our ability to innovate has made us a leader in our field. We intend to foster our rich history of innovation to gain access to new opportunities and expand our existing markets.

Our Q1 results were driven largely by our molecular collections and our Human Immunodeficiency Virus (or “HIV”) self-test businesses.

- Consolidated net revenues for the quarter were \$42 million, a 29% increase from the year-ago period. Product revenue growth for Q1 was 22%.
- Our molecular business delivered revenues of \$18.4 million, which represents a 72% increase over Q1 of last year.
- Our international HIV sales grew 117% for the quarter, driven primarily by our HIV self-test business. This increase largely offset a decline in domestic HIV revenues and lower international Hepatitis C virus (or “HCV”) test sales caused by the non-renewal of a large government supply contract in support of a country-wide HCV eradication program.
- Gross margin increased 344 basis points from Q4 2017.
- We reported a loss of \$2.1 million or \$0.03 per share. As Ron will explain in greater detail, this resulted from \$0.10 per share in non-recurring charges associated with the previously announced management transition.
- We ended Q1 with nearly \$180 million in cash and cash equivalents on our balance sheet.

So with that, let me now turn the call over to Ron. After his detailed financial review, I will provide some business updates and then we both will take your questions.

First Quarter 2018 Financial Results – Ron Spair

Thanks Steve, and good afternoon everyone.

Revenues – Ron Spair

2018 is off to a great start. Our first quarter consolidated net revenues increased 29% to \$42.0 million, compared to \$32.5 million reported in the first quarter of 2017. Our consolidated net product revenues rose 22% to \$38.3 million compared to the prior-year period. Higher sales of our molecular collections products and the OraQuick® HIV self-test were the main drivers of this performance.

Our molecular revenues rose 72% to \$18.4 million in the first quarter of 2018 compared to \$10.7 million in the first quarter of 2017. Sales of our products to commercial customers increased 97% to \$14.3 million, largely due to our \$143 million agreement to supply Oragene® devices to a leading consumer genomics customer coupled with higher sales to other large customers. Microbiome sales continued to gain traction and increased 66% to \$1.3 million in the first quarter of 2018 as compared to the first quarter of 2017.

International HIV sales increased 117% to \$5.7 million from \$2.6 million in the first quarter of 2017 due to higher sales of our OraQuick® HIV self-test into Africa and higher sales of our professional product in parts of Asia and Europe, partially offset by a decline in sales to the Middle East. The tests shipped into Africa during the quarter were subject to the support payments under our charitable support agreement with the Bill & Melinda Gates Foundation (“Gates Foundation”) and included countries outside of the UNITAID/Population Services International (or “PSI”) Self-Testing Africa, (or “STAR” initiative). Product revenue during the first quarter of 2018 included approximately \$985,000 of support payments associated with this agreement.

Domestic professional HIV sales continue to decline and decreased 12% to \$3.3 million in the first quarter of 2018, compared to \$3.8 million in the first quarter of 2017, due to previously discussed market factors.

International HCV sales in the first quarter of 2018 decreased 85% to \$665,000 from \$4.4 million in the same period of 2017, primarily due to the non-renewal of a foreign government supply contract in support of a country-wide HCV eradication program. Also contributing to this decline was a large one-time order which occurred in the first quarter of 2017 but did not reoccur in the first quarter of 2018. Domestic HCV sales decreased 5% in the first quarter of 2018 to \$1.6 million from \$1.7 million in the prior-year period, primarily due to the impact of grant funding delays that negatively affected our hospital customers and the fact that a large NGO discontinued its testing program.

Sales of our cryosurgical systems product decreased 9% in the first quarter of 2018 to \$2.8 million compared to \$3.1 million in the first quarter of 2017. Sales of our domestic Histofreezer® products sold to physician offices decreased 42% to \$875,000 primarily due to the timing of orders placed by our distributors and competitive losses. Sales of our international OTC cryosurgical product increased 28% to \$1.5 million in the first quarter of 2018 compared to \$1.2 million in the first quarter of 2017 due to higher sales in Latin America.

Other revenues were \$3.7 million in the current quarter, representing \$1.6 million of royalty income associated with a litigation settlement agreement, \$1.5 million of funding from the Biomedical Advanced Research and Development Authority (or “BARDA”) for our Ebola and Zika products, and \$529,000 of cost reimbursement under our charitable support agreement with the Gates Foundation.

Gross Margin – Ron Spair

Gross margin for the first quarter of 2018 was 58% compared to 62% reported for the first quarter of 2017. Margin for the current quarter decreased primarily due to an increase in lower margin product sales and a decrease in the absorption of fixed costs as a result of lower production levels in the first quarter of 2018 compared to the first quarter of 2017 which benefitted from the large foreign government HCV eradication program. These declines in gross margin were partially offset by the increase in Other Revenues and a reduction in scrap and spoilage costs.

As we look forward, we currently expect gross margins for Q2 to approximate those of Q1. During the second half of the year, we expect gross margins to increase somewhat based on the projected sales mix and certain assumptions regarding foreign currency exchange rates and projected scrap and spoilage.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the first quarter of 2018 were \$25.0 million compared to \$4.4 million in the comparable period of 2017. This increase was largely due to the inclusion in Q1 2018 of \$6.4 million of transition costs associated with Doug Michels' and my retirements and the related costs of hiring Steve Tang and my CFO successor. In addition, the first quarter of 2017 included the gain from our litigation settlement of \$12.5 million which was recorded as an expense reduction. We had no similar gain in the first quarter of 2018. Lastly, Q1 2018 includes higher spending on our Ebola and Zika products and higher staffing and consulting costs, partially offset by a reduction in legal expenses.

Income Taxes – Ron Spair

Income tax expense was \$2.0 million in the first quarter of 2018 compared to \$3.9 million in the same period last year and consists entirely of Canadian taxes due. Income tax expense for Q1 2017 included the additional taxes due as a result of the \$12.5 million litigation settlement gain.

Net Income – Ron Spair

From a bottom line perspective, we reported a net loss of \$2.1 million, or \$0.03 per share, for Q1 2018, compared to net income of \$12.4 million, or \$0.21 per share, for Q1 2017. The transition costs previously discussed approximated \$0.10 per share in the first quarter of 2018 while the litigation settlement gain in the first quarter of 2017 approximated \$0.16 per share on an after-tax basis. I should note that the \$6.4 million in management transition costs primarily reflect non-cash stock compensation charges.

Cash Flow from Operations and Liquidity – Ron Spair

Turning to our balance sheet and cash flow, we continue to maintain a solid cash and liquidity position. Our cash and investments balance at March 31, 2018 was \$178.4 million compared to \$176.6 million at December 31, 2017. Cash generated by operating activities during the first quarter of 2018 was \$7.6 million compared to \$12.6 million in the same period of 2017 which included the \$12.5 million litigation settlement.

Second Quarter 2018 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the second quarter of 2018, we are projecting revenues to range between \$42.0 million and \$42.5 million and consolidated net income of approximately \$0.03 per share. These results reflect the final management transition costs of approximately \$1.7 million.

And with that, I will now turn the call back over to Steve.

Business Update – Steve Tang

Thanks Ron.

Molecular Business Update – Steve Tang

Molecular

So as you've heard, our molecular business performed very well in Q1 with revenues up 72% from the prior year period. We acquired 72 new customers during the quarter in this business segment. It is important to note that we are now seeing for the first time two of our top 20 customers purchasing both genomics and microbiome products as research continues to show the utility of combining these two fields of study. We believe this type of synergy between our product lines is a very encouraging trend and will continue.

Genomics

In our genomics business, sales to commercial customers were the primary growth driver with revenue increasing 97%. We won 10 new commercial accounts in Q1, of which 5 are consumer genomics companies.

Large epidemiological studies continue to represent an attractive opportunity for the business. In Q1, the Simon's Foundation renewed its supply agreement for 125,000 of our FDA cleared Oragene®•Dx saliva collection kits, along with fulfilment services to meet their recruitment goals. The Scripps Research Institute and the Mayo Clinic also selected Oragene®•Dx and our fulfilment services for a pilot of 13,000 individuals for the recruitment of rural and underserved populations into the "All of Us" program. As reported in the New York Times, yesterday, this program is a historic effort to gather data from one million or more people living in the United States to accelerate research and improve health, through precision medicine.

On the academic side, we reported modest revenue growth compared to the prior year quarter. However, we posted 66% sequential growth from Q4 of last year.

Microbiome

Our Microbiome business also continued to grow with sales for the quarter up 66% compared to the prior year period and up 15% sequentially over Q4 of last year.

We expect microbiome sales to become an increasingly important part of our business. As previously mentioned, two microbiome purchasers have moved into the top 20 molecular accounts. Of our top 20 microbiome customers purchasing in Q1, 17 are repeat purchasers having made multiple purchases over the last 12 months, and 12 are commercial customers.

Our services business posted a solid quarter in Q1. Customer highlights include a venture-backed bio-pharma customer with multiple phase II programs under way to develop microbial therapeutics to treat gastro-intestinal infections and inflammatory diseases. This customer uses our kits to collect standardized stool microbiome samples from multiple clinical and academic sites across North America and the European Union ("EU"). They also send biopsy specimens and biological material from animal models to our services facility for processing and analysis.

We also closed a deal in Scandinavia where there is a history of large cohort studies with the University of Turku purchasing 10,000 OMNIGene®•GUT kits. The group investigates the clinical role of gut microbiota in certain clinical conditions by studying both the composition and the metabolic capabilities of the gut bacteria.

Finally, in the very near future we expect to start shipping product to fulfill our supply agreement with the Harvard T.P. Chan School of Public Health. We announced this agreement last quarter for the supply of kits for a microbiome specific re-collection of the Nurse's Health Study II Cohort.

As stated in prior calls, we see a similarity between the early days of research activity with microbiome testing and the initial development of human genomics testing. That similarity gives us good reason to believe that we may see the same robust growth trajectory in the microbiome market that we have experienced in genomics. In fact, given the repeat testing requirements in the microbiome market, this could very well become an even larger opportunity than genomics.

Infectious Disease Testing – Steve Tang

Turning to infectious disease, the trends we have seen in recent periods continue to impact this part of our business.

HIV Business

Once again, the highlight for the quarter was our international HIV business. As discussed in prior calls, Population Services International (“PSI”) has initiated Phase II of the Self-Testing in Africa (“STAR”) project, which is expected to deploy 4 million HIV self-tests into an expanded list of African countries, with the largest being South Africa. During the quarter, we filled orders for our OraQuick® HIV self-test under Phase II as well as from a growing number of countries outside of the STAR program as they begin to scale up their testing activities. These other countries are using United States Agency for International Development (or “USAID”) and the President’s Emergency Plan for AIDS Relief (or “PEPFAR”) funding to purchase our product.

An important growth driver for our HIV self-test is the charitable support agreement with the Gates Foundation. The more favorable pricing we can offer as a result of this agreement is stimulating additional demand in a growing number of countries in Africa and elsewhere.

During Q1, we shipped approximately 1.3 million HIV self-tests to both STAR and non-STAR countries, which represents a 30% increase over the number of units shipped in Q4 of last year. In the second quarter of this year, we expect to ship more self-tests than we shipped in the first quarter. To date, based on initial expressions of interest, ongoing pilot studies and scale up efforts, we are selling or promoting our self-test in approximately 40 countries in Sub-Saharan Africa, West Africa, Asia, Central Asia and Latin America. One of the larger efforts underway is securing in-country registrations for our product in the growing number of countries we intend to serve. Our efforts to register our HIV self-test in the countries covered by the Gates agreement are largely on track as we have prioritized completing regulatory work in the countries most likely to implement HIV self-testing on a broad basis.

As mentioned on the last call, another promising opportunity in many countries is the pharmacy market, even though that market is not covered by the Gates agreement. We continue to support pharmacy pilot programs initiated by PSI primarily in Sub-Saharan Africa and continue to believe the pharmacy channel will eventually be important to our self-testing business.

We are also continuing to work with the Gates Foundation and other large global funding organizations to promote our charitable support agreement and the value of HIV self-testing. We remain very optimistic about HIV self-testing and believe this will continue to be an important source of future growth for our infectious disease business.

As Ron noted, our domestic HIV business has continued to decline and this was more than offset by the growth in international HIV sales. Although we have secured some fairly sizable customer wins on the domestic front recently, largely due to product performance and the strength of our product portfolio, we expect the same domestic trends to impact future periods. These negative trends are largely the result of reduced U.S.-based budgets, continued competition and pressure to move to fourth generation automated laboratory testing solutions.

HCV Business

As you heard earlier, our total HCV revenues for Q1 declined from the prior year quarter, primarily as the result of the non-renewal of a large foreign government supply contract. Our domestic business was also down slightly compared to last year, primarily due to grant funding delays and a large NGO discontinuing its HCV screening efforts.

Nevertheless, we do remain confident in our overall HCV business and believe it will continue to be a source of growth for our Company. Domestically, we expect to see more investments in HCV screening as government and state organizations allocate resources to deal with the Opioid crisis and resulting HCV infections. We also continue to see customers here in the U.S. shifting as much money and resources as possible to support HCV testing and treatment programs despite the overall funding challenges.

On a global basis, the interest in HCV testing and treatment continues to expand as the cost of HCV therapies is now reaching extremely low levels globally. We recently attended the International Liver Meeting in Paris where the WHO continues to execute against its strategy to eliminate HCV and hepatitis B by the year 2030. Many of the sessions at the meeting focused on the elimination of HCV and how to start test and treat programs on the local level. As a result of these market conditions, we continue to believe high prevalence countries will eventually take on large scale screening programs. Despite these helpful market conditions, significant logistical and funding issues still need to be resolved for many of these programs. For this reason, we have not included any major new elimination programs in our current revenue forecast and will treat them as pure upside through the remainder of the year.

Operations Update – Steve Tang

Turning to operations, our capacity balancing efforts have continued.

- Work with our Thailand contractor has started to add additional manufacturing and packaging rooms to be used for the supply of non-U.S. and non-CE marked OraQuick® product. This contractor is negotiating a lease for the additional space needed and the plan is to install equipment to increase capacity by 50% by the end of 2018.
- A fourth automated assembly line for Oragene® collection kits has been built and delivered and is now being validated at our contract manufacturer in Canada. A fifth automated assembly line has been ordered with delivery and installation planned for late 2018.
- Work is also underway for a new automated assembly line for our OMNIgene®•Gut product. The goal is to complete construction, installation and validation of the equipment by year end. The automated line will provide capacity for sales growth and support for upcoming clinical work involving the OMNIgene® product.
- Lastly, construction of a newly leased warehouse here in Bethlehem has been completed and the Certificate of Occupancy was recently received. Environmental qualification and equipment validation is underway and regulatory submissions will follow.

Management Changes

A final area I want to address is the recent management changes here at OraSure. As for my transition, things are proceeding smoothly, in large part because of my seven years of prior service on OraSure's Board of Directors and because I had an opportunity to work closely with Doug Michels before his departure at the end of March. The executive team has also done a wonderful job in assisting with this transition. Since my April 1st start date as CEO, I have been actively learning more about our business, shareholders, customers, and stakeholders, as well as getting to know our management team and employees a bit better.

One of my primary focus areas has been the ongoing examination of our long-term business strategy. That exercise is progressing on schedule and we expect it to be completed and reviewed with the Board sometime during the summer. For obvious competitive reasons, we will not be able to foreshadow the specific goals and objectives we have developed in the strategy work, but we will share with you some initial elements of our plan at a higher level, when appropriate. New initiatives will be more evident as we begin to implement our strategy. We will update you on those initiatives as they occur in future periods. So, more to come on that front.

A key part of our updated strategy is the identification of business development opportunities. So I am very pleased that we were able to bring David Rappaport on board as our new Senior Vice President, Business Development. Most recently, David served as Senior Vice President, Health Care Investment Banking at Raymond James & Associates where he provided investment banking services in the firm's life sciences practice. He also has prior experience as a health care investment banker at several other firms. David is highly qualified and I look forward to the positive impact that his new energy and new ideas will bring to the business development function here at the Company.

As you know, the other big change that is coming is the appointment of a new Chief Financial Officer who will be replacing Ron when he retires. That effort has also been progressing and is nearing completion. We expect to have something to announce on that front in the very near future. In the meantime, I would like to thank Ron for his tireless 16 years of service to OraSure as CFO and COO. He is a remarkable senior executive, who has led us well to our current success and has helped position us for further success.

Conclusion – Steve Tang

So, in conclusion, we have a lot to be excited about at OraSure. Our business is strong and driving consistently solid results. We have many growth opportunities that are still in the early days of their potential. The Company has never been on more solid financial footing with nearly \$180 million in cash and no debt. We are close to completing our strategic development work and our manufacturing capacity is now aligned with the expected future demand for our products.

As I said in my opening remarks, innovation is crucial for ongoing market leadership. Fostering a culture of innovation is paramount to me and OraSure and has and will be the fuel for our continued growth. I am highly confident that our future holds great promise, because of what I've learned in the past seven years about our business, our people, and the opportunities before us.

So with that, we will now take your questions. Operator, please proceed.

* * * *

[Q&A session]

Final Conclusion – Steve Tang

Thank you for participating on today's call and for your continued interest in OraSure. Have a good afternoon and evening.

Important Information

This document contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements;

ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration (“FDA”) or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company’s products; impact of significant customer concentration in the genomics business; impact of increased reliance on U.S. government contracts; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing, collection or other products; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention (“CDC”) or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company’s stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in credit agreements; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in the Company’s Securities and Exchange Commission (“SEC”) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2017, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this call, and we undertake no duty to update these statements.