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

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): August 8, 2018**

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

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**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**

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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.

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**Item 2.02 – Results of Operations and Financial Condition.**

On August 8, 2018, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended June 30, 2018 and financial guidance for the third 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 August 8, 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 Roberto Cuca, the Company’s Chief Financial Officer discussed the Company’s consolidated financial results for the quarter ended June 30, 2018, provided financial guidance for the third quarter of 2018 and described certain business developments. A copy of the prepared remarks of Dr. Tang and Mr. Cuca 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**

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#"><u>Press Release, dated August 8, 2018, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2018 and financial guidance for the third quarter of 2018.</u></a>
99.2	<a href="#"><u>Prepared Remarks of Dr. Stephen S. Tang and Roberto Cuca for OraSure Technologies, Inc. Second Quarter 2018 Analyst/ Investor Conference Call Held August 8, 2018.</u></a>

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**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: August 8, 2018

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary



OraSure Technologies, Inc.

Company Contact:

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### OraSure Announces 2018 Second Quarter Financial Results

**BETHLEHEM, PA** – August 8, 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 three and six months ended June 30, 2018.

#### Financial Highlights

- Consolidated net revenues for the second quarter of 2018 were \$43.6 million, a 9% increase from the second quarter of 2017. Consolidated net product revenues were \$38.8 million, representing a 1% decrease from the second quarter of 2017.
  - Consolidated net revenues for the six months ended June 30, 2018 were \$85.6 million, an 18% increase from the comparable period of 2017. Consolidated net product revenues for the first six months of 2018 were \$77.1 million, representing a 9% increase over the first half of 2017.
  - Net molecular collection systems revenues were \$17.2 million during the second quarter of 2018, which represents a 7% increase over the second quarter of 2017. Net molecular collection systems revenues during the six months ended June 30, 2018 were \$35.6 million, a 33% increase from the comparable period of 2017.
  - International sales of the Company's OraQuick® HIV products of \$7.4 million increased 265% compared to the second quarter of 2017. International sales of the Company's OraQuick® HIV products of \$13.1 million increased 180% compared to the first six months of 2017. The increases in both periods were primarily the result of higher sales of the Company's OraQuick® HIV Self-Test.
  - International sales of the Company's OraQuick® HCV product of \$1.5 million decreased 72% for the second quarter of 2018 compared to the second quarter of 2017. International sales of the Company's OraQuick® HCV product of \$2.1 million for the first six months of 2018 decreased 78% from the comparable period of 2017. These declines were 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 \$4.1 million of sales during the second quarter of 2017 and \$6.9 million during the first six months of 2017.
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- Consolidated net income for the second quarter of 2018 was \$4.1 million, or \$0.07 per share on a fully diluted basis, which compares to consolidated net income of \$5.4 million, or \$0.09 per share on a fully diluted basis, for the second quarter of 2017. Consolidated net income for the six months ended June 30, 2018 was \$2.0 million, or \$0.03 per share on a fully diluted basis, which compares to consolidated net income of \$17.9 million, or \$0.30 per share on a fully diluted basis, for the comparable period of 2017. Consolidated net income for the current quarter and year to date period included \$2.2 million and \$8.6 million, respectively, of transition costs associated with the retirement of the Company's Chief Executive Officer and Chief Financial Officer and the hiring of their successors. These transition costs approximated \$0.04 and \$0.14 per share, respectively, for the three and six month periods ended June 30, 2018, and primarily consisted of non-cash stock compensation charges. Consolidated net income for the six months ended June 30, 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 a fully diluted after-tax basis in that period.
- Cash and investments totaled \$181.2 million at June 30, 2018.

“Our financial results for the second quarter of 2018 exceeded expectations and continued the solid performance started in Q1,” said Dr. Stephen S. Tang, President and CEO of OraSure Technologies. “Continued strong international sales of our HIV Self-Test and another strong quarter by our molecular collections business were the primary drivers of this performance. We expect that our HIV Self-Test and molecular businesses will continue to be key growth contributors for the rest of 2018.”

## Financial Results

Consolidated net product revenues for the second quarter of 2018 decreased 1% from the comparable period of 2017, primarily as a result of lower sales of the Company's OraQuick® HCV and cryosurgical systems products and lower domestic sales of the professional OraQuick® HIV test, partially offset by higher international sales of the OraQuick® HIV Self-Test and higher sales of the Company's molecular collections products.

Consolidated net product revenues for the first six months of 2018 increased 9% over the comparable period of 2017, primarily as a result of higher sales of the Company's molecular collection systems products and higher international sales of the OraQuick® HIV Self-Test, partially offset by lower sales of the Company's HCV product, lower domestic sales of the professional OraQuick® HIV test and lower sales of the Company's cryosurgical systems products.

Sales of the OraQuick® HIV Self-Test for the three and six months ended June 30, 2018 included \$1.7 million and \$2.7 million, respectively, of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation (“Gates Foundation”).

Consolidated other revenues were \$4.8 million and \$1.0 million for the second quarter of 2018 and 2017, respectively. Consolidated other revenues were \$8.5 million and \$2.1 million for the first six months of 2018 and 2017, respectively. Other revenues in the second quarter of 2018 included royalty income of \$2.1 million associated with a litigation settlement agreement, Ebola and Zika-related funding received from the U.S. Biomedical Advanced Research Development Authority (“BARDA”) of \$1.9 million and cost reimbursement under the Company's charitable support agreement with the Gates Foundation of \$795,000, which is separate from the support payments mentioned above. Other revenues in the first six months of 2018 included royalty income from the litigation settlement of \$3.7 million, BARDA funding of \$3.5 million, and cost reimbursement from the Gates Foundation of \$1.3 million. Other revenues in the second quarter and first six months of 2017 consisted only of BARDA funding.

Consolidated gross profit percentage was 59% for the three and six months ended June 30, 2018 and 63% for the three and six months ended June 30, 2017. Gross profit percentage declined in both periods primarily due to an increase in lower profit percentage product sales partially offset by an increase in other revenues.

Consolidated operating expenses increased to \$20.3 million during the second quarter of 2018 compared to \$18.6 million in the second quarter of 2017. For the six months ended June 30, 2018, consolidated operating expenses were \$45.3 million, an increase of \$22.3 million from the \$23.0 million reported for the six months ended June 30, 2017. The quarter increase was largely due to the inclusion of \$2.2 million of retirement-related transition costs as discussed above and increased spending in research and development, partially offset by lower staffing costs. The increase for the year to date period was largely due to the inclusion of \$8.6 million of transition costs and higher spending on research and development and sales and marketing, partially offset by the absence of the \$12.5 million litigation gain associated with the settlement of litigation against Ancestry.com DNA and its contract manufacturer that was included in the first half of 2017. There was no similar gain recorded during the first half of 2018.

The Company reported operating income of \$5.6 million in the second quarter of 2018, compared to operating income of \$6.9 million in the second quarter of 2017. Operating income for the six months ended June 30, 2018 was \$5.1 million compared \$22.8 million for the six months ended June 30, 2017.

Income tax expense was \$2.2 million during the second quarter of 2018 compared to \$1.6 million recorded in the second quarter of 2017. Income tax expense was \$4.2 million during the first six months of 2018 compared to \$5.5 million during the first six months of 2017. Income tax expense in 2018 reflects the higher pre-tax income generated by the Company's Canadian subsidiary. Income tax expense in the first six months of 2017 included the additional taxes due as a result of the \$12.5 million litigation settlement gain.

The Company's cash and investment balance totaled \$181.2 million at June 30, 2018, compared to \$176.6 million at December 31, 2017. For the six months ended June 30, 2018, the Company generated \$13.9 million in cash from operations.

### **Third Quarter 2018 Outlook**

The Company expects consolidated net revenues to range from \$44.0 million to \$45.5 million and is projecting consolidated net income of \$0.10 to \$0.12 per share for the third quarter of 2018.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
<b>Results of Operations</b>				
Net revenues	\$ 43,625	\$ 40,176	\$ 85,612	\$ 72,722
Cost of products sold	17,730	14,699	35,250	26,935
Gross profit	25,895	25,477	50,362	45,787
Operating expenses:				
Research and development	4,261	3,338	8,336	6,308
Sales and marketing	7,429	7,502	14,928	14,379
General and administrative	8,647	7,750	22,038	14,842
Gain on litigation settlement	—	—	—	(12,500)
Total operating expenses	20,337	18,590	45,302	23,029
Operating income	5,558	6,887	5,060	22,758
Other income	736	96	1,148	563
Income before income taxes	6,294	6,983	6,208	23,321
Income tax expense	2,173	1,555	4,206	5,452
Net income	\$ 4,121	\$ 5,428	\$ 2,002	\$ 17,869
Earnings per share:				
Basic	\$ 0.07	\$ 0.09	\$ 0.03	\$ 0.31
Diluted	\$ 0.07	\$ 0.09	\$ 0.03	\$ 0.30
Weighted average shares:				
Basic	61,100	58,478	60,983	57,708
Diluted	62,244	60,728	62,379	59,755

**Summary of Net Revenues by Market and Product (Unaudited)**

	Three Months Ended June 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2018	2017		2018	2017
<b>Market</b>					
Infectious disease testing	\$ 15,919	\$ 16,663	(4) %	36 %	41 %
Risk assessment testing	3,315	3,238	2	8	8
Cryosurgical systems	2,392	3,174	(25)	6	8
Molecular collection systems	17,192	16,057	7	39	40
Net product revenues	38,818	39,132	(1)	89	97
Other	4,807	1,044	360	11	3
Net revenues	\$ 43,625	\$ 40,176	9 %	100 %	100 %

	Six Months Ended June 30,					
	Dollars			Percentage of Total Net Revenues		
	2018	2017	% Change	2018	2017	
<b>Market</b>						
Infectious disease testing	\$ 30,090	\$ 31,245	(4) %	35 %	43 %	
Risk assessment testing	6,316	6,368	(1)	7	9	
Cryosurgical systems	5,177	6,237	(17)	6	8	
Molecular collection systems	35,553	26,764	33	42	37	
Net product revenues	77,136	70,614	9	90	97	
Other	8,476	2,108	302	10	3	
Net revenues	\$ 85,612	\$ 72,722	18 %	100 %	100 %	

	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	% Change	2018	2017	% Change
	<b>OraQuick® Revenues</b>					
Domestic HIV	\$ 3,881	\$ 4,965	(22) %	\$ 7,293	\$ 8,779	(17) %
International HIV	7,397	2,025	265	13,067	4,669	180
Domestic OTC HIV	1,308	1,894	(31)	2,941	3,436	(14)
Net HIV revenues	12,586	8,884	42	23,301	16,884	38
Domestic HCV	1,730	2,382	(27)	3,358	4,091	(18)
International HCV	1,473	5,261	(72)	2,138	9,664	(78)
Net HCV revenues	3,203	7,643	(58)	5,496	13,755	(60)
Net product revenues	\$ 15,789	\$ 16,527	(4) %	\$ 28,797	\$ 30,639	(6) %

	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	% Change	2018	2017	% Change
	<b>Cryosurgical Systems Revenues</b>					
Domestic professional	\$ 1,068	\$ 1,445	(26) %	\$ 1,943	\$ 2,941	(34) %
International professional	264	243	9	413	373	11
Domestic OTC	295	347	(15)	584	632	(8)
International OTC	765	1,139	(33)	2,237	2,291	(2)
Net product revenues	\$ 2,392	\$ 3,174	(25) %	\$ 5,177	\$ 6,237	(17) %

	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	% Change	2018	2017	% Change
	<b>Molecular Collection Systems Revenues</b>					
Commercial Genomics	\$ 12,263	\$ 12,815	(4) %	\$ 26,519	\$ 20,072	32 %
Academic Genomics	3,105	2,399	29	5,937	5,083	17
Microbiome	1,824	843	116	3,097	1,609	92
Net product revenues	\$ 17,192	\$ 16,057	7 %	\$ 35,553	\$ 26,764	33 %



	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	% Change	2018	2017	% Change
<b>Other Revenues</b>						
Royalty income	\$ 2,092	\$ —	N/A	\$ 3,694	\$ —	N/A
BARDA funding	1,920	1,044	84 %	3,458	2,108	64 %
Charitable support reimbursement	795	—	N/A	1,324	—	N/A
Other revenues	<u>\$ 4,807</u>	<u>\$ 1,044</u>	360 %	<u>\$ 8,476</u>	<u>\$ 2,108</u>	302 %

### Condensed Consolidated Balance Sheets (Unaudited)

	June 30, 2018	December 31, 2017
<u>Assets</u>		
Cash and cash equivalents	\$ 71,069	\$ 72,869
Short-term investments	74,269	83,028
Accounts receivable, net	31,648	42,521
Inventories	20,599	19,343
Other current assets	4,637	4,144
Property and equipment, net	23,946	21,372
Intangible assets, net	6,622	8,223
Goodwill	19,231	20,083
Long-term investments	35,828	20,690
Other non-current assets	4,513	3,928
Total assets	<u>\$ 292,362</u>	<u>\$ 296,201</u>
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 9,659	\$ 10,228
Deferred revenue	1,621	1,314
Other current liabilities	9,837	20,695
Other non-current liabilities	4,474	3,932
Deferred income taxes	1,600	1,951
Stockholders' equity	265,171	258,081
Total liabilities and stockholders' equity	<u>\$ 292,362</u>	<u>\$ 296,201</u>

	Six Months Ended June 30,	
	2018	2017
<b>Additional Financial Data (Unaudited)</b>		
Capital expenditures	\$ 4,484	\$ 1,567
Depreciation and amortization	\$ 3,746	\$ 2,891
Stock-based compensation	\$ 11,262	\$ 3,631
Cash provided by operating activities	\$ 13,928	\$ 21,704

### Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2018 second quarter financial results, certain business developments and financial guidance for the third quarter of 2018, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Dr. Stephen S. Tang, President and Chief Executive Officer, and Roberto Cuca, Chief Financial 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 #4795505 or go to OraSure Technologies' web site, [www.orasure.com](http://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, August 15, 2018, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #4795505.

## **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 Second Quarter**  
**Analyst/Investor Conference Call**  
**August 8, 2018**

**Prepared Remarks of Dr. Stephen S. Tang and Roberto Cuca**

**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.

I am very pleased to report another successful quarter from both a financial and operational standpoint.

Our performance for the second quarter was strong and exceeded expectations on both the top and bottom lines. The two key drivers of growth, molecular collections and our HIV self-test franchise, continue to demonstrate consistent strength and momentum.

Consolidated net revenues for the quarter were \$43.6 million, a 9% increase from the year-ago period. For the first six months of this year, our revenues grew 18% over a highly successful 2017. Some specific highlights from the quarter include the following:

- Net molecular revenues increased 7% for the second quarter and 33% for the six month period.
  - International HIV sales grew 265% and 180% for the quarter and six months ended June 30, 2018, respectively. This growth was driven primarily by our HIV self-test.
  - We reported consolidated net income of \$4.1 million, or \$0.07 per share, for the quarter despite incurring \$2.2 million, or \$0.04 per share, in non-recurring transition charges associated with the executive management changes occurring earlier this year.
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- We ended Q2 with over \$181 million in cash and cash equivalents on our balance sheet.

We also completed an important initiative during the second quarter. As explained in prior calls, we undertook a thorough review of our business strategy. This process started while I was still Chairman of the Board of Directors and continued after I became CEO in April. We reviewed the findings with our Board in July and the Board enthusiastically approved the strategy. Later on in the call, I will share with you several key insights from the strategy review.

As you know, Roberto Cuca's appointment as Chief Financial Officer became effective during the second quarter. He has been with the Company a little more than two months now and this is the first earnings call since he became the Company's CFO. We couldn't be more pleased to have Roberto officially join our senior management team.

So with that, let me now turn the call over to Roberto for a detailed financial review of the quarter. After that, I will provide some business updates and then we will open the call for your questions.

### **Second Quarter 2018 Financial Results – Roberto Cuca**

Thanks Steve, and good afternoon everyone.

As Steve mentioned, OraSure continued its strong performance in 2018 with our second quarter revenue and EPS handily exceeding the guidance we issued at our last earnings call. So let's review what drove those numbers to be higher than what we anticipated and shared with the investment community.

Our second quarter net revenues of \$43.6 million exceeded the top end of our guidance range by over a million dollars. This variance was driven largely by royalty income and funding from the U.S. Biomedical Advanced Research Development Authority ("BARDA") that both exceeded our May estimates. The royalty income was less easily forecasted because this was only the second quarter in which we received it, and the BARDA funding simply reflected a greater uptick in R&D productivity than we had achieved in the past. Because neither of these non-product revenue items has associated cost of goods sold, their benefit falls directly to the bottom line and contributed to our EPS of \$0.07 per share outperforming our guidance of approximately \$0.03 per

share. Moreover, we saw some savings in the second quarter's operating expenses as we adjusted time lines in executing various research projects and marketing programs. These programs and expenses were consciously delayed until the completion and read-out to the Board of our strategic review in order to align spending with the approved strategy beginning in the second half of this year.

I'll now go into more detail on our Q2 financial results.

### **Revenues – Roberto Cuca**

Our second quarter consolidated net revenues increased 9% to \$43.6 million, compared to \$40.2 million reported in the second quarter of 2017. Our consolidated net product revenues decreased 1% to \$38.8 million compared to the prior-year period. Higher sales of our OraQuick® HIV self-test and molecular collections products were able to offset declines in other product lines.

Our molecular revenues rose 7% to \$17.2 million in the second quarter of 2018 compared to \$16.1 million in the second quarter of 2017. Sales of our products to academic customers increased 29% to \$3.1 million largely due to increased shipments for a study on autism combined with customer ordering patterns. Sales of our products to commercial customers decreased 4% to \$12.3 million, largely due to the loss of a customer that switched to a different extraction technology. Microbiome sales continued to expand, increasing 116% to \$1.8 million in the second quarter of 2018 as compared to the second quarter of 2017.

International HIV sales increased 265% to \$7.4 million from \$2.0 million in the second quarter of 2017 due to higher sales of our OraQuick® HIV self-test into Africa. 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 and a majority of our volume this quarter came from countries outside of the UNITAID/Population Services International (or "PSI") Self-Testing Africa (or "STAR") initiative, demonstrating wider implementation of country-wide pilots and initiatives. Product revenue during the second quarter of 2018 included approximately \$1.7 million of support payments associated with the Gates agreement.

Domestic professional HIV sales continue to decline and decreased 22% to \$3.9 million in the second quarter of 2018, compared to \$5.0 million in the second quarter of 2017, due to previously described market factors.

International HCV sales in the second quarter of 2018 decreased 72% to \$1.5 million from \$5.3 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 and the loss of a multi-national humanitarian organization customer who switched to a competing product due to cost. These losses were partially offset by an increase in sales into Asia and Africa as a result of the implementation of new programs or studies. Domestic HCV sales decreased 27% in the second quarter of 2018 to \$1.7 million from \$2.4 million in the prior-year period, primarily due to the non-renewal or delay of grant funding and the discontinuation of a large NGO testing program.

Sales of our cryosurgical systems product decreased 25% in the second quarter of 2018 to \$2.4 million compared to \$3.2 million in the second quarter of 2017. Sales of our domestic Histofreezer® products sold to physician offices decreased 26% to \$1.1 million primarily due to the timing of orders placed by our distributors and competitive losses. Sales of our international OTC cryosurgical product decreased 33% to \$765,000 in the second quarter of 2018 compared to \$1.1 million in the second quarter of 2017 primarily due to lower sales in Latin America.

Other revenues were \$4.8 million in the current quarter, representing \$2.1 million of royalty income associated with a litigation settlement agreement, \$1.9 million of funding from BARDA for the development of our Ebola and Zika products, and \$795,000 of cost reimbursement under our charitable support agreement with the Gates Foundation.

### **Gross Profit – Roberto Cuca**

Gross profit percentage for the second quarter of 2018 was 59% compared to 63% reported for the second quarter of 2017. Gross profit percentage for the current quarter decreased versus the prior year primarily due to product mix, partially offset by the aforementioned increase in Other Revenues.

Gross profit percentage increased versus the immediately preceding quarter, and we expect this trajectory to continue through the second half of the year based on our forecasted sales mix and our expectations regarding foreign currency exchange rates and projected scrap and spoilage.

### **Operating Expenses – Roberto Cuca**

Our consolidated operating expenses for the second quarter of 2018 were \$20.3 million compared to \$18.6 million in the comparable period of 2017. This increase was largely due to the inclusion in Q2 2018 of \$2.2 million of transition costs associated with the retirement of our former CFO. Q2 2018 also includes higher spending on our research and development projects partially offset by lower staffing costs.

### **Income Taxes – Roberto Cuca**

Income tax expense was \$2.2 million in the second quarter of 2018 compared to \$1.6 million in the same period last year and consists entirely of Canadian taxes due and is reflective of the higher pre-tax earnings generated by our Canadian subsidiary.

### **Net Income – Roberto Cuca**

We reported net income of \$4.1 million, or \$0.07 per share, for Q2 2018, compared to net income of \$5.4 million, or \$0.09 per share, for Q2 2017. The transition costs previously described approximated \$0.04 per share in the second quarter of 2018 and primarily reflect non-cash stock compensation charges.

### **Cash Flow from Operations and Liquidity – Roberto Cuca**

We continue to maintain a solid cash and liquidity position. Our cash and investments balance at June 30, 2018 was \$181.2 million compared to \$176.6 million at December 31, 2017. Cash generated by operating activities during the first six months of 2018 was \$13.9 million compared to \$21.7 million in the same period of 2017 which included a \$12.5 million litigation settlement.

### **Third Quarter 2018 Consolidated Financial Guidance – Roberto Cuca**

Turning to guidance for the third quarter of 2018, we are projecting revenues of \$44.0 million to \$45.5 million and consolidated net income of \$0.10 to \$0.12 per share.

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



## **Business Update – Steve Tang**

Thanks Roberto.

## **Molecular Business Update – Steve Tang**

### **Molecular**

As discussed earlier, our molecular revenues in Q2 grew 7% over the prior year quarter, which is impressive given the very difficult comparison resulting from our strong performance in 2017. The consumer genomics market, which includes our largest customer, experienced significant growth last year. Demand for our products during the second quarter of 2017 increased dramatically and has generally remained at a much higher level than in prior periods. In addition, we are starting to see more identifiable trends in purchasing patterns. There is a noticeable uptick in seasonal consumer genomics demand tied primarily to annual retail promotional events and the holiday shopping season. As a result, we expect to see a more variable progression of revenue from quarter to quarter. Given that, it is best to view our progress on an annual basis as quarterly progressions can vary. Importantly, we still expect to see continued growth in our molecular business in 2018 with the growth rate for the full year likely to be in the double digit range when compared to 2017.

Our molecular business remains very strong and we are seeing growth from both new customer acquisitions and sales to existing customers. About 11% of Q2 orders came from more than 100 first time purchasers and 18 of our top 20 customers showed solid growth on a trailing 12-month basis. One of our priorities has been to negotiate multi-year supply agreements with as many customers as possible. We have made great progress in these efforts and now have 7 of our top 20 customers purchasing products under multi-year arrangements. The use of multi-year agreements should aid our ability to forecast revenues going forward.

We now have over 300 accounts purchasing both genomics and microbiome products including three of our top 20 customers. We continue to believe this type of synergy between product lines is a very positive trend for our business and is likely to increase in the foreseeable future. We also acquired five new customers for our GenoFIND™ customization and fulfillment services. So now, half of our top 20 customers use these services. We believe our GenoFIND™ services

provides significant value to our customers by speeding the time to market and improving the overall quality of their offerings.

### **Genomics**

On the genomics side, we had a very good quarter in that we acquired 22 new commercial accounts, seven of which are test service providers. We also reported strong revenue growth of 29% over the prior year in our academic business, which represents 10% sequential growth from the first quarter of 2018. The second quarter represented our best performance in the Asia Pacific market with over \$1.0 million in revenue. This represents a 44% growth over the second quarter of last year. This type of growth in the Asia Pacific market is expected to continue throughout the remainder of this year.

One of the more important transactions we completed during the quarter was a multi-year supply agreement with Invitae for our Oragene®• Dx product. Invitae is a genetic testing company that serves researchers, medical professionals and the pharmaceutical industry. Initial orders under this new agreement began shipping in the second quarter. We also closed an agreement with Embark Vet for the purchase of our PERFORMAgene product for the collection of saliva from canines to provide breed, health and traits information through DNA testing. We are excited about the potential of the canine testing market and believe it can have a positive impact on our business. This area represents an interesting opportunity as pet owners are willing to spend money on the health of their pets and often have more than one dog over the course of their lifetime.

### **Microbiome**

Our microbiome business posted its best quarter ever with Q2 sales up 116% compared to the prior year period and up 43% sequentially over Q1 of this year. This is our fourth consecutive quarter of sequential growth and the ninth out of the past ten quarters where we have posted year-over-year growth.

The overall health of this business is apparent by the increasing demand for both our collection products and service offerings, along with the growing geographic diversity of our revenue with

customers in North America, Europe, the Middle East and Asia Pacific. The growth in microbiome sales was largely driven by significant device usage in the direct-to-consumer microbiome market where we saw 176% growth from the second quarter of 2017. We also saw increased demand for both devices and lab services from boutique wellness companies and pharmaceutical companies in support of microbiome-focused clinical trials. With respect to services, we are seeing an increasing number of samples processed from the use of our OMNIgene® collection device, especially by repeat customers. Importantly, five microbiome purchasers have now moved into our top 20 molecular accounts and all of these purchasers are commercial entities. Of our top 20 microbiome customers purchasing in the second quarter, 11 were commercial customers and three were purchasing both collection devices and lab services.

Of our top 20 microbiome customers, five use our products to enable service offerings to their customers, six are undertaking clinical trials in support of therapeutic and/or diagnostic development and the remainder are engaged in academic research. So our product offerings are now meeting an increasingly broad range of customer needs. What all of these customers have in common is that they are pursuing actionable insights about human health by analyzing the microbiome, and they value the products and services we provide.

We are confident that microbiome will become a substantial contributor to our top line in the coming years. Moreover, this business could easily outpace genomic testing volumes one day due to the multiple samples that need to be collected from the same individual given the constantly changing organisms found in the microbiome. For this reason, we are very excited about this market opportunity.

### **Infectious Disease Testing – Steve Tang**

#### **HIV Business**

Turning to infectious disease, our global HIV business delivered a strong performance with revenues growing 42% for the second quarter compared to the prior year period. The main reason for this was our international business, which was up 265% for the quarter.

The primary growth driver was our HIV self-test business. During the second quarter, we shipped 2.1 million self-tests, a 61% increase over the first quarter of this year. As you know, over the past several periods much of the demand for this product has come from the STAR program. To date, we have shipped approximately 2.7 million out of the 4.0 million tests planned for Phase II of the STAR program.

In addition to shipments under the STAR program, we are beginning to see significant uptake in various public health sectors in a number of African countries. Examples include pilot programs designed to demonstrate the effectiveness of HIV self-testing, programs targeting the use of our self-test in various public sector channels intended to serve marginalized populations, early adoption programs in various countries, and targeted campaigns intended to raise awareness about HIV self-testing.

An important growth driver for our HIV self-test is the Charitable Support Agreement with the Gates Foundation. This agreement covers 50 countries and the support payments allow us to offer more favorable pricing which is stimulating demand for our test. To date, between initial interest, pilots and scale-up activities, we are now serving well over 40 countries in Sub-Saharan Africa, West Africa, Asia, Central Asia and Latin America with our self-testing product. It is important to remember that a majority of our self-testing revenue came from non-STAR purchasers during the second quarter. As discussed in prior calls, we are also continuing to pursue opportunities in the pharmacy market as an additional market channel in many countries, even though these sales are not covered by the Gates Agreement.

We continue to believe HIV self-testing represents a significant growth opportunity for OraSure over the next several years. The World Health Organization and UNITAID recently issued a global market and technology landscape report on rapid HIV self testing. In addition to recognizing the importance of HIV self testing to reach people at risk who may not otherwise get tested, the report stated that the available procurement forecasts suggest significant growth in the global market for HIV self testing in both the public and private sectors up to and beyond 2020. The report further states that the numbers are expected to increase from about 1 million tests in 2017 to an estimated 16.4 million tests by the end of 2020. Obviously, these are projections, but they provide further evidence supporting our optimistic outlook for this part of our business.

## HCV Business

As you heard earlier, international HCV revenues for Q2 declined from the prior year quarter, primarily as the result of the non-renewal of a large foreign government supply contract and the loss of a large international NGO customer as a result of price competition. Our domestic business was also down compared to last year, primarily due to grant funding delays and a large NGO discontinuing its HCV screening efforts.

Nevertheless, we remain confident in our overall HCV business and believe it will continue to be a source of future growth. Interest in HCV testing remains high and we are seeing the potential for increased available funding for testing programs in the near future.

Domestically, we are seeing funding support from pharmaceutical companies that are offering testing grants. For example, Gilead recently announced a grant program to support the elimination of HCV in HIV-infected and high-risk HIV-uninfected populations. The program budget is \$3.0 million with awards expected to be made in December 2018. We are also seeing legislative initiatives moving through Congress that should improve available funding for HCV test programs. The recent fiscal 2018 spending bill passed in March included improved funding for Federal programs that support HIV and HCV testing. An example is a 15% funding increase received by the Division of Viral Hepatitis at the Centers for Disease Control and Prevention, in order to bolster the activities of state and local health departments. We are also seeing efforts by Congress to address the opioid epidemic, which we expect to include HCV testing initiatives. Finally, Congress is advancing a bill to establish a rapid Hepatitis C outreach testing program with veteran service organizations and the Veterans Administration (“VA”). In its current form, this bill would mandate roughly 350,000 rapid outreach tests to reach Vietnam era veterans outside of the VA system in an attempt to gauge feasibility for a national program and to establish a prevalence number for this community. These types of developments are obviously positive and we believe supports the view that funding for HCV testing may improve in future periods.

On the international front, interest in HCV testing and treatment continues to expand, largely as a result of the availability of low-cost HCV therapies. We are seeing a number of opportunities in various geographies around the world. An example is the growth in sales in both Asia and Africa where our HCV revenues increased 138% in Q2 compared to 2017. This reflects an increase in

demand from existing customers, favorable timing of orders and new customers that purchased our product. We will continue to pursue these various international opportunities.

### Operations Update – Steve Tang

Turning to operations, as a reminder from prior calls, over the past year or so we have focused much effort on balancing and expanding our production capacity. We have made good progress not only here in Bethlehem, but also in Canada and at our Thailand supplier. We are confident that we are making the changes needed to meet the future demand for our products.

### Strategy Update

The final area I will address today is our recently completed long-term strategy review. This review included an assessment of market trends and competition, an inventory of core capabilities and modeling of several potential business strategies. This work was shared with and endorsed by our Board last month. Today, I would like to share a few key themes from that work, with the caveat that some of our work must remain confidential due to competitive reasons.

First, and most importantly, we see significant growth potential in our core molecular and infectious disease businesses. Several marketplace trends, including the growth in consumer genomics, the high and growing interest in microbiome and systems biology, and the ongoing global focus and funding for the eradication of HIV and HCV, all signal opportunities for these businesses with appropriate investment. The overarching principle underlying our strategy is to maximize the growth potential of our assets and core strengths. We will achieve that by making both internal and external investments targeting the acquisition of other companies and technologies. In our external business development activities, we may consider the acquisition of earlier stage entities that are serving less developed markets, in addition to more established revenue producing entities that would be accretive. I expect the specific outcome of this updated strategy will become more evident in the coming months. However, in the meantime I can share some future overarching themes with you now.

On the molecular side, our core saliva genomics business remains central to our overall molecular strategy and we intend to invest and grow this key business. We also intend to expand our

product portfolio with the introduction of new products that build on our core strengths in the areas of multi-omics and systems biology. This focus will apply to both our genomics and microbiome businesses. We will also look to further enhance our end-to-end service offerings, primarily in the microbiome area, through customization, fulfillment, laboratory and analytics services.

In infectious disease, we will continue to focus on expanding our core HIV and HCV franchises globally through innovative testing programs, new registrations and collaborations with our customers and other stakeholders. Additionally, we intend to protect and grow our HIV professional and self-testing businesses through product improvements and enhanced performance claims. Beyond HIV and HCV, we intend to leverage our strengths and relationships with existing customers by expanding our portfolio with products synergistic with our existing products.

We are very pleased to have completed our detailed strategy review and we can now focus our attention on implementation. I look forward to updating you in the coming months on our progress against these strategic goals.

**Conclusion – Steve Tang**

So, in conclusion, this is an exciting time for OraSure. The Company is well positioned and continues to deliver strong financial results. That combined with a solid balance sheet affords us the opportunity to enhance our growth potential.

We have a number of exciting organic growth opportunities before us, many of which are still in the early days of their potential, especially the microbiome. We also have the infrastructure in place to screen, evaluate and acquire complementary external technologies or companies on a timely basis. Our new head of business development is busy these days, to say the least. Having completed our strategic development work, our priorities are clear and we will endeavor to build on our core strengths in order to deepen the bond with our existing customers and build relationships with new ones and other stakeholders. We will do that by putting our strong balance sheet to work while remaining selective about what we pursue and the valuation we will pay.

More than four months ago I became CEO and have gotten to know the Company on a deeper level. I can say without hesitation, I'm even more impressed by the strength of our management team, the quality of our products and the outlook for OraSure. I will continue to advance innovation here at the Company because I believe that it is crucial to our continued growth. I intend to do this by prioritizing efforts to foster a culture that empowers our management team to innovate and then rewards them for their success. I am confident that we have the right strategy in place and the other necessary pieces to take the Company to the next level.

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

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**[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.