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): November 7, 2018

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

Delaware	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

220 East First Street **Bethlehem, Pennsylvania**	**18015-1360**
(Address of Principal Executive Offices)	**(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 November 7, 2018, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended September 30, 2018 and financial guidance for the fourth 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 November 7, 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 September 30, 2018, provided financial guidance for the fourth 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

Exhibit Number	Description
99.1	Press Release, dated November 7, 2018, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2018 and financial guidance for the fourth quarter of 2018.
99.2	Prepared Remarks of Dr. Stephen S. Tang and Roberto Cuca for OraSure Technologies, Inc. Third Quarter 2018 Analyst/ Investor Conference Call Held November 7, 2018.

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: November 7, 2018

By: */s/ Jack E. Jerrett*
Jack E. Jerrett
Senior Vice President, General Counsel and Secretary

Exhibit 99.1

OraSure Technologies, Inc.

Company Contact:

Roberto Cuca
Chief Financial Officer
610-882-1820
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www.orasure.com

OraSure Announces 2018 Third Quarter Financial Results

BETHLEHEM, PA – November 7, 2018 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its financial results for the three and nine months ended September 30, 2018.

Financial Highlights

- Net revenues for the third quarter of 2018 were $45.9 million, an 8% increase from the third quarter of 2017. Net product revenues were $43.5 million, representing a 6% increase from the third quarter of 2017.
- Net revenues for the nine months ended September 30, 2018 were $131.5 million, a 14% increase from the comparable period of 2017. Net product revenues for the first nine months of 2018 were $120.6 million, representing an 8% increase over the first nine months of 2017.
- Net molecular collection systems revenues were $25.5 million during the third quarter of 2018, which represents a 37% increase over the third quarter of 2017. Net molecular collection systems revenues during the nine months ended September 30, 2018 were $61.0 million, a 35% increase from the comparable period of 2017.
- International sales of the Company's OraQuick® HIV products of $4.3 million increased 41% compared to the third quarter of 2017. For the first nine months of 2018, international sales of the Company's OraQuick® HIV products of $17.4 million increased 125% compared to the first nine 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 $1.2 million decreased 81% for the third quarter of 2018 compared to the third quarter of 2017. International sales of the Company's OraQuick® HCV product of $3.3 million for the first nine months of 2018 decreased 79% from the comparable period of 2017. These declines were primarily the 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 $4.7 million of sales during the third quarter of 2017 and $11.6 million during the first nine months of 2017.

- Net income for the third quarter of 2018 was $8.1 million, or $0.13 per share on a fully diluted basis, which compares to net income of $5.8 million, or $0.09 per share on a fully diluted basis, for the third quarter of 2017. Net income for the nine months ended September 30, 2018 was $10.1 million, or $0.16 per share on a fully diluted basis, which compares to net income of $23.6 million, or $0.39 per share on a fully diluted basis, for the comparable period of 2017. Net income for the year-to-date period included $8.6 million of transition costs associated with the retirement of the Company's former Chief Executive Officer and Chief Financial Officer and the hiring of their successors. These transition costs approximated $0.14 per share for the nine month period ended September 30, 2018 and primarily consisted of non-cash stock compensation charges. Net income for the nine months ended September 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 $0.15 per share on a fully diluted after-tax basis in that period.
- Cash and investments totaled $192.1 million at September 30, 2018.

"Our solid third quarter performance was driven by strong growth in our molecular collections and international HIV Self-Test businesses," said Dr. Stephen S. Tang, President and Chief Executive Officer of OraSure Technologies. "An abundance of opportunity remains in the growth drivers for our business and capitalizing on these opportunities will remain a priority for our management team. In addition, as we execute against our strategic goals, we continue to actively explore ways to leverage our strong balance sheet to further enhance our growth. We are very well positioned to compete in our key markets and expect to deliver a strong end to the year."

Financial Results

Net product revenues for the third quarter of 2018 increased 6% from 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 Company's OraQuick® HCV test and lower domestic sales of the professional OraQuick® HIV test.

Net product revenues for the first nine months of 2018 increased 8% 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 nine months ended September 30, 2018 included $840,000 and $3.6 million, respectively, of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation").

Other revenues were $2.4 million and $1.2 million for the third quarter of 2018 and 2017, respectively. Other revenues were $10.9 million and $3.3 million for the first nine months of 2018 and 2017, respectively. Other revenues in the third quarter of 2018 included royalty income of $1.1 million associated with a litigation settlement agreement, Ebola and Zika-related funding received from the U.S. Biomedical Advanced Research Development Authority ("BARDA") of $1.1 million and cost reimbursement under the Company's charitable support agreement with the Gates Foundation of $220,000, which is separate from the support payments mentioned above. Other revenues in the first nine months of 2018 included royalty income associated with the litigation settlement of $4.8 million, BARDA funding of $4.5 million, and cost reimbursement from the Gates Foundation of $1.5 million. Other revenues in the third quarter of 2017 included $939,000 of BARDA funding and $218,000 of cost reimbursement. Revenues in the first nine months of 2017 consisted of $3.0 million of BARDA funding and $218,000 of cost reimbursement.

Gross profit percentage was 62% and 60% for the three and nine months ended September 30, 2018, respectively, and 58% and 61% for the three and nine months ended September 30, 2017, respectively. Gross profit percentage in the current quarter benefited from lower manufacturing costs associated with the Company's Oragene® product, lower royalty expense, and the increase in other revenues. The decline in gross profit percentage for the first nine months of 2018 was primarily due to an increase in lower profit percentage product sales partially offset by the increase in other revenues.

Operating expenses increased modestly to $17.7 million during the third quarter of 2018 compared to $17.3 million in the third quarter of 2017. For the nine months ended September 30, 2018, operating expenses were $63.0 million, an increase of $22.6 million from the $40.4 million reported for the nine months ended September 30, 2017. The third quarter increase was largely due to higher research and development spending and higher commissions and consulting costs, partially offset by lower staffing expenses. The increase for the nine-month period was largely due to the inclusion of $8.6 million of management transition costs and higher spending on research and development and sales and marketing during the period and 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 nine months of 2017. There was no similar gain recorded during the first nine months of 2018.

The Company reported operating income of $10.9 million in the third quarter of 2018, compared to operating income of $7.3 million in the third quarter of 2017. Operating income for the nine months ended September 30, 2018 was $15.9 million compared $30.1 million for the nine months ended September 30, 2017.

Income tax expense was $3.3 million during the third quarter of 2018 compared to $1.7 million recorded in the third quarter of 2017. Income tax expense was $7.5 million during the first nine months of 2018 compared to $7.1 million during the first nine 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 nine 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 $192.1 million at September 30, 2018, compared to $176.6 million at December 31, 2017. For the nine months ended September 30, 2018, the Company generated $24.8 million in cash from operations.

Fourth Quarter 2018 Outlook

The Company expects net revenues to range from $46.5 million to $48.0 million - which implies full year 2018 revenue growth of 7% over 2017 - and is projecting net income of $0.09 to $0.11 per share for the fourth quarter of 2018.

Financial Data

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

Unaudited

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Results of Operations				
Net revenues	$ 45,885	$ 42,314	$ 131,497	$ 115,036
Cost of products sold	17,340	17,670	52,590	44,605
Gross profit	28,545	24,644	78,907	70,431
Operating expenses:				
Research and development	3,855	3,228	12,191	9,536
Sales and marketing	7,304	7,162	22,232	21,541
General and administrative	6,529	6,935	28,567	21,777
Gain on litigation settlement	—	—	—	(12,500)
Total operating expenses	17,688	17,325	62,990	40,354
Operating income	10,857	7,319	15,917	30,077
Other income	510	113	1,658	676
Income before income taxes	11,367	7,432	17,575	30,753
Income tax expense	3,271	1,669	7,477	7,121
Net income	$ 8,096	$ 5,763	$ 10,098	$ 23,632
Earnings per share:				
Basic	$ 0.13	$ 0.10	$ 0.17	$ 0.40
Diluted	$ 0.13	$ 0.09	$ 0.16	$ 0.39
Weighted average shares:				
Basic	61,208	60,090	61,059	58,511
Diluted	62,606	62,172	62,539	60,569

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2018	2017	% Change	2018	2017
Market					
Infectious disease testing	$ 12,417	$ 16,577	(25) %	27 %	39 %
Risk assessment testing	2,842	3,149	(10)	6	7
Cryosurgical systems	2,696	2,879	(6)	6	7
Molecular collection systems	25,495	18,552	37	56	44
Net product revenues	43,450	41,157	6	95	97
Other	2,435	1,157	110	5	3
Net revenues	$ 45,885	$ 42,314	8 %	100 %	100 %

	Nine Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2018	2017	% Change	2018	2017
Market					
Infectious disease testing	$ 42,506	$ 47,822	(11) %	33 %	42 %
Risk assessment testing	9,159	9,517	(4)	7	8
Cryosurgical systems	7,874	9,116	(14)	6	8
Molecular collection systems	61,047	45,316	35	46	39
Net product revenues	120,586	111,771	8	92	97
Other	10,911	3,265	234	8	3
Net revenues	$ 131,497	$ 115,036	14 %	100 %	100 %

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
OraQuick® Revenues						
Domestic HIV	$ 2,749	$ 3,622	(24) %	$ 10,043	$ 12,401	(19) %
International HIV	4,328	3,069	41	17,395	7,738	125
Domestic OTC HIV	1,706	1,515	13	4,646	4,951	(6)
Net HIV revenues	8,783	8,206	7	32,084	25,090	28
Domestic HCV	2,066	1,889	9	5,424	5,980	(9)
International HCV	1,168	6,154	(81)	3,306	15,817	(79)
Net HCV revenues	3,234	8,043	(60)	8,730	21,797	(60)
Net product revenues	$ 12,017	$ 16,249	(26) %	$ 40,814	$ 46,887	(13) %

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Cryosurgical Systems Revenues						
Domestic professional	$ 1,349	$ 1,426	(5) %	$ 3,292	$ 4,368	(25) %
International professional	220	179	23	633	552	15
Domestic OTC	333	325	2	917	957	(4)
International OTC	794	949	(16)	3,032	3,239	(6)
Net product revenues	$ 2,696	$ 2,879	(6) %	$ 7,874	$ 9,116	(14) %

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Molecular Collection Systems Revenues						
Commercial Genomics	$ 21,505	$ 14,544	48 %	$ 48,024	$ 34,615	39 %
Academic Genomics	2,299	3,232	(29)	8,236	8,316	(1)
Microbiome	1,691	776	118	4,787	2,385	101
Net product revenues	$ 25,495	$ 18,552	37 %	$ 61,047	$ 45,316	35 %

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Other Revenues						
Royalty income	$ 1,132	$ —	N/A	$ 4,827	$ —	N/A
BARDA funding	1,083	939	15 %	4,540	3,047	49 %
Charitable support reimbursement	220	218	1	1,544	218	608
Other revenues	$ 2,435	$ 1,157	110 %	$ 10,911	$ 3,265	234 %

Condensed Consolidated Balance Sheets (Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 78,146	$ 72,869
Short-term investments	72,192	83,028
Accounts receivable, net	33,284	42,521
Inventories	19,899	19,343
Other current assets	4,376	4,144
Property and equipment, net	24,395	21,372
Intangible assets, net	6,053	8,223
Goodwill	19,568	20,083
Long-term investments	41,788	20,690
Other non-current assets	4,606	3,928
Total assets	$ 304,307	$ 296,201
Liabilities and Stockholders' Equity		
Accounts payable	$ 8,064	$ 10,228
Deferred revenue	3,106	1,314
Other current liabilities	10,250	20,695
Other non-current liabilities	4,649	3,932
Deferred income taxes	1,484	1,951
Stockholders' equity	276,754	258,081
Total liabilities and stockholders' equity	$ 304,307	$ 296,201

	Nine Months Ended September 30,	
Additional Financial Data (Unaudited)	2018	2017
Capital expenditures	$ 5,938	$ 3,462
Depreciation and amortization	$ 5,588	$ 4,589
Stock-based compensation	$ 12,526	$ 5,213
Cash provided by operating activities	$ 24,807	$ 30,361

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2018 third quarter financial results, certain business developments and financial guidance for the fourth 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 #8850417 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, November 14, 2018, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #8850417.

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 or other 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.

# # #

Exhibit 99.2

OraSure Technologies, Inc.

2018 Third Quarter

Analyst/Investor Conference Call

November 7, 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 Jeanne. Good afternoon everyone and welcome to our call.

I am pleased to report that our third quarter results were strong, driven by continued strength from our molecular collections and HIV Self-Test businesses.

Net revenues for the quarter increased 8% from the year-ago period and rose 14% during the first nine months of this year. And that was on top of a very strong 2017 performance. Some specific highlights include the following:

- Net molecular revenues increased 37% for the third quarter and 35% for the nine month period.
- International HIV sales grew 41% and 125% for the quarter and nine months ended September 30, 2018, respectively. This growth was primarily the result of higher sales of our HIV Self-Test.
- We reported quarterly net income of $8.1 million and we ended the third quarter with over $192 million in cash and cash equivalents on our balance sheet.

I would also point out that not only was Q3 a success from a financial performance standpoint, but we also advanced on the goals we adopted from our strategic review. That type of important progress cannot always be detailed in real time due to competitive and other reasons, but I can say

that we are actively working to implement our new strategy and expect that these efforts will further enhance our growth potential.

Starting with today's call, we are taking a somewhat different approach to our prepared marks, in part based on your feedback. Our prepared comments will focus more on the drivers of our current and future growth and we will spend more time discussing key factors that will impact the business going forward. We have also received feedback concerning the length of our prepared remarks and believe that these changes will help streamline the process. As always, we will gladly take your questions on any aspect of the business. For more detailed information about our quarterly performance, I would refer you to our earnings release and the 10-Q when it is filed in the next day or so.

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

Third Quarter 2018 Financial Results – Roberto Cuca

Thanks Steve, and good afternoon everyone.

As Steve mentioned, we are very pleased with our results for the third quarter of 2018 as OraSure continues progress towards a very successful year.

Our third quarter net revenues increased 8% to $45.9 million, compared to $42.3 million reported in the third quarter of 2017. Our net product revenues increased 6% to $43.5 million compared to the prior-year period. Higher sales of our molecular collections products and OraQuick® HIV Self-Test more than offset declines in other product lines.

Our molecular revenues rose 37% to $25.5 million in the third quarter of 2018 compared to $18.6 million in the third quarter of 2017. Sales of our genomic products to commercial customers increased 48% to $21.5 million, largely due to higher customer demand, primarily from a large consumer genomics customer. Microbiome sales also continued to expand, growing 118% to $1.7 million in the third quarter of 2018 from the same period last year.

International HIV sales increased 41% to $4.3 million from $3.1 million in the third quarter of 2017 due to higher sales of our OraQuick® HIV Self-Test into Africa. A majority of our volume this quarter came from countries outside of the UNITAID/Population Services International Self-Testing Africa (“STAR”) initiative, demonstrating continuing growth of country-wide pilots and initiatives. Tests shipped to African countries both in and outside the STAR initiative during the quarter were subject to support payments under our charitable support agreement with the Bill and Melinda Gates Foundation.

Domestic HIV sales decreased 13% to $4.5 million in the third quarter of 2018, compared to $5.1 million in the third quarter of 2017.

International HCV sales in the third quarter of 2018 decreased 81% to $1.2 million from $6.2 million in the same period of 2017, primarily due to the non-renewal of a foreign government supply contract for a country-wide HCV eradication program. Domestic HCV sales increased 9% in the third quarter of 2018 to $2.1 million from $1.9 million in the prior-year period.

Other revenues were $2.4 million in the current quarter, compared to $1.2 million in the prior year. The increase is largely due to royalty income associated with a litigation settlement agreement.

Gross profit percentage for the third quarter of 2018 was 62% compared to 58% reported for the third quarter of 2017. Gross profit percentage for the current quarter benefitted from lower manufacturing costs associated with our Oragene® product, lower royalty expense and the increase in Other Revenues.

Our operating expenses for the third quarter of 2018 were $17.7 million compared to $17.3 million in the comparable period of 2017. This increase was largely due to higher spending on our research and development projects and increased commissions and consulting costs, partially offset by a decrease in staffing expenses.

Income tax expense was $3.3 million in the third quarter of 2018 compared to $1.7 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.

We reported net income of $8.1 million, or $0.13 per share, for Q3 2018, compared to net income of $5.8 million, or $0.09 per share, for Q3 2017.

We continue to maintain a solid cash and liquidity position. Our cash and investments balance at September 30, 2018 was $192.1 million compared to $176.6 million at December 31, 2017. Cash generated by operating activities during the first nine months of 2018 was $24.8 million compared to $30.4 million in the same period of 2017 which included a $12.5 million litigation settlement.

Turning to guidance for the fourth quarter of 2018, we are projecting revenues of $46.5 to $48.0 million and net income of $0.09 to $0.11 per share. Our revenue expectation implies full year 2018 revenue growth from 2017 of 7% and sequential growth from the third quarter of 1% to 5%. As we've described previously, last year some of our consumer genomics customers experienced unexpectedly positive responsiveness to their winter holiday promotional activities and discounting with the result that they purchased inventory for the holidays deeper into the fourth quarter than they otherwise might have. Based on recent discussions, we understand that they are better prepared for this year's holiday season and that their purchases will be more evenly distributed between the third and fourth quarters. As a result, we do not anticipate experiencing as substantial a revenue progression from the third to fourth quarters of this year as we saw last year.

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

Business Update – Steve Tang

Thanks Roberto.

Let me start with our molecular collections business.

Molecular Business Update – Steve Tang

Our Q3 molecular revenues grew 48% sequentially over the previous period and, as Roberto noted, 37% over the prior year quarter. Continued strong sales in the consumer genomics market was the primary growth driver. This reflects the seasonal variability of our molecular revenues that I mentioned in our last earnings call, as our customers purchase in preparation for annual retail

promotional events and the holiday shopping season. As a reminder, this large component of our revenue tracks like a consumer product rather than a typical healthcare diagnostic test and this should be factored in when developing quarterly expectations. It is best to view the growth of the consumer genomics business on an annual basis since the quarterly progressions may vary.

Our overall molecular performance reflects a consistent level of new business coming from first time purchasers. Q3 was the second consecutive quarter with over 100 new customers for this segment. There was also continued strength from our top 20 customers with 19 of 20 showing double or triple digit growth in the trailing 12-month period as compared to the previous 12-month period. This strong performance from both new and existing molecular customers further supports our expectation that the full-year growth rate for 2018 will be solidly in the double digit range.

Several international markets have also shown growth in Q3 versus the prior year period. Specific markets include the Asia Pacific region, with growth of 12% over Q3 2017, and the Middle East and North Africa, which collectively increased 219% over Q3 2017. We believe that each of these regions could continue to show significant growth as our products achieve greater penetration and brand awareness.

Genomics

In the genomics part of our business, sales to commercial customers drove 75% sequential revenue growth over the previous quarter and 48% growth over Q3 of the prior year. We won 29 new commercial accounts during Q3, and a total of 61 new accounts during the first 9 months of 2018 compared to 43 for the entire calendar year last year. Many of these new accounts are pharmacogenetic testing providers or customers in the health and wellness space. A positive sign for us is that several customers are standardizing their collections using our FDA Class II- cleared sponge based collector, ORAcollect® ● Dx. It is important to understand that these sales are not cannibalizing Oragene® sales as these customers require a sponge or swab collector like ORAcollect® for their analysis applications. We are seeing a trend of new commercial purchasers for this product coming primarily from the diagnostic, pharmacogenomics and nutrition fields.

Sales to the Asia Pacific market have also continued to grow with large accounts from the direct-to-consumer (“DTC”), pharmacogenomics and health and wellness testing markets. The

fact that we continue to secure large contracts in Asia indicates the preference of these customers for using our FDA-cleared, high-quality DNA sample collection kits with their tests.

On the academic front, we continued to see the impact of large epidemiological studies. One important example is from a hospital network in France dedicated to fighting cancer, that will be conducting a large study with a cohort of 50,000 breast cancer survivors and women with a family history of breast cancer using our Oragene® kit. We are also encouraged by the recent announcements concerning the NIH budget increases that should directly impact the number and size of research studies in genomics.

Microbiome

Turning to our microbiome business, our Q3 sales, which include both collection devices and services, were up 118% compared to Q3 2017. In aggregate, approximately 80% of the revenue experienced in Q3 was a result of strengthening demand among existing customers, while 20% came from first time purchasers. Our ability to continue attracting new customers is important because of the positive impact on future growth. Our experience with new customers is that they typically start with small pilot projects before moving on to larger studies and larger purchases. We expect continued new customer acquisition and increased sales to existing customers to be important growth drivers for this part of the business.

Microbiome sampling device revenues increased 83% in Q3 over the prior year period, the majority of which came from companies offering microbiome consumer testing services. In fact, we have begun to see many new customers with unique types of DTC offerings. One such customer recently signed a multi-year supply agreement to launch a new “multi-omic” DTC offering in Europe. This customer analyzes both human DNA and gut microbiome data to provide personalized information on hereditary conditions as well as digestive health. We expect this customer to contribute to microbiome revenues in future quarters. Another new supply agreement was recently signed with a customer that will enable healthcare professionals to use the results of microbiome analysis to manage the nutritional health of patients. These types of agreements further underscore the utility of microbiome information and its potential to impact healthcare.

Lastly, our microbiome services business continues to gain traction. Q3 was the best quarter ever for this service offering with revenues growing 331% over the prior year quarter. This growth is being driven mainly by pharmaceutical and small biotech companies using our GenoFIND™ laboratory and bioinformatics services to understand changes in the microbiome profile. In this space, we see potential demand in many research fields, but we are focusing on customers that offer therapeutic, nutritional and cosmetic interventions. As microbiome discovery programs grow in scale and complexity, so do our services contracts. The average contract size in Q3 2018 was two times larger than in the prior year quarter. Based on the first-hand knowledge we have gained about this market through our participation in microbiome standards working groups, we expect the microbiome field will evolve to larger study sizes, longitudinal patient monitoring and multi-omics solutions to enable meaningful discovery. All of these factors are expected to play to our strengths and support long-term revenue growth.

Infectious Disease Testing – Steve Tang

HIV Business

Turning to infectious disease, our global HIV business grew 7% in the third quarter compared to the prior year period. A 41% increase in international sales more than offset a decline in the domestic HIV business.

Once again, the primary growth driver was our HIV Self-Test in the international marketplace. Over the past several quarters, much of the demand for this product has come from the STAR program, and we continue to ship product under Phase II of that program. However, I want to call your attention to an important aspect of our global HIV business. The market is evolving and growing, and product sales supporting the STAR program are becoming a smaller percentage of our HIV Self-Test business. We are now seeing a majority of the self-test demand coming from countries outside of the STAR program and we expect that to continue in Q4. It is important to understand that trend when assessing the future potential of this business.

As the self-testing market continues to develop and countries that have participated in the STAR project start to scale up their programs, we are seeing some distinctive ordering patterns, driven largely by these country implementations. When these countries start to scale their screening

programs, they need to ensure that the programs can ramp without interruption. As a result, they are ordering larger quantities of product up front in order to execute their programs and then do not order again until needed to continue their testing. This ordering pattern is also present in new countries that have not participated in the STAR program. This type of purchasing pattern inherently creates unevenness in the amount of product we supply on a quarter-to-quarter basis. So, if we experience somewhat reduced purchases in a particular quarter, that does not necessarily indicate a negative trend for the market. Rather, it is likely part of the normal purchasing pattern for new customers.

As we've shared previously, our Charitable Support Agreement with the Gates Foundation has been a key factor for this business, allowing us to offer more favorable pricing in 50 countries in Sub-Saharan Africa, West Africa, Asia, Central Asia and Latin America. We continue to make great progress under this agreement, with sales to new and existing customers in over 40 of the countries. To date, we have completed registrations for our Self-Test in 10 countries, submissions are pending in an additional 10 countries, and new submissions are being prepared for 24 countries. The vast majority of this regulatory activity is targeted at the countries covered by the Gates agreement. The significant time we have spent educating customers and promoting the pricing we can offer under the Gates agreement has paid dividends and this should continue. Additionally, it will be necessary for governments to develop and execute "in country" awareness campaigns to assist in motivating patients to self test for HIV. We are currently working with countries who are piloting such initiatives.

We previously mentioned the report issued by the World Health Organization and UNITAID on the global market for rapid HIV self-testing. That report recognized the importance of HIV self-testing to reach people at risk in developing countries and stated that the available procurement forecasts suggest that demand for self-tests is expected to increase from about 1 million tests in 2017 to an estimated 16.4 million tests by the end of 2020. While this is not our projection, we think the strong growth projected by this report is consistent with what we are seeing in the market.

On prior calls, we had also mentioned that UNITAID would be funding a self-testing program in West Africa. We are now seeing the impact of this additional funding and expect shipments

supported by this program to begin as early as the fourth quarter of this year. While this is certainly positive, it should be noted that the UNITAID program is quite a bit smaller than the STAR program. Nevertheless, it is evidence of the continued support HIV self-testing is receiving in the international market.

HCV Business

With respect to our global HCV business, revenues declined in the third quarter, primarily as the result of funding challenges and the difficult comparison caused by the non-renewal of a large foreign government supply contract.

Nevertheless, we remain confident in our overall HCV business and believe it will continue to be a source of future growth, largely because interest in eradicating HCV and testing remains high both here in the U.S. and in international markets.

On the domestic front, our Q3 sales improved from the prior year period and we think funding conditions may improve next year. As discussed on our last call, some legislative developments suggest that additional funding may become available. Recently, a new piece of bipartisan legislation was signed into law which is designed to help states and community-based organizations mobilize resources in response to new HIV and Hepatitis infections resulting from the ongoing opioid crisis. This new legislation authorizes annual funding of $40 million over a five-year period for the Centers for Disease Control and Prevention to support enhanced surveillance, increased HIV and HCV testing, and improved linkage to care.

On the international front, interest in HCV testing and treatment remains strong primarily as a result of the availability of low-cost HCV therapies. We remain active in discussions with various countries as there are a number of attractive opportunities we hope to secure. I would also point out that we do not include any contributions from international HCV in our guidance. As governments allocate funding for HCV we would anticipate testing needs to increase.

Other Matters – Steve Tang

Lastly, as you will see in a few days, a new Chief Accounting Officer will be signing our 10-Q for the third quarter. Michele Miller was recently promoted to Vice President, Finance and Controller and will be responsible for all accounting functions in both the U.S. and Canada. Michele began her career at Ernst and Young and joined OraSure in 2007, starting as Manager, Financial Reporting, and serving as Director, Financial Reporting since December 2011. Michele's 11 years with OraSure and her strong professional background in accounting and finance position her well for this new role.

I would like to congratulate Michele on her promotion and I look forward to working with her in this new role.

Conclusion – Steve Tang

So, in conclusion, we have a great deal to offer current and potential investors. We continue to post strong performance and make progress on our strategic initiatives. Our molecular and HIV Self-Test businesses are well positioned to remain solid contributors. We have a proven and experienced management team in place that is well suited to deliver on our objectives. Our key markets are well defined with several still in their early stages, and we are consistently adding a steady stream of new customers each quarter. There is no shortage of applications these days that require genetic testing and we continue to see microbiome research growing at a rapid rate. Our high quality HIV and HCV tests have proven their utility around the globe. We do think our HIV Self-Test will continue to flourish internationally and are hopeful that HCV will once again regain its momentum. And lastly, we are actively exploring ways to leverage our very strong balance sheet to enhance our growth profile. For those reasons, I believe the Company is well positioned for future success, and that is why we believe our best days remain ahead of us.

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 the Company's 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 or other 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 the Company’s 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 OraSure Technologies undertakes no duty to update these statements**.**