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): February 6, 2019

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 February 6, 2019, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the full year and quarter ended December 31, 2018 and financial guidance for the first quarter of 2019. 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 February 6, 2019, 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 full year and quarter ended December 31, 2018, provided financial guidance for the first quarter of 2019 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 February 6, 2019, Announcing Consolidated Financial Results of OraSure Technologies, Inc. for the Full Year and Quarter Ended December 31, 2018 and Financial Guidance for the First Quarter of 2019.
99.2	Prepared Remarks of Dr. Stephen S. Tang and Roberto Cuca for OraSure Technologies, Inc. Full Year and Fourth Quarter 2018 Analyst/ Investor Conference Call Held February 6, 2019.

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: February 6, 2019

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

OraSure Technologies, Inc.

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OraSure Announces 2018 Full Year and Fourth Quarter Financial Results

BETHLEHEM, PA – February 6, 2019 – (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 full year and fourth quarter of 2018.

Financial Highlights

- Net revenues for the year ended December 31, 2018 were $181.7 million, a 9% increase from 2017. Net product revenues were $165.4 million, representing 2% growth over 2017.
- Net revenues for the fourth quarter of 2018 were $50.2 million, a 3% decrease from the fourth quarter of 2017. Net product revenues were $44.8 million, representing an 11% decrease from the fourth quarter of 2017.
- Molecular collection systems net revenues for the full year 2018, including royalty income from a litigation settlement, were $96.1 million, up 28% from 2017. Molecular collection systems net revenues including royalty income were $30.2 million during the fourth quarter of 2018, up 2% from the fourth quarter of 2017. Molecular collection systems net product revenues during the year ended December 31, 2018 were $86.5 million, a 15% increase from the comparable period of 2017. Molecular collection systems net product revenues were $25.4 million during the fourth quarter of 2018, which represents a 15% decrease from the fourth quarter of 2017.
- For the full year of 2018, international sales of the Company's OraQuick® HIV products were $21.8 million, an increase of 93% compared to 2017. International sales of the Company's OraQuick® HIV products of $4.4 million in the fourth quarter of 2018 increased 23% compared to the fourth quarter of 2017. The increases in both periods were primarily the result of higher sales of the Company's OraQuick® HIV Self-Test.
- Full year 2018 international sales of the Company's OraQuick® HCV product of $4.9 million decreased 71% from 2017. International sales of the Company's OraQuick® HCV product of $1.6 million increased 40% for the fourth quarter of 2018 compared to the fourth quarter of 2017. The decline for the full year was 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 $11.8 million in sales during the full year of 2017 and

$270,000 during the fourth quarter of 2017. The increase in the fourth quarter was due to continued growth in Asia and Africa.

- Net income for the year ended December 31, 2018 was $20.4 million, or $0.33 per share on a fully diluted basis, which compares to net income of $30.9 million, or $0.51 per share on a fully diluted basis, for 2017. Net income for 2018 included $1.2 million of pre-tax transaction costs associated with two recent acquisitions that closed in early January 2019 and $9.6 million of pre-tax transition costs associated with the retirement of the Company's former Chief Executive Officer and Chief Financial Officer and the hiring of their successors. The transaction costs were $0.02 per share and the transition costs were $0.15 per share for the year ended December 31, 2018. The transition costs primarily consisted of non-cash stock compensation charges. Net income for the year ended December 31, 2017 included a $12.5 million gain related to the settlement of litigation against Ancestry.com DNA and its contract manufacturer. This gain was accounted for as a reduction of operating expenses and amounted to $0.15 per share on a fully diluted after-tax basis in that period.
- Net income for the fourth quarter of 2018 was $10.3 million, or $0.16 per share on a fully diluted basis, which compares to net income of $7.3 million, or $0.12 per share on a fully diluted basis, for the fourth quarter of 2017. Net income for the fourth quarter of 2018 included $1.2 million of pre-tax transaction costs related to the recent acquisitions and $974,000 of pre-tax transition costs associated with the Company's executive management changes. The transaction and transition costs together were $0.04 per share for the fourth quarter of 2018. The transition costs in the fourth quarter consisted of non-cash stock compensation charges.
- Cash and investments totaled $201.3 million at December 31, 2018.

"With the highest annual revenues in our history and strong profitability, 2018 was another financially successful year for OraSure. Our OraQuick® international HIV business and our Molecular business continued to drive performance with double-digit growth from 2017 to 2018. Our 2018 microbiome revenues nearly doubled when compared to 2017," said OraSure President and Chief Executive Officer, Dr. Stephen S. Tang. "2018 was also a pivotal year strategically. The acquisitions we announced in January were the first outcomes of our robust innovation-driven growth strategy. I am confident we have the right strategy and talent in place to deliver against our strategic objectives. We begin 2019 poised to leverage our strengths, grow our product portfolio and expand into new markets."

Financial Results

Net product revenues for the year ended December 31, 2018 increased 2% over 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.

Net product revenues for the fourth quarter of 2018 decreased 11% from the comparable period of 2017, primarily as a result of lower sales of the Company's molecular collections products and lower domestic sales of the Company's HIV and HCV tests, partially offset by higher international sales of the OraQuick® HIV Self-Test and OraQuick® HCV test.

Sales of the OraQuick® HIV Self-Test for the year and three months ended December 31, 2018 included $4.4 million and $855,000, respectively, of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation"), while the year and three months ended December 31, 2017 included $1.0 million and $589,000, respectively, of such payments.

Royalty income from a litigation settlement associated with a molecular collection device was $9.7 million for the full year and $4.8 million for the fourth quarter of 2018. There were no such royalties in 2017. Other revenues were $6.7 million and $5.1 million for the full year of 2018 and 2017, respectively. Other revenues were $578,000 and $1.8 million for the fourth quarter of 2018 and 2017, respectively. Other revenues in the full year of 2018 increased due to higher Ebola and Zika-related funding received from the U.S. Biomedical Advanced Research Development Authority ("BARDA") and increased cost reimbursement from the Gates Foundation. Other revenues decreased in the fourth quarter of 2018 largely due to lower BARDA funding and lower cost reimbursement under the Company's charitable support agreement with the Gates Foundation.

Gross profit percentage was 63% and 69% for the year and three months ended December 31, 2018, respectively, compared to 59% and 55% and for the year and three months ended December 31, 2017, respectively. Gross profit percentage in the full year of 2018 benefited from improved product mix associated with an increase in higher gross profit percentage product sales, lower manufacturing costs associated with the Company's Oragene® product, increased royalty income and other revenues, lower scrap and spoilage costs and lower royalty expense. Gross profit percentage in the current quarter benefited from improved product mix associated with an increase in higher profit percentage product sales, increased royalty income, lower manufacturing costs associated with the Company's Oragene® product, lower scrap and spoilage costs and lower royalty expense partially offset by a decrease in other revenues.

For the year ended December 31, 2018, operating expenses were $85.2 million, an increase of $26.5 million from the $58.7 million reported for the year ended December 31, 2017. The increase for the full year period was largely due to the inclusion of $9.6 million of transition costs associated with executive management changes, $1.2 million of transaction costs associated with the Company's recent acquisitions 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 2017. There was no similar gain recorded during 2018.

Operating expenses increased to $22.2 million during the fourth quarter of 2018 compared to $18.4 million in the fourth quarter of 2017. The fourth quarter increase was largely due to the inclusion of $1.2 million of transaction costs associated with the recent acquisitions, $973,000 of additional transition costs associated with the management changes, and higher commissions, consulting costs and other staffing costs, partially offset by the absence of a cost write-off in the fourth quarter of 2017 resulting from the non-renewal of a large HCV supply contact. A similar write-off did not recur in the fourth quarter of 2018.

Operating income for the year end December 31, 2018 was $28.4 million compared $40.2 million for the year ended December 31, 2017. The Company reported operating income of $12.5 million in the fourth quarter of 2018, compared to operating income of $10.2 million in the fourth quarter of 2017.

For the year ended December 31, 2018, other income increased to $3.3 million from $794,000 in the comparable period of 2017. Other income increased to $1.6 million during the fourth quarter of 2018 compared to $118,000 in the fourth quarter of 2017. The increase in other income for the full year 2018 is largely due to increased foreign currency gains associated with the strengthening of the Canadian dollar and higher interest income, partially offset by an increase in investment losses associated with the Company's deferred compensation plan. The increase in other income in the fourth quarter of 2018 is also largely due to increased foreign currency gains and higher interest income earned on the Company's investment balances.

Income tax expense was $11.3 million during the full year of 2018 compared to $10.1 million during the full-year of 2017. Income tax expense was $3.8 million during the fourth quarter of 2018 compared to

$3.0 million recorded in the fourth quarter of 2017. Income tax expense in 2018 reflects the higher pre-tax income generated by the Company's Canadian subsidiary. Income tax expense in 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 $201.3 million at December 31, 2018, compared to $176.6 million at December 31, 2017. For the year ended December 31, 2018, the Company generated $39.1 million in cash from operations.

First Quarter 2019 Outlook

The Company expects net revenues to range from $29.0 million to $30.5 million and is projecting a net loss of $0.06 to $0.07 per share for the first quarter of 2019. The foregoing guidance includes the expected revenue contribution from the two acquisitions that closed in early January 2019 and transaction costs approximating $0.01 per share, but does not account for any additional transaction and integration costs of those or any other completed transactions, which cannot be reasonably estimated at this time.

"We believe that revenues for the second half of 2019 will be materially greater than in the first half of the year, as we have experienced in the past. Additionally, we expect that performance by our core businesses combined with additional acquisitions will support our growth in future periods," Dr. Tang said.

Financial Data

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

Unaudited

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Results of Operations				
Net revenues	$ 50,246	$ 52,028	$ 181,743	$ 167,064
Cost of products sold	15,540	23,503	68,130	68,108
Gross profit	34,706	28,525	113,613	98,956
Operating expenses:				
Research and development	4,059	3,829	16,250	13,365
Sales and marketing	8,377	6,991	30,609	28,532
General and administrative	9,758	7,544	38,325	29,321
Gain on litigation settlement	—	—	—	(12,500)
Total operating expenses	22,194	18,364	85,184	58,718
Operating income	12,512	10,161	28,429	40,238
Other income	1,629	118	3,287	794
Income before income taxes	14,141	10,279	31,716	41,032
Income tax expense	3,843	2,963	11,320	10,084
Net income	$ 10,298	$ 7,316	$ 20,396	$ 30,948
Earnings per share:				
Basic	$ 0.17	$ 0.12	$ 0.33	$ 0.52
Diluted	$ 0.16	$ 0.12	$ 0.33	$ 0.51
Weighted average shares:				
Basic	61,268	60,652	61,112	59,050
Diluted	62,511	62,371	62,532	61,024

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

	Three Months Ended December 31,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2018	2017		2018	2017
Market					
Infectious disease testing	$ 13,643	$ 14,129	(3) %	27 %	27 %
Risk assessment testing	2,898	3,141	(8)	6	6
Cryosurgical systems	2,894	3,163	(9)	6	6
Molecular collection systems	25,407	29,784	(15)	50	58
Net product revenues	44,842	50,217	(11)	89	97
Royalty income	4,826	-	N/A	10	-
Other	578	1,811	(68)	1	3
Net revenues	$ 50,246	$ 52,028	(3) %	100 %	100 %

	Year Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2018	2017	% Change	2018	2017
Market					
Infectious disease testing	$ 56,148	$ 61,951	(9) %	31 %	37 %
Risk assessment testing	12,058	12,659	(5)	7	8
Cryosurgical systems	10,767	12,279	(12)	6	7
Molecular collection systems	86,455	75,099	15	47	45
Net product revenues	165,428	161,988	2	91	97
Royalty income	9,653	-	N/A	5	-
Other	6,662	5,076	31	4	3
Net revenues	$ 181,743	$ 167,064	9 %	100 %	100 %

	Three Months Ended December 31,			Year Ended December 31,		
	2018	2017	% Change	2018	2017	% Change
OraQuick® Revenues						
Domestic HIV	$ 4,974	$ 6,494	(23) %	$ 19,663	$ 23,847	(18) %
International HIV	4,399	3,563	23	21,794	11,301	93
Net HIV revenues	9,373	10,057	(7)	41,457	35,148	18
Domestic HCV	2,066	2,468	(16)	7,490	8,448	(11)
International HCV	1,598	1,144	40	4,904	16,961	(71)
Net HCV revenues	3,664	3,612	1	12,394	25,409	(51)
Net product revenues	$ 13,037	$ 13,669	(5) %	$ 53,851	$ 60,557	(11) %

	Three Months Ended December 31,			Year Ended December 31,		
	2018	2017	% Change	2018	2017	% Change
Molecular Collection Systems Revenues						
Genomics	$ 23,505	$ 28,679	(18) %	$ 79,765	$ 71,611	11 %
Microbiome	1,902	1,105	72	6,690	3,488	92
Net product revenues	$ 25,407	$ 29,784	(15) %	$ 86,455	$ 75,099	15 %

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 88,438	$ 72,869
Short-term investments	68,134	83,028
Accounts receivable, net	34,842	42,521
Inventories	22,888	19,343
Other current assets	5,010	4,144
Property and equipment, net	24,299	21,372
Intangible assets, net	5,137	8,223
Goodwill	18,521	20,083
Long-term investments	44,752	20,690
Other non-current assets	3,550	3,928
Total assets	$ 315,571	$ 296,201
Liabilities and Stockholders' Equity		
Accounts payable	$ 10,598	$ 10,228
Deferred revenue	3,521	1,314
Other current liabilities	13,861	20,695
Other non-current liabilities	901	3,932
Deferred income taxes	3,312	1,951
Stockholders' equity	283,378	258,081
Total liabilities and stockholders' equity	$ 315,571	$ 296,201

	Year Ended December 31,	
Additional Financial Data (Unaudited)	**2018**	**2017**
Capital expenditures	$ 6,344	$ 4,337
Depreciation and amortization	$ 7,222	$ 6,402
Stock-based compensation	$ 15,237	$ 6,973
Cash provided by operating activities	$ 39,090	$ 28,156

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2018 fourth quarter and full year financial results, certain business developments and financial guidance for the first quarter of 2019, 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 #2986827 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, February 13, 2019, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #2986827.

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: successfully managing and integrating acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; 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 or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; 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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Exhibit 99.2

OraSure Technologies, Inc.

2018 Fourth Quarter and Full Year

Analyst/Investor Conference Call

February 6, 2019

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 delighted to report that 2018 was a financially successful and strategically important year for OraSure. We posted solid year over year organic revenue growth after coming off a record performance in 2017. We successfully managed the transition of senior management and completed an extensive and thorough review of our corporate strategy. The Company wasted no time implementing that strategy as evidenced by the two acquisitions we announced a few weeks ago.

OraSure is well positioned to compete in multiple markets with large growth opportunities and we are highly optimistic about our future prospects. Although some important aspects of what we accomplished in 2018 may not be evident in today's results, we believe they will become apparent in the coming years. We expect 2018 will be seen as a pivotal time in the Company's history, as our innovation growth strategy took flight, expanding our reach in molecular diagnostics and driving our business internationally.

Looking at our full year results, you will see solid growth in the areas that we are targeting and where we are investing. Importantly, as we endeavored to transform the composition of our top-line, we did not lose our focus on the bottom line and posted strong profitability. We believe we have identified select opportunities that will drive our next wave of growth.

For the full year 2018, our net revenues grew by a solid 9% over the prior year period and reached the highest level in our history. We also continued to deliver strong profitability.

- A major contributor was our OraQuick® HIV international business which grew by 93% for the year, primarily due to strong HIV self-test sales.
- Our molecular business also contributed, with revenues up more than 15% for the full year.
- Our microbiome business continued an important trend in 2018, with revenues nearly doubling when compared to 2017.
- Finally, we ended the year in an extremely strong financial position with no debt and cash balances exceeding $200 million for the first time ever.

During the fourth quarter, our consolidated net income improved 41% from the prior year quarter. This strong bottom line performance was generated by a number of factors:

- International sales of our OraQuick® HIV and HCV products rose 23% and 40%, respectively, compared to the fourth quarter of 2017.
- Although Q4 molecular collection revenues were down due to unusually high sales to our consumer genomics customers in the fourth quarter in 2017, driven by atypical ordering patterns, we saw strong growth elsewhere in both our genomics and microbiome businesses during the current quarter. We see this as a positive trend for the future of our molecular business.
- Other revenues for the quarter rose almost 200% compared to Q4 of 2017, as a result of close to $5 million in royalties from a litigation settlement agreement.
- Our gross profit improved by more than 25% over the fourth quarter of 2017.

On the strategic front, we began aggressively implementing our innovation growth strategy. Following an intense period of due diligence and negotiation towards the end of 2018, we opened the new year by closing two strategic acquisitions which will add new products and technologies and new market reach. We believe both companies will eventually become strong contributors to our business.

Strong financial results and important progress in executing against our long-term strategy were a great way to end 2018 and begin the new year. With that, let me now turn the call over to Roberto

for his financial review. I will then follow up on some of the key factors driving our business and we will then open the call for your questions.

Fourth Quarter 2018 Financial Results – Roberto Cuca

Thanks Steve, and good afternoon everyone.

Our fourth quarter net revenues decreased 3% to $50.2 million, from $52.0 million reported in the fourth quarter of 2017. Our net product revenues decreased 11% to $44.8 million compared to the prior-year period.

Our molecular net revenues including royalty income increased 2% to $30.2 million in the fourth quarter compared to $29.8 million in 2017. Royalty income was $4.8 million in Q4 2018. No royalty income was recorded in 2017. Molecular product revenues decreased 15% to $25.4 million in the fourth quarter of 2018 compared to $29.8 million in the fourth quarter of 2017. Sales of our genomic products declined 18% to $23.5 million, largely due to lower sales to a large consumer genomics customer. The primary reason for this is that sales to this customer in the fourth quarter of 2017 were unusually high as a result of unexpected consumer demand which occurred during that quarter. Microbiome sales also expanded, growing 72% to $1.9 million in the fourth quarter of 2018 compared to the same period last year.

International HIV sales increased 23% to $4.4 million from $3.6 million in the fourth quarter of 2017 due to higher sales of our OraQuick® HIV Self-Test into Africa and increased sales of our professional product in Asia and Europe. Once again, 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 program during the quarter were subject to support payments under our charitable support agreement with the Bill and Melinda Gates Foundation.

Domestic HIV sales decreased 23% to $5.0 million in the fourth quarter of 2018, compared to $6.5 million in the fourth quarter of 2017 largely due to customer ordering patterns and other factors we have previously discussed.

International HCV sales in the fourth quarter of 2018 increased 40% to $1.6 million from $1.1 million in the same period of 2017, primarily due continued growth in Asia and Africa.

Domestic HCV sales decreased 16% in the fourth quarter of 2018 to $2.1 million from $2.5 million in the prior-year period largely due to customer ordering patterns.

Other revenues were $578,000 in the current quarter, compared to $1.8 million in the prior year. The decrease is largely due to a decrease in BARDA funding and cost reimbursement under our charitable support agreement with the Gates Foundation.

Gross profit percentage for the fourth quarter of 2018 was 69% compared to 55% reported for the fourth quarter of 2017. Gross profit percentage for the current quarter benefitted from improved product mix, the increase in royalty income, lower manufacturing costs associated with our Oragene® product, lower scrap and spoilage costs, and lower royalty expense.

Our operating expenses for the fourth quarter of 2018 were $22.2 million compared to $18.4 million in the comparable period of 2017. Operating expense in the fourth quarter of 2018 included $1.2 million of transaction costs associated with our recent acquisitions and $973,000 of additional transition costs associated with executive management changes that occurred earlier in the year. Higher commissions and consulting and other staffing costs further contributed to the increase in operating expenses.

Income tax expense was $3.8 million in the fourth quarter of 2018 compared to $3.0 million in the same period last year and consists largely of Canadian taxes due and is reflective of the higher pre-tax earnings generated by our Canadian subsidiary.

We reported net income of $10.3 million, or $0.16 per share, for Q4 2018, compared to net income of $7.3 million, or $0.12 per share, for Q4 2017.

We continue to maintain a solid cash and liquidity position. Our cash and investments balance at December 31, 2018 was $201.3 million compared to $176.6 million at December 31, 2017. Cash generated by operating activities during 2018 was $39.1 million compared to $28.2 million in the same period of 2017 which included a $12.5 million litigation settlement.

Turning to guidance for the first quarter of 2018, we are projecting revenues of $29.0 to $30.5 million and net loss of $0.06 to $0.07 per share. This projection is largely driven by lower expected sales to a large consumer genomics customer. As stated on prior calls, sales to this customer were unusually high in Q4 of 2017 and moved to what appeared to be a more normal level in Q4 of 2018 in response to seasonal retail promotional activity at the end of the year.

This large customer is now further changing its purchasing patterns and promotional strategies, which, in turn, is driving our guidance for Q1 of this year. We only recently learned of their lower purchasing intentions, and although disappointing, we expect the effect of these changes will be moderated over the course of the year by opportunistic growth in other genomics accounts. For that reason, we do not view Q1 as an indication of the success we anticipate for the rest of 2019. Our expectation is that the second half of 2019 will deliver higher revenues than the first half, much as we have seen in 2017 and 2018. We are also confident in our ability to deliver profitability in 2019.

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

Business Update – Steve Tang

Thanks Roberto. Let's take a look at some of our key growth drivers.

Global HIV Testing – Steve Tang

Our Global HIV testing business delivered outstanding results in 2018, largely as a result of HIV Self-Test sales in the international marketplace. Fourth quarter self-testing volumes were up sequentially from the third quarter and total year volumes were up significantly over 2017. As Roberto noted, international HIV sales grew 23% in the fourth quarter and almost doubled for the full-year when compared to 2017.

As you know, the HIV Self-Test business was jump started by the Self Testing Africa, or STAR program, that Roberto mentioned. The market has evolved quite a bit since that program was launched in 2015. During Q4, 64% of orders occurred outside of the STAR program and 58% of our self-test sales for all of 2018 were a result of non-STAR orders. This demonstrates significant

positive momentum and growth for this business as the market continues to expand organically beyond the initial countries we served when this product was first launched.

A key driver for HIV self testing has been our Charitable Support Agreement with the Gates Foundation, targeting 50 countries in Sub-Saharan Africa, West Africa, Asia, Central Asia and Latin America. We continue to support new registrations in the countries covered by this agreement along with ongoing educational efforts to promote the attractive pricing we can offer, thanks to the Gates Foundation.

While demand for our self-test product can be, and likely will be, a bit choppy on a quarter-to-quarter basis as countries develop their testing programs and understand ongoing demand needs, the overall trend for this business is very positive. We continue to believe the projections in the report issued by the World Health Organization and UNITAID on the global market for rapid HIV self-testing, are directionally correct. As you may recall, that report suggested that the demand for self tests is expected to increase from about 1 million in 2017 to a range which averages out to 16 million tests annually by the end of 2020, with the high end of that range reaching just over 19 million tests. We believe the market conditions will continue to drive strong growth for HIV self testing throughout 2019 and beyond.

Molecular Business Update – Steve Tang

Turning to our other main growth platform, full-year molecular collections revenues delivered a solid 15% growth rate over 2017. Although the contribution from our consumer genomics customers is changing when compared to prior years, this does not dampen the outlook for genomics or the overall prospects for our molecular business, as evidenced by the fact that we acquired 56 new customers in Q4 and 332 for the whole year.

The genomics business saw revenue growth of 11% for the full year. Although consumer genomics is, and will continue to be, an important part of our genomics business, we are also seeing growth in other areas of the genomics market. For example, 2018 saw renewed strength from academic customers with revenue growth reaching 16% for the full year. Our academic

business continues to benefit from large epidemiological studies. For example, a clinical study called “My Personal Breast Screening Project” is testing 50,000 women for their individual risk of developing breast cancer and investigating whether mammography screening could be improved by personalized, individual risk-based screening. The study is being financed by the European Union under the Innovation Horizon 2020 program and is being conducted by UNICANCER which is the center for cancer prevention in France and the principal operator of academic cancer research in Europe.

We also saw extraordinary growth from our ORAcollect® business, particularly in the second half of the year, with global revenues up more than 200% for both the fourth quarter and full year of 2018 when compared to 2017. This was driven in part by one of our top 20 customers in Asia, who is using our ORACollect® test kit. We are encouraged by demand for our genomics business in Asia, where revenue from one of our top three customers grew 184% in Q4 and 175% for the full year when compared to 2017. Revenue from another top 20 customer in Asia increased by more than 450% in Q4 and by 500% for the year.

In the microbiome market, we delivered another record performance in 2018 with fourth quarter revenues up 72% and full year revenues up 92% when compared to 2017. Again, we are seeing growth in Asia, where microbiome revenues increased 72% in Q4 compared to Q3 and 62% compared to the fourth quarter of 2017. Similarly, microbiome revenues in Europe increased 191% sequentially in Q4 and 221% compared to Q4 of 2017. One of our top microbiome customers is starting a phase II clinical trial and has signed a microbiome services contract to be executed in 2019. During the fourth quarter we signed five new pharma and one new direct-to-consumer, or “DTC,” customers in the microbiome space. One example of a new DTC customer, for whom we are providing both kits and services, is Onegevity Health, a consumer health intelligence company that combines a multiomic artificial intelligence platform with consumer friendly products and services focused on personalized health and wellness.

So, stepping back to look at the bigger picture, our molecular business is becoming broader and is showing good strength beyond one or two large customers. The list of our top 20 molecular accounts reveals some interesting trends.

- 18 of our top 20 Molecular accounts drove higher sales for the most recent 12-month trailing period compared to the prior period, with 17 showing double or triple-digit revenue growth rates.
- For the first time, two microbiome customers are now in the top 20 and a new academic customer also joined the top 20 list.
- Two of our top 20 customers are located in Asia and one of these customers is in the top three.
- Seven of our top 20 customers are currently under multi-year supply agreements.
- Half of our top 20 customers use our customization services.
- Finally, one of our top ten customers provides direct-to-consumer canine testing services – and claims Oprah as a fan! She put the test on her list of her Favorite Things for 2018.

These statistics point to the growing strength and diversity of our Molecular business.

Business Development – Steve Tang

I also want to touch on our mergers and acquisitions activity, and in particular our recent acquisitions of CoreBiome and Novosanis.

Starting with CoreBiome, we are very excited to have this company on board. This is exactly the type of transaction we seek to target, as it broadens our reach in Molecular and meets our innovation criteria.

CoreBiome is a Minnesota-based microbiome services provider spun out of the University of Minnesota. It was founded by three leading domain experts in microbiome informatics, genomics methods and clinical lab operations. CoreBiome's proprietary technology provides fast, information-rich characterizations of microbiome diversity and function, and pairs that information with machine learning and expert analytics. This acquisition positions OraSure to become a leading end-to-end solution provider for researchers, direct-to-consumer companies and therapeutics and diagnostic development customers, covering everything from sample collection to delivery of a final analysis. This is an important part of our innovation growth strategy.

We expect to see a powerful synergy from combining CoreBiome's platform with the proprietary sampling and stabilization technology and deeper sales and marketing resources of our subsidiary, DNA Genotek. We are enthusiastic about this addition to our evolving multiomics business. Our hope is that this acquisition will look prescient in a few years, as we expect the microbiome market to continue to post strong growth for years to come.

Novosanis was also spun out of a university setting – this time in Belgium with technology coming from the University of Antwerp. Novosanis expands our collection capabilities into the urine market and also broadens our addressable markets. Its primary technology, called Colli-Pee, is the only available easy-to-use device suited for standardized volumetric collection of first-void urine in the privacy of a user's home or a clinic. We believe the Colli-Pee product line offers important competitive advantages for urine testing with first applications in the liquid biopsy market for prostate and bladder cancers, as well as sexually transmitted infections. Novosanis expands our product portfolio and advances our expertise in the non-invasive sample collection and stabilization landscape.

Together, these acquisitions support our efforts to expand even deeper into the multiomics and systems biology arenas.

Both companies were relatively low cost, tuck-in type acquisitions for our Molecular business. We are making good progress with our integration activities as we leverage the strengths from both organizations. And we are already seeing new customer contracts generated at both companies. We are excited to combine the broader resources of the OraSure sales, operations and research organizations to supplement the innovative new technologies developed by these important additions to the OraSure family.

I cannot emphasize enough that these acquisitions represent clear progress as we execute our innovation growth strategy and supplement our core business with focused strategic acquisitions. These transactions are the first steps, in what we expect will be a broader and ongoing growth story. So please stay tuned.

Conclusion - Steve Tang

In closing, I want to thank all those at the Company who made 2018 such a success. We accomplished a great deal but our work to implement our innovation growth strategy has just begun. If you listened to our presentation recently at the JP Morgan conference, you may recall the discussion of a relatively little known topic to many – multiomics.

Genomics was the first frontier, microbiome is the next, and multiomics is the emerging frontier…where science provides further insights beyond proteomics and metabolomics as our best view of how the human body responds to our genes and environment.

Multiomics provides a thorough, multifactorial examination of health. This area is still largely in its infancy, where we want to take an early leadership position to capture the large sample collection and testing opportunities we anticipate in the years to come.

As you've heard today, we're building on our core strengths in the areas of innovative tools and services to expand even deeper into the multiomics and systems biology arena.

Multiomics requires the ability to analyze and interpret massive data sets to extrapolate a comprehensive view of health and wellbeing.

By examining the "omes" – the genome, proteome, trans-criptome, epigenome and the microbiome, we can assess all aspects of what is in us and on us, to inform our health.

Broadly speaking, the markets we serve aim to understand the continuum of wellness through disease, by profiling well-characterized patient populations with molecular techniques.

Genomics has been hugely informative to this end. But when you zoom out, you quickly realize that our 23,000 genes encode only a small fraction of our biochemical potential. Microbes, which colonize us, inside and out, collectively encode 10 times more genetic and functional potential.

Only recently has the scientific community developed the computational and wet-lab tools to harness the relatively new branch of multiomics.

Technological advances have enabled the study of physiological and cellular changes, at different molecular levels. Multiomics lets us integrate data from large populations, to potentially impact prevention, improve diagnostics, and more effectively treat complex diseases such as cancer and diabetes.

The potential of this multiomics approach is demonstrated by the fact that 40% of our microbiome customers were or are customers of our genomics product line. And we are well positioned to capitalize on opportunities across multiple sample types and analytes… and from existing Oragene® and OMNIgene® customers as they expand their research and offerings to incorporate more aspects of health through systems biology.

We also believe there will be continued strong growth from our HIV self-test business and we are optimistic that there is additional potential for our OraQuick® HCV product line. And, as we recently demonstrated, our strong balance sheet will enable us to continue executing on our long-term growth strategy, in very concrete ways, by acquiring new products and technologies. I am confident our strategy is on target and I look forward to updating you on our progress as we move through the new year.

And 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: successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; 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 or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; 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**.**