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 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 February 7, 2018, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter and full year ended December 31, 2017 and financial guidance for the first 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 February 7, 2018, the Company held a webcast conference call with analysts and investors, during which Douglas A. Michels, the Company's President and Chief Executive Officer, and Ronald H. Spair, the Company's Chief Financial Officer and Chief Operating Officer, discussed the Company's consolidated financial results for the quarter and full year ended December 31, 2017, provided financial guidance for the first quarter of 2018 and described certain business developments. A copy of the prepared remarks of Messrs. Michels and Spair is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

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

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated February 7, 2018, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31 2017 and financial guidance for the first quarter of 2018.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full-Year 2017 Analyst/ Investor Conference Call Held February 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: February 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:

Ronald H. Spair
Chief Financial Officer
610-882-1820
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www.orasure.com

OraSure Announces Record 2017 Fourth Quarter and Full-Year Financial Results

BETHLEHEM, PA – February 7, 2018 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its consolidated financial results for the fourth quarter and full-year ended December 31, 2017.

Financial Highlights

- Consolidated net revenues for the fourth quarter of 2017 were $52.0 million, a 47% increase from the fourth quarter of 2016. Consolidated net product revenues were $50.2 million, representing a 75% increase over the fourth quarter of 2016.
- Consolidated net revenues for the year ended December 31, 2017 were $167.1 million, a 30% increase from the comparable period of 2016. Consolidated net product revenues were $162.0 million, representing a 51% improvement from 2016.
- Net molecular collection systems revenues were $29.8 million during the fourth quarter of 2017, which represents a 248% increase over the fourth quarter of 2016. Net molecular collection systems revenues during the year ended December 31, 2017 were $75.1 million, a 133% increase from 2016.
- International sales of the Company's OraQuick® HIV products of $3.6 million increased 171% compared to the fourth quarter of 2016. International OraQuick® HIV sales for year ended December 31, 2017 were $11.3 million, a 115% increase over 2016. The increase in international HIV sales for both periods was primarily the result of higher sales of the Company's HIV self-test.

- International sales of the Company's OraQuick® HCV product of $1.1 million for the fourth quarter of 2017 decreased 61% compared to the fourth quarter of 2016 as a result of the non-renewal of a foreign government supply contract in support of a countrywide HCV eradication program. International OraQuick® HCV sales for the year ended December 31, 2017 were $17.0 million, a 156% increase over the full year of 2016.
- Consolidated net income for the fourth quarter of 2017 was $7.3 million, or $0.12 per share on a fully diluted basis, which compares to consolidated net income of $7.2 million, or $0.13 per share on a fully diluted basis, for the fourth quarter of 2016. Consolidated net income for the year ended December 31, 2017 was $30.9 million, or $0.51 per share on a fully-diluted basis, which compares to consolidated net income of $19.7 million, or $0.35 per share, for the comparable period of 2016.
- Cash and investments totaled $176.6 million and working capital amounted to $189.7 million at December 31, 2017.

"Our fourth quarter and full year 2017 financial results were outstanding," said Douglas A. Michels, President and CEO of OraSure Technologies. "We reported record revenues and profitability for the year as a result of the exceptional performance of our molecular business and strong growth in our international HIV and HCV businesses. Our Company is in great shape financially and we are starting 2018 in a very solid position with significant momentum in our molecular and infectious disease businesses."

Financial Results

Consolidated net product revenues for the fourth quarter of 2017 increased 75% over the comparable period of 2016, primarily as a result of higher sales of the Company's molecular collections products and higher international sales of the OraQuick® HIV self-test, partially offset by lower international sales of the OraQuick® HCV test. Fourth quarter 2017 sales of the OraQuick® HIV self-test included $589,000 of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation").

Consolidated net product revenues for the full year of 2017 increased 51% over 2016. This increase was primarily the result of higher sales of the Company's molecular collections and OraQuick® HCV products and higher international sales of the OraQuick® HIV self-test, partially offset by lower domestic sales of the Company's professional OraQuick® HIV product and lower cryosurgical product sales. Full-year 2017 sales of the OraQuick® HIV self-test included $1.0 million of support payments under the Gates Foundation agreement.

Consolidated other revenues for the quarter and year ended December 31, 2017 were $1.8 million and $5.1 million, respectively. This compares to consolidated other revenues for the fourth quarter and full year of 2016 of $6.9 million and $21.3 million, respectively. Other revenues in the fourth quarter of 2017 included $1.3 million of Ebola and Zika-related funding received from the U.S. Biomedical Advanced Research Development Authority ("BARDA") and $470,000 in cost reimbursement under the Company's charitable support agreement with the Gates Foundation. Other revenues in the fourth quarter of 2016 included $747,000 of BARDA funding and $6.1 million of exclusivity revenues recognized under the Company's HCV co-promotion agreement with AbbVie, which terminated on December 31, 2016. Other revenues for the full-year 2017 included $4.4 million of BARDA funding and $689,000 of cost reimbursement under the Gates Foundation agreement. Other revenues in 2016 included $2.3 million of BARDA funding and $18.9 million of AbbVie exclusivity revenues.

Consolidated gross margin was 55% and 59% for the three months and year ended December 31, 2017, respectively. Consolidated gross margin for the three months and year ended December 31, 2016 was 67% and 69%, respectively. Gross margin for the current quarter and the full year of 2017 decreased primarily due to the absence of AbbVie exclusivity revenues during these periods, an increase in lower margin product sales, and higher scrap and spoilage costs.

Consolidated operating expenses increased to $18.4 million during the fourth quarter of 2017 compared to $16.9 million in the fourth quarter of 2016. This increase was largely due to higher research and development expenses resulting from increased lab supplies and staffing costs and from the inclusion in the fourth quarter of 2016 of a payment to settle a claim against one of the Company's raw material suppliers, which reduced research and development expenses by $1.4 million. A similar payment was not received in the fourth quarter of 2017. The current quarter increase was partially offset by a decrease in general and administrative expense associated with lower legal fees and a decrease in costs caused by the absence of a corporate restructuring which occurred in the fourth quarter of 2016, partially offset by higher consulting costs and a cost write-off in the fourth quarter of 2017 resulting from the non-renewal of a foreign government supply contract in support of a country-wide HCV eradication program.

For the year ended December 31, 2017, consolidated operating expenses were $58.7 million, a $9.0 million decrease from the $67.8 million reported for the year ended December 31, 2016. This decrease was primarily due to a $12.5 million gain on a litigation settlement reported earlier this year, the absence of costs associated with the AbbVie HCV co-promotion agreement, and lower legal fees, partially offset by higher staffing costs and increased research and development expenses due to the supplier claim settlement and higher supply costs.

Operating income rose 44% to $10.2 million in the fourth quarter of 2017 compared to $7.1 million in the fourth quarter of 2016. Operating income for the year ended December 31, 2017 was $40.2 million, a 99% increase over 2016.

Income tax expense was $3.0 million during the fourth quarter of 2017 compared to a $31,000 income tax benefit recorded in the fourth quarter of 2016. For the year ended December 31, 2017, income tax expense was $10.1 million, a $9.5 million increase from the $603,000 reported for the year ended December 31, 2016. Full-year 2017 income tax expense included the additional taxes due as a result of the $12.5 million litigation settlement gain. The increases in income tax expense in both the quarter and year ended December 31, 2017 were also a result of the higher pre-tax income generated by the Company's Canadian subsidiary during both periods.

The Company's cash and investment balance totaled $176.6 million at December 31, 2017, compared to $120.9 million at December 31, 2016. Working capital was $189.7 million at December 31, 2017, compared to $139.1 million at December 31, 2016. For the year ended December 31, 2017, the Company generated $28.2 million in cash from operations.

First Quarter 2018 Outlook

In January 2018, the Company announced the appointment of Dr. Stephen Tang as the Company's new President and CEO, effective April 1, 2018. Dr. Tang will replace Douglas A. Michels, the Company's current President and CEO, who will be retiring on March 31, 2018. The Company has also recently announced that Ronald H. Spair, the Company's Chief Financial Officer and Chief Operating Officer, will be retiring on or before June 30, 2018.

Charges associated with these transitions are expected to total $6.8 million in the first quarter of 2018. These charges primarily reflect non-cash charges associated with modifications to existing stock grants held by the retiring executives and expenses associated with the onboarding of the Company's new President and CEO.

The Company expects consolidated net revenues to range from $40.0 million to $41.0 million and is projecting a consolidated net loss of approximately $0.06 per share for the first quarter of 2018. The projected net loss includes the transition costs noted above.

Financial Data

Unaudited

	Three months ended December 31,		Year ended December 31,	
	2017	2016	2017	2016
Results of Operations				
Net revenues	$52,028	$35,499	$167,064	$128,198
Cost of products sold	23,503	11,545	68,108	40,171
Gross profit	28,525	23,954	98,956	88,027
Operating expenses:				
Research and development	3,829	1,207	13,365	9,754
Sales and marketing	6,991	7,121	28,532	29,652
General and administrative	7,544	8,553	29,321	28,356
Gain on litigation settlement	—	—	(12,500)	—
Total operating expenses	18,364	16,881	58,718	67,762
Operating income	10,161	7,073	40,238	20,265
Other income	118	92	794	58
Income before income taxes	10,279	7,165	41,032	20,323
Income tax expense (benefit)	2,963	(31)	10,084	603
Net income	$ 7,316	$ 7,196	$ 30,948	$ 19,720
Earnings per share:				
Basic	$ 0.12	$ 0.13	$ 0.52	$ 0.35
Diluted	$ 0.12	$ 0.13	$ 0.51	$ 0.35
Weighted average shares:				
Basic	60,652	55,811	59,050	55,615
Diluted	62,371	57,232	61,024	56,513

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2017	2016	% Change	2017	2016
Market					
Infectious disease testing	$14,129	$13,679	3%	27%	39%
Risk assessment testing	3,141	3,322	(5)	6	9
Cryosurgical systems	3,163	3,071	3	6	9
Molecular collection systems	29,784	8,565	248	58	24
Net product revenues	50,217	28,637	75	97	81
Other	1,811	6,862	(74)	3	19
Net revenues	$52,028	$35,499	47%	100%	100%

	Year Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2017	2016	% Change	2017	2016
Market					
Infectious disease testing	$ 61,951	$ 48,408	28%	37%	38%
Risk assessment testing	12,659	13,068	(3)	8	10
Cryosurgical systems	12,279	13,234	(7)	7	10
Molecular collection systems	75,099	32,214	133	45	25
Net product revenues	161,988	106,924	51	97	83
Other	5,076	21,274	(76)	3	17
Net revenues	$167,064	$128,198	30%	100%	100%

	Three Months Ended December 31,			Year Ended December 31,		
	2017	2016	% Change	2017	2016	% Change
HIV Revenues						
Domestic	$ 4,614	$5,054	(9)%	$17,015	$21,499	(21)%
International	3,563	1,314	171	11,301	5,248	115
Domestic OTC	1,880	1,747	8	6,832	6,320	8
Net product revenues	$10,057	$8,115	24%	$35,148	$33,067	6%

	Three Months Ended December 31,			Year Ended December 31,		
	2017	2016	% Change	2017	2016	% Change
HCV Revenues						
Domestic	$2,468	$ 2,218	11%	$ 8,448	$ 7,436	14%
International	1,144	2,908	(61)	16,961	6,630	156
Net product revenues	3,612	5,126	(30)	25,409	14,066	81
Amortization of exclusivity payments	—	6,114	(100)	—	18,951	(100)
Net HCV-related revenues	$3,612	$11,240	(68)%	$25,409	$33,017	(23)%

	Three Months Ended December 31,			Year Ended December 31,		
	2017	2016	% Change	2017	2016	% Change
Cryosurgical Systems Revenues						
Domestic professional	$1,032	$1,389	(26)%	$ 5,400	$ 5,545	(3)%
International professional	245	165	48	797	771	3
Domestic OTC	273	288	(5)	1,230	1,350	(9)
International OTC	1,613	1,229	31	4,852	5,568	(13)
Net product revenues	$3,163	$3,071	3%	$12,279	$13,234	(7)%

	Three Months Ended December 31,			Year Ended December 31,		
	2017	2016	% Change	2017	2016	% Change
Molecular Collection Systems Revenues						
Commercial Genomics	$26,978	$5,760	368%	$61,594	$20,767	197%
Academic Genomics	1,701	2,411	(29)	10,017	10,312	(3)
Microbiome	1,105	394	180	3,488	1,135	207
Net product revenues	$29,784	$8,565	248%	$75,099	$32,214	133%

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2017	December 31, 2016
Assets		
Cash and cash equivalents	$ 72,869	$ 109,790
Short-term investments	83,028	11,160
Accounts receivable, net	42,521	19,827
Inventories	19,343	11,799
Other current assets	4,144	3,865
Property and equipment, net	21,372	20,033
Intangible assets, net	8,223	10,337
Goodwill	20,083	18,793
Long-term investments	20,690	—
Other non-current assets	3,928	2,331
Total assets	$ 296,201	$ 207,935
Liabilities and Stockholders' Equity		
Accounts payable	$ 10,228	$ 4,633
Deferred revenue	1,314	1,388
Other current liabilities	20,695	11,314
Other non-current liabilities	3,932	2,304
Deferred income taxes	1,951	2,446
Stockholders' equity	258,081	185,850
Total liabilities and stockholders' equity	$ 296,201	$ 207,935

	Year Ended December 31,	
Additional Financial Data (Unaudited)	**2017**	**2016**
Capital expenditures	$ 4,337	$ 4,353
Depreciation and amortization	$ 6,402	$ 5,640
Stock-based compensation	$ 6,973	$ 6,063
Cash provided by operating activities	$28,156	$24,598

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2017 fourth quarter and full-year financial results, certain business developments and financial guidance for the first quarter of 2018, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Douglas A. Michels, President and Chief Executive Officer, and Ronald H. Spair, Chief Financial Officer and Chief Operating Officer. The call will include prepared remarks by management and a question and answer session.

In order to listen to the conference call, please either dial 844-831-3030 (Domestic) or 315-625-6887 (International) and reference Conference ID #5872026 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 14, 2018, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #5872026.

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 increased reliance on U.S. government contracts; failure of distributors or

other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing, collection or other products; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in credit agreements; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could affect our results are discussed more fully in the Company's Securities and Exchange Commission ("SEC") filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2016, 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.

2017 Fourth Quarter and Full-Year

Analyst/Investor Conference Call

February 7, 2018

Prepared Remarks of Douglas A. Michels and Ronald H. Spair

Please see "Important Information" at the conclusion of the following prepared remarks

Introduction – Doug Michels

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

I am pleased to report that we ended the year on a high note. We delivered outstanding results for both Q4 and the full-year 2017, with record revenues and strong profitability. We are delighted with our performance.

With respect to Q4, the Company's results were driven largely by a significant increase in molecular collection sales and continued strong growth in our HIV self-test business. There are many highlights:

- Our consolidated net revenues reached an all-time high for the quarter at $52 million, representing a 47% increase from the year-ago period. Product revenue growth for Q4 was an extraordinary 75%.
- Our molecular business delivered another record performance. Q4 revenues reached $29.8 million, which represents a 248% increase over Q4 of last year.
- Our infectious disease revenues also rose during Q4 as a result of a 171% increase in international HIV sales driven primarily by our HIV self-test business. The increase in international HIV sales more than offset a reduction in international HCV sales caused by the non-renewal of a large government supply contract in support of a country-wide HCV eradication program.

- Operating income for Q4 rose 44% and we generated $7.3 million in consolidated net income, or $0.12 per share on a fully diluted basis. For the full year, we had consolidated net income of $30.9 million or $0.51 per share.
- We ended 2017 with $177 million in cash and cash equivalents which represents a $56 million improvement from the end of 2016.
- By any measure, 2017 was truly an outstanding year for the Company.

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

Fourth Quarter 2017 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

As you can see from our press release and Doug's brief introduction, 2017 was a very successful year with our fourth quarter revenues reaching record levels. Our fourth quarter consolidated net revenues increased 47% to $52.0 million, compared to $35.5 million reported in the fourth quarter of 2016. Notably, our consolidated net product revenues rose 75% to $50.2 million compared to the prior-year period. Higher sales of our molecular products and the OraQuick® HIV self-test were the main drivers of this performance.

Our molecular revenues rose 248% to $29.8 million in the fourth quarter of 2017 compared to $8.6 million in the fourth quarter of 2016. Sales of our Oragene® product to commercial customers increased 368% to $26.9 million, largely due to our new $143 million agreement to supply Oragene® devices to a leading consumer genomics customer coupled with higher sales to our other large customers. Microbiome sales continued to gain traction and increased 180% to $1.1 million in the fourth quarter of 2017 as compared to the fourth quarter of 2016. Academic sales decreased 29% to $1.7 million due to customer ordering patterns.

International HIV sales increased 171% to $3.6 million from $1.3 million in the fourth quarter of 2016 due to higher sales of our OraQuick® HIV self-test into Africa. The tests shipped into Africa during the quarter were subject to the support payments under our charitable support agreement with the Gates Foundation and included countries outside of the STAR initiative. Product revenue during the fourth quarter of 2017 included approximately $589,000 of support payments associated with this agreement.

Domestic professional HIV sales decreased 9% to $4.6 million in the fourth quarter of 2017, compared to $5.0 million in the fourth quarter of 2016, due to factors we have previously discussed.

International HCV sales in the fourth quarter of 2017 decreased 61% to $1.1 million from $2.9 million in the same period of 2016, primarily due to the non-renewal of a foreign government supply contract in support of a country-wide HCV elimination program combined with lower sales in Asia. Domestic HCV sales rose 11% in the fourth quarter of 2017 to $2.5 million from $2.2 million in the prior-year period, primarily due to increased HCV purchases by public health customers.

Other Revenues were $1.8 million in the current quarter, representing $1.3 million of funding we received from BARDA for our rapid Ebola and Zika products and $470,000 in reimbursement of certain non-product costs under our agreement with the Gates Foundation. This cost reimbursement is separate from the product support payments I previously mentioned. Other Revenues in the fourth quarter of 2016 totaled $6.9 million and included $747,000 in BARDA funding and $6.1 million of exclusivity revenues under the AbbVie HCV co-promotion agreement which terminated effective December 31, 2016.

Gross Margin – Ron Spair

Gross margin for the fourth quarter of 2017 was 55% compared to 67% reported for the fourth quarter of 2016. Margin for the current quarter decreased primarily due to the absence of AbbVie exclusivity revenues in 2017, an increase in lower margin product sales, and higher scrap and spoilage costs.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the fourth quarter of 2017 were $18.4 million compared to $16.9 million in the comparable period of 2016. This increase was largely due to higher lab supplies, staffing and consulting costs, and costs incurred in the fourth quarter of 2017 as a result of the non-renewal of the foreign government HCV supply contract. In addition, fourth quarter 2016 costs were reduced by $1.4 million as a result of a settlement payment received in connection with a dispute with a supplier of raw materials. These expense increases were partially offset by lower legal fees and the absence in Q4 2017 of costs associated with a corporate restructuring which occurred in the fourth quarter of 2016.

Income Taxes – Ron Spair

Income tax expense was $3.0 million in the fourth quarter of 2017 compared to an income tax benefit of $31,000 in the same period last year and consists entirely of Canadian taxes due.

Late in the fourth quarter, the Tax Cuts and Jobs Act was signed into law. In addition to lowering the U.S. corporate tax rate to 21%, other provisions of the law include a mandatory deemed repatriation tax on earnings and profits of offshore entities, a tax on global intangible low tax income, accelerated deductibility of capital expenditures and the elimination of the deductibility of executive compensation above a certain threshold. In collaboration with our outside tax advisors, we have conducted an analysis of the impact of the tax law changes on the Company and have several preliminary observations.

The mandatory deemed repatriation tax calculated through 2017 on the accumulated earnings and profits of our Canadian subsidiary, DNA Genotek, has been offset through the utilization of $24.0 million of our net operating losses in the U.S. We are now in a position to repatriate accumulated cash at our subsidiary subject to certain limitations without the imposition of further U.S. taxes, should we elect to do so.

Beginning in January 2018, our earnings and profits in Canada will be subject to the U.S. tax imposed on global intangible low tax income. Due to the rules in the U.S. tax code associated with the utilization of net operating loss carryforwards and tax credits, we will utilize our net operating losses to fully offset this tax obligation. It should be noted that for U.S. federal tax purposes, we do not envision paying cash taxes in 2018.

Net Income – Ron Spair

From a bottom line perspective, we reported net income of $7.3 million, or $0.12 per share on a fully diluted basis, for the fourth quarter of 2017, compared to net income of $7.2 million, or $0.13 per share, for the same period of 2016.

Cash Flow from Operations and Liquidity – Ron Spair

Turning to our balance sheet and cash flow, we continue to maintain a solid cash and liquidity position. Our cash and investments balance at December 31, 2017 was $176.6 million compared to $120.9 million at December 31, 2016. Cash generated by operating activities during of 2017 was $28.2 million compared to $24.6 million in the same period of 2016.

First Quarter 2018 Consolidated Financial Guidance – Ron Spair

During Q1-2018, we announced the upcoming retirement of Doug Michels, our current President and CEO, the appointment of Dr. Stephen Tang as his successor, as well as my expected retirement. Charges associated with these transitions are expected to total $6.8 million in Q1-2018 and $1.7 million in Q2-2018. These charges are primarily non-cash charges associated with modifications to existing stock grants made to the retiring executives and expenses associated with the onboarding of our new President and CEO.

So as we look at overall Q1-2018 guidance, we currently expect revenues to range between $40.0 million and $41.0 million and a consolidated net loss of approximately $0.06 per share, inclusive of our transition costs.

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

Business Update – Doug Michels

Thanks Ron.

Molecular Business Growth Drivers – Doug Michels

As noted previously, our molecular business performed exceptionally well in 2017, with full-year revenues more than doubling when compared to 2016. Of our top 20 customers, 17 increased their purchases year-over-year, with our top two accounts growing an aggregate of 371% for the full-year. Our fourth quarter molecular revenues reached an all-time record of $29.8 million, which represents a 248% increase over Q4 of last year and sequential growth over the third quarter of 61%.

Genomics

Our commercial genomics business continues to be the primary growth driver for our molecular business, with most of the growth occurring in the direct-to-consumer and clinical genetic testing markets. For the full-year 2017, 14 of our top 15 commercial genomics accounts increased purchases over 2016, with triple digit growth in nine of these accounts and strong double digit growth in five. We are seeing market adoption of personal genome services on a global scale and we believe this trend will continue and support future growth for our business.

On the international front, we continue to see strong growth, particularly in Asia, where our revenues grew approximately 93% in Q4-2017 compared to the prior year period. Q4 was our best quarter ever for sales in Japan, where revenue grew 226% compared to Q4 of 2016. Revenue in China grew 114% in Q4 and 78% for the full-year 2017, compared to the prior year periods. We recently closed a large repeat order with a direct-to-consumer firm in China offering whole genome sequencing using our Oragene® device. We also acquired a new customer in China that will be offering one of the first genetic-based skin care products. We expect demand from these and other customers to continue to drive revenue growth in China and other parts of Asia in 2018 and beyond.

Microbiome

2017 microbiome revenues essentially tripled from 2016 and our Q4 revenues grew 180% compared to the prior year quarter. The increase in sales reflects our continued acquisition of new customers and strong repeat business from existing customers. In this regard, over 57% of our Q4 purchasers were repeat customers and represented 70% of our microbiome revenue for the period. We also continue to leverage our relationships with existing genomics customers, with sales to these existing customers representing 40% of our microbiome purchasers in 2017.

A key factor driving business growth has been microbiome-based discovery work where our product is being used in support of clinical trials. During Q4, approximately 28% of our microbiome revenues were generated in support of clinical trials being conducted or sponsored by biopharma customers. The average dollar value of our microbiome-related services agreements has also doubled in size compared to 2016 and over 50% of our services customers typically return as repeat purchasers within 12 months.

An exciting new project in the microbiome space is our collaboration with Janssen, a subsidiary of J&J, and DNA Nexus, to provide product to approximately 1,000 labs around the world as part of the MOSAIC standards challenge project. MOSAIC is a cloud-based microbiome informatics platform that provides a secure and collaborative space where researchers can develop, improve, compare and share methods in microbiome research. For this work, it is essential to start with a known sample input, which means that stabilization and standardization are critical for activities that occur downstream. Our microbiome products are uniquely qualified to meet these requirements.

We are also happy to announce that our OMNIgene® line of products has been selected by Harvard's T.P. Chan School of Public Health for a microbiome specific re-collection of the Nurse's Health Study II Cohort. There are a few final details of this supply arrangement being discussed, which should be finalized very soon. Under this project, 75,000 samples are expected to be collected over a 12-month period beginning in the second quarter of this year. The samples will be housed in the newly created Biobank for Microbiome Research in Massachusetts. We are extremely happy that our technology has been chosen for one of the most highly regarded epidemiological studies in the world as it expands to include microbiome information.

Infectious Disease Testing – Doug Michels

Turning to infectious disease, our revenues grew moderately for Q4, but are up 28% for the full-year compared to 2016.

HIV Business

Our international HIV business was a major growth driver throughout 2017 and turned in another strong performance in Q4, where revenues rose 171% compared to Q4 2016. This growth is primarily the result of HIV self-test sales in Africa.

As discussed in prior calls, Population Services International ("PSI") has initiated Phase II of the Self-Testing in Africa ("STAR") project, which is expected to deploy 4 million self-tests into an expanded list of African countries, with the largest being South Africa. We have already started fulfilling orders under Phase II and we expect this will continue throughout 2018.

We continue to benefit from our charitable support agreement with the Gates Foundation, as the more favorable pricing we can now offer is stimulating additional demand. We expect to ship 30-40% more HIV self-tests in Q1-2018 than we did in Q4 of last year.

We are also seeing increasing self-test demand outside of the STAR project. As an example, we expect to begin deploying tests in the second half of 2018 under a new initiative funded by a large NGO. This program will target the Francophone countries and we expect this initiative will be large, although not as comprehensive as the STAR project. We are also participating in pilot programs initiated by PSI to provide our self tests into the pharmacy market in Sub-Sahara Africa. The pharmacy channel will be important in order to fully realize the benefit of self-testing in these markets.

Our international HIV sales more than offset the declines in our U.S. HIV business. We are continuing to experience the same domestic trends seen in the past, with declines resulting from the CDC's preference for a fourth generation automated laboratory testing solution, price competition and funding pressures in the public health market. Nevertheless, we continue to implement programs to mitigate the impact of these factors on our business.

HCV Business

As Ron noted, our Q4 HCV revenues declined when compared to the fourth quarter of 2016, although our overall HCV business performed very well for the full year. The main reason for the Q4 decline was the non-renewal of a foreign government supply contract in support of a country-wide HCV eradication program, which we discussed at length during our last earnings call.

Our HCV domestic business increased revenues 11% in Q4 compared to the year-ago period. This growth reflects contribution from all three of the major markets in this business, which include public health, hospitals and physician's offices. Our customers continue to find the resources needed to support HCV testing and treatment programs despite continued funding challenges domestically.

Operations Update – Doug Michels

Turning to operations, we have continued the capacity expansion efforts described in prior calls.

- The second manufacturing and packaging room at our Thailand contractor, which was previously installed, has now been validated. This doubles the manufacturing capacity of this site and will be used for the supply of non-U.S. and non-CE marked OraQuick® product. During 2018, we plan to build additional capacity in Thailand to meet the demand forecasted for 2019 and beyond.
- As noted on our last call, a fourth automated assembly line for Oragene® collection kits has been built and is expected to be fully operational in April of this year.

- Lastly, construction of the new leased warehouse here in Bethlehem is progressing on schedule. After completion of environmental qualification and submission for regulatory approval, we expect the new warehouse to be operational in April.

New Director Appointment

A final point I want to address is a recent addition to our Board of Directors. Dr. Aradhana Sarin has been appointed as a Class II Director with her initial term expiring at the Company's 2020 Annual Meeting of Stockholders. Aradhana currently serves as the head of business development at Alexion Pharmaceuticals, a global biopharmaceutical company. She has over 20 years of professional experience in global health care, primarily with large financial institutions that include Citi Global Banking, UBS and J.P. Morgan. Aradhana is a physician and early in her career she practiced for several years in both India and Africa. We could not be more pleased to have Aradhana join our Board.

Conclusion – Doug Michels

So, in conclusion, we delivered excellent financial results for both Q4 and the full year 2017. The molecular collections business and the OraQuick® HIV self test were the primary drivers of this performance. We expect that continued strength in these businesses will be a big part of our performance in 2018. We are also making the necessary investments in our manufacturing capacity to meet the expected future demand for our products.

I am confident that as you come to know Steve Tang, you will understand why he was chosen to lead the Company. He is an impressive individual and a talented executive. I fully expect that he will take OraSure to new heights. In summary, our business has never been stronger, and we are starting the new year with significant momentum. We expect 2018 to be another successful year.

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

* * * *

[Q&A session]

Final Conclusion – Doug Michels

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 increased reliance on U.S. government contracts; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing, collection or other products; changes in market acceptance of products based

on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in credit agreements; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission ("SEC" filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2016, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this call, and we undertake no duty to update these statements.