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

FORM 8-K

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

Date of Report (Date of earliest event reported): November 1, 2017

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

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

220 East First Street **Bethlehem, Pennsylvania**	**18015-1360**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 – Results of Operations and Financial Condition.

On November 1, 2017, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter and nine-month period ended September 30, 2017, and providing financial guidance for the fourth quarter of 2017. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

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

Item 7.01 – Regulation FD Disclosure.

On November 1, 2017, 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 nine-month period ended September 30, 2017, provided financial guidance for the fourth quarter of 2017 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 November 1, 2017, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and nine-month period ended September 30, 2017, and providing financial guidance for the fourth quarter of 2017.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Third Quarter 2017 Analyst/ Investor Conference Call held November 1, 2017.

Signatures

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

ORASURE TECHNOLOGIES, INC.

Date: November 1, 2017

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

OraSure Technologies, Inc.

Company Contact:

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

OraSure Announces 2017 Third Quarter Financial Results

BETHLEHEM, PA – November 1, 2017 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its consolidated financial results for the three and nine months ended September 30, 2017.

Financial Highlights

- Consolidated net revenues for the third quarter of 2017 were $42.3 million, a 31% increase from the third quarter of 2016. Consolidated net product revenues were $41.2 million, representing a 62% increase over the third quarter of 2016.
- Consolidated net revenues for the nine months ended September 30, 2017 were $115.0 million, a 24% increase from the comparable period of 2016. Consolidated net product revenues were $111.8 million, representing a 43% increase over the first nine months of 2016.
- Net molecular collection systems revenues were $18.6 million during the third quarter of 2017, which represents a 123% increase over the third quarter of 2016. Net molecular collection systems revenues during the nine months ended September 30, 2017 were $45.3 million, a 92% increase from the comparable period in 2016.
- Total OraQuick® HCV sales of $8.0 million for the third quarter of 2017 increased 185% compared to the third quarter of 2016 and included a 376% increase in international sales of the product from the prior year quarter. OraQuick® HCV sales were $21.8 million in the first nine months of 2017, a 144% increase over the first nine months of 2016 and included a 325% increase in international sales of the product from the prior year period.

- Net revenues from international sales of the Company's OraQuick® HIV products of $3.1 million increased 176% compared to the third quarter of 2016. Total international OraQuick® HIV sales for the nine months ended September 30, 2017 were $7.7 million, a 97% increase over the first nine months of 2016.
- Consolidated net income for the third quarter of 2017 was $5.8 million, or $0.09 per share on a fully diluted basis, which compares to consolidated net income of $6.2 million, or $0.11 per share on a fully diluted basis, for the third quarter of 2016. Consolidated net income for the nine months ended September 30, 2017 was $23.6 million, or $0.39 per share on a fully-diluted basis, which compares to consolidated net income of $12.5 million, or $0.22 per share, for the comparable period of 2016. Results for the first nine months of 2017 included a $12.5 million pre-tax gain related to a litigation settlement that was accounted for as a reduction of operating expenses.
- Cash and investments totaled $180.3 million and working capital amounted to $182.7 million at September 30, 2017.

"We are very pleased with the Company's third quarter financial results," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "Sales of our molecular collections products during the quarter were particularly strong and our infectious disease business experienced strong growth compared to the prior year quarter. We continue to deliver on our strategic growth priorities and we expect our strong performance to continue into the fourth quarter."

Financial Results

Consolidated net product revenues for the third quarter of 2017 increased 62% over the comparable period of 2016. Consolidated net product revenues for the first nine months of 2017 increased 43% over the comparable period of 2016. These increases were 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. Product revenues associated with the 2017 sales of the OraQuick® HIV self-test include $458,000 of support payments associated with the charitable support agreement with the Bill and Melinda Gates Foundation ("Gates Foundation").

Consolidated other revenues for the third quarter and first nine months of 2017 were $1.2 million and $3.3 million, respectively. This compares to consolidated other revenues for the third quarter and first nine months of 2016 of $6.8 million and $14.4 million, respectively. Other revenues in the third quarter of 2017 included $939,000 of funding received from the U.S. Biomedical Advanced Research Development Authority ("BARDA") and $218,000 in cost reimbursement under the Company's charitable support agreement with the Gates Foundation. Other revenues in the third quarter of 2016 included $676,000 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 in the first nine months of 2017 included $3.1 million of BARDA funding and $218,000 of cost reimbursement under the Gates Foundation agreement. Other revenues in the first nine months of 2016 included $1.6 million of BARDA funding and $12.8 million of AbbVie exclusivity revenues.

Consolidated gross margin was 58% and 61% for the three and nine months ended September 30, 2017, respectively. Consolidated gross margin for the three and nine months ended September 30, 2016 was 70% and 69%, respectively. Gross margin for the current quarter and the first nine months 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 $17.3 million during the third quarter of 2017 compared to $16.5 million in the third quarter of 2016. For the nine months ended September 30, 2017, consolidated operating expenses were $40.4 million, a $10.5 million decrease from the $50.9 million reported for the nine months ended September 30, 2016. The quarterly increase was largely due to higher sales and marketing expenses resulting from higher staffing costs, higher external commissions to be paid to certain international distributors, and an increase in our allowance for doubtful accounts related to a genomics customer. The reduction in the nine-month period 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.

Operating income increased 19% to $7.3 million in the third quarter of 2017 compared to $6.1 million in the third quarter of 2016. Operating income for the nine months ended September 30, 2017 was $30.1 million, a 128% increase over the comparable period in 2016.

The Company's cash and investment balance totaled $180.3 million at September 30, 2017, compared to $120.9 million at December 31, 2016. Working capital was $182.7 million at September 30, 2017, compared to $139.1 million at December 31, 2016. For the nine months ended September 30, 2017, the Company generated $30.4 million in cash from operations.

Fourth Quarter 2017 Outlook

The Company expects consolidated net revenues to range from $45 million to $46 million and is projecting consolidated net income of $0.08 to $0.09 per share for the fourth quarter of 2017.

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

Unaudited

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Results of Operations				
Net revenues	$42,314	$32,251	$115,036	$92,699
Cost of products sold	17,670	9,576	44,605	28,626
Gross profit	24,644	22,675	70,431	64,073
Operating expenses:				
Research and development	3,228	3,196	9,536	8,547
Sales and marketing	7,162	6,428	21,541	22,531
General and administrative	6,935	6,907	21,777	19,803
Gain on litigation settlement	—	—	(12,500)	—
Total operating expenses	17,325	16,531	40,354	50,881
Operating income	7,319	6,144	30,077	13,192
Other income (expense)	113	498	676	(34)
Income before income taxes	7,432	6,642	30,753	13,158
Income tax expense	1,669	400	7,121	634
Net income	$ 5,763	$ 6,242	$ 23,632	$12,524
Earnings per share:				
Basic	$ 0.10	$ 0.11	$ 0.40	$ 0.23
Diluted	$ 0.09	$ 0.11	$ 0.39	$ 0.22
Weighted average shares:				
Basic	60,090	55,653	58,511	55,549
Diluted	62,172	56,530	60,569	56,273

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2017	2016	% Change	2017	2016
Infectious disease testing	$ 16,577	$10,412	59%	39%	32%
Risk assessment testing	3,149	3,481	(10)	7	11
Cryosurgical systems	2,879	3,240	(11)	7	10
Molecular collection systems	18,552	8,327	123	44	26
Net product revenues	41,157	25,460	62	97	79
Other	1,157	6,791	(83)	3	21
Net revenues	$ 42,314	$32,251	31%	100%	100%

	Nine Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2017	2016	% Change	2017	2016
Infectious disease testing	$ 47,822	$34,729	38%	42%	37%
Risk assessment testing	9,517	9,746	(2)	8	10
Cryosurgical systems	9,116	10,162	(10)	8	11
Molecular collection systems	45,316	23,649	92	39	26
Net product revenues	111,771	78,286	43	97	84
Other	3,265	14,413	(77)	3	16
Net revenues	$115,036	$92,699	24%	100%	100%

	Three Months Ended September 30,			Nine Months Ended September 30,		
HIV Revenues	2017	2016	% Change	2017	2016	% Change
Domestic	$3,622	$4,858	(25)%	$12,401	$16,446	(25)%
International	3,069	1,110	176	7,738	3,934	97
Domestic OTC	1,515	1,311	16	4,951	4,574	8
Net product revenues	$8,206	$7,279	13%	$25,090	$24,954	1%

HCV Revenues	Three Months Ended September 30, 2017	2016	% Change	Nine Months Ended September 30, 2017	2016	% Change
Domestic	$1,889	$1,529	24%	$ 5,980	$ 5,218	15%
International	6,154	1,293	376	15,817	3,722	325
Net product revenues	8,043	2,822	185	21,797	8,940	144
Amortization of exclusivity payments	—	6,114	(100)	—	12,837	(100)
Net HCV-related revenues	$8,043	$8,936	(10)%	$21,797	$21,777	0%

Cryosurgical Systems Revenues	Three Months Ended September 30, 2017	2016	% Change	Nine Months Ended September 30, 2017	2016	% Change
Domestic professional	$1,426	$1,456	(2)%	$4,368	$ 4,155	5%
International professional	179	162	10	552	607	(9)
Domestic OTC	325	339	(4)	957	1,062	(10)
International OTC	949	1,283	(26)	3,239	4,338	(25)
Net product revenues	$2,879	$3,240	(11)%	$9,116	$10,162	(10)%

Condensed Consolidated Balance Sheets (Unaudited)

	September 30, 2017	December 31, 2016
Assets		
Cash and cash equivalents	$ 78,610	$ 109,790
Short-term investments	83,372	11,160
Accounts receivable, net	28,099	19,827
Inventories	16,859	11,799
Other current assets	2,395	3,865
Property and equipment, net	21,496	20,033
Intangible assets, net	8,972	10,337
Goodwill	20,257	18,793
Long-term investments	18,290	—
Other non-current assets	3,909	2,331
Total assets	$ 282,259	$ 207,935
Liabilities and Stockholders' Equity		
Accounts payable	$ 9,624	$ 4,633
Deferred revenue	1,186	1,388
Other current liabilities	15,813	11,314
Other non-current liabilities	3,928	2,304
Deferred income taxes	2,194	2,446
Stockholders' equity	249,514	185,850
Total liabilities and stockholders' equity	$ 282,259	$ 207,935

Additional Financial Data (Unaudited)

	Nine Months Ended September 30,	
	2017	2016
Capital expenditures	$ 3,462	$ 3,512
Depreciation and amortization	$ 4,589	$ 4,152
Stock-based compensation	$ 5,213	$ 4,438
Cash provided by operating activities	$30,361	$25,180

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2017 third quarter financial results, certain business developments and financial guidance for the fourth quarter of 2017, 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 #90105011 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 November 8, 2017, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #90105011.

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, high unemployment levels and poor credit 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 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; history of losses and ability to achieve 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; ability to successfully renew contracts or enter into new contracts with existing customers; 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 press release and OraSure Technologies undertakes no duty to update these statements.

# # #

OraSure Technologies, Inc.
2017 Third Quarter
Analyst/Investor Conference Call
November 1, 2017

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 another outstanding quarter. Revenues exceeded our guidance and reached a record level. On the bottom line, our results were strong and met expectations. The strong quarterly performance is further evidence that our products are well suited to address the large market opportunities we are pursuing in both the molecular collection and infectious disease businesses. We continue to believe that these opportunities are in the very early stages of development and that we are well positioned to capitalize on them. Additionally, we are making the necessary investments to increase manufacturing capacity in Bethlehem, in Canada and in Thailand to meet the growing demand for our products.

Our Q3 performance was primarily driven by growth in our molecular collection and HCV businesses. We also reported strong sales of our OraQuick® HIV self-test, reflecting the impact of World Health Organization ("WHO") prequalification, the expansion of the Self Testing in Africa ("STAR") project and our work under the charitable support agreement with the Gates Foundation.

With respect to the quarter -

- Our consolidated net revenues grew 31% compared to the year ago period and topped $42 million for the first time. This is the second consecutive quarter of $40 million or more in revenues. Product revenue growth for Q3 was an extraordinary 62%.

- Our molecular business delivered another record performance. Q3 revenues reached $18.6 million, which represents a 123% increase over Q3 of last year.
- Our infectious disease business also performed extremely well, with 59% revenue growth from the year-ago period. Significant increases in both international and domestic sales of our HCV product and strong growth in HIV self-test revenues were the primary contributors.
- On the bottom line, we generated $0.09 per share and we ended Q3 with over $180 million in cash and cash equivalents.

In short, Q3 continued the strong growth we have seen throughout the year and represents further progress in advancing our strategic priorities. We expect this trend to continue in Q4 as well.

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

Ron...

Third 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 continues to be a very successful year. Our third quarter consolidated net revenues increased 31% to $42.3 million, compared to $32.3 million reported in the third quarter of 2016. Notably, our consolidated net product revenues rose 62% to $41.2 million compared to the prior-year period. Higher sales of our molecular products, OraQuick® HCV, and the OraQuick® HIV self-test, were the main drivers of this performance.

Our molecular revenues rose 123% to $18.6 million in the third quarter of 2017 compared to $8.3 million in the third quarter of 2016. Sales of our Oragene® product to commercial customers increased 157% and academic sales rose 46%, largely due to higher customer demand and customer ordering patterns.

International sales of our HCV test in the third quarter of 2017 rose 376% to $6.1 million from $1.3 million in the same period of 2016, primarily due to the continued shipment of product to a foreign government pursuant to a previously announced countrywide elimination program. Domestic OraQuick® HCV product sales rose 24% in the third quarter of 2017 to $1.9 million from $1.5 million in the prior-year period, primarily due to increased HCV purchases by public health customers.

International sales of our HIV test increased 176% to $3.1 million from $1.1 million in the third quarter of 2016 largely due to higher sales of our OraQuick® HIV self-test into Africa. The majority of tests shipped into Africa during the quarter were subject to the support payments under our charitable support agreement with the Gates Foundation. Product revenue during the third quarter of 2017 included approximately $458,000 of support payments associated with this agreement.

Domestic professional HIV sales decreased 25% to $3.6 million in the third quarter of 2017, compared to $4.9 million in the third quarter of 2016, as a result of competition from other products, customer ordering patterns and some impact from recent severe weather conditions.

Other Revenues were $1.2 million in the current quarter, representing $939,000 of funding we received from BARDA for our rapid Ebola and Zika products and $218,000 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 third quarter of 2016 totaled $6.8 million and included $676,000 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 third quarter of 2017 was 58% compared to 70% reported for the third quarter of 2016. Margin for the current quarter decreased primarily due to the absence of AbbVie exclusivity revenues in 2017 as a result of the termination of our agreement at the end of 2016, an increase in lower margin product sales, and higher scrap and spoilage costs.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the third quarter of 2017 were $17.3 million compared to $16.5 million in the comparable period of 2016. This increase was largely due to higher staffing costs, higher external commissions paid to certain international distributors, and an increase in our allowance for doubtful accounts.

Income Taxes – Ron Spair

Income tax expense was $1.7 million in the third quarter of 2017 compared to $400,000 in the same period last year and consists entirely of Canadian taxes due.

Net Income – Ron Spair

From a bottom line perspective, we reported net income of $5.8 million, or $0.09 per share on a fully diluted basis, for the third quarter of 2017, compared to net income of $6.2 million, or $0.11 per share, for the same period of 2016.

Cash Flow from Operations and Liquidity – Ron Spair

Turning briefly to our balance sheet and cash flow, we continue to maintain a solid cash and liquidity position. Our cash and investments balance at September 30, 2017 was $180.3 million compared to $120.9 million at December 31, 2016. Cash generated by operating activities for the first nine months of 2017 was $30.4 million compared to $25.2 million in the same period of 2016.

Fourth Quarter 2017 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the fourth quarter of 2017, we are projecting consolidated net revenues of approximately $45 million to $46 million. We are also projecting consolidated net income of approximately $0.08 to $0.09 per share for Q4 of 2017.

As we look a bit further out to Q1 of 2018, our current thinking is that we may see a step down in our molecular collection systems business due to seasonality associated with our expected performance in Q4 of 2017. This together with what has been a historically lower quarter for infectious disease and cryosurgery revenues could result in our total Q1 revenues being down sequentially while being up by about 25% when compared to Q1 of 2017. We will be fine tuning our expectations for Q1-2018 on our 4th quarter call but we wanted to manage your expectations in advance.

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

Business Update – Doug Michels

Thanks, Ron. I'll now provide a few business updates, starting with our molecular business since that was the most significant contributor to our strong Q3 performance.

Molecular Business Growth Drivers – Doug Michels

Our molecular business performed exceptionally well in Q3, as it did during the first half of the year. Revenues in the quarter increased 123% compared to last year and we expect this trend to continue in Q4.

Genomics

A primary driver was continued growth in our commercial genomics business, both compared to the prior year quarter and sequentially from Q2 of this year. Revenues grew as a result of the addition of new customers and higher sales to many of our largest customers. During the quarter, 16 of our top 20 molecular customers increased their purchases over the prior-year period. Year to date, 19 of the top 20 customers generated higher sales when compared to last year.

Our genomics business also benefitted from higher international sales and expanded adoption of our services offerings.

- Our international business doubled from the prior year quarter and delivered double digit sequential growth from Q2.
- Our GenoFind services business had another record quarter in Q3, delivering a four-fold increase from the prior year quarter and double the revenue from the previous quarter. Growth from existing customers as well as the acquisition of new business continues to drive the strong performance of our services business.
- Finally, we won a significant new contract during Q3 to provide customized collection devices and GenoFind services for a pharmacogenomics pilot focusing on members of a state-wide retirement group benefit plan. While this is a pilot program, we

believe this could expand into a much broader opportunity involving a large number of retirees under the plan. In addition, it could serve as a model for adoption by other similar state-wide benefit plans seeking to perform pharmacogenomic testing.

Microbiome

Our Microbiome business continued to deliver strong revenue performance during Q3, which represented a doubling of revenues from the prior year quarter. The ongoing acquisition of new customers and strong repeat business from existing customers in both the academic and commercial markets are driving our microbiome revenue.

A growing number of current microbiome customers are repeat purchasers with the largest customers purchasing in more than two quarters during each of the past two years. In addition, our microbiome service offerings are up 250% over the prior year quarter as both academic and commercial customers leverage our end–to-end offerings for sample processing and analysis. Aggregate microbiome revenues during the first three quarters now total $2.4 million, which substantially exceeds the $1.1 million recorded for all of 2016.

In short, we continue to see strong interest in our microbiome products and services and are very optimistic about the future for this part of the business.

Infectious Disease Testing – Doug Michels

In the infectious disease area, the main drivers continue to be international HCV and HIV self-test sales.

HCV Business

Our international HCV business continued its strong growth in Q3, largely due to demand for countrywide elimination initiatives and related government supply agreements we have previously highlighted. As Ron noted, our Q3 revenues increased 376% compared to the prior year quarter.

We have previously mentioned our ongoing discussions with a large government customer to renew our existing supply arrangement. For some time, the indication from this customer had been that the contract would likely be renewed at a volume well in excess of the existing contract. Our renewal discussions continued along these lines until just last week when, unfortunately, this customer advised us that it intends to transition its rapid HCV testing to an all laboratory-based model in the next contract period because of budget pressures.

This development came as quite a surprise, given prior discussions and negotiations with this customer. We had been engaged in discussions for a straight-forward renewal and expansion of our supply arrangement, but late in the discussions the government decided to move to a tender process requiring a broader set of components to support HCV testing. We participated in this tender with our distributor. Although we were told that our rapid HCV test provided the best technical solution to meet their needs, in the end the customer decided to adopt a laboratory testing solution based solely on cost. The winning bidder apparently offered pricing that was not even close to being economically viable for us.

We received repeated feedback from the customer that our HCV test performed very well and that the testing program was extremely successful, which made news of the change even more surprising. We continue to believe that our rapid HCV test can and will perform a much needed role in broad based HCV testing programs, especially where much of the testing occurs in rural or remote areas of a country. Our OraQuick® HCV oral fluid test is ideal for those locations since laboratory testing requires a blood collection and more involved process to deliver samples

to a laboratory. We understand that some officials in the government share this view and continue to advocate for our product, so we are hopeful that in future periods we might again participate in this government's program with the OraQuick® HCV test.

In the meantime, the level of interest in HCV testing and treatment remains strong globally and we are continuing to market our product for other large scale screening programs. Although international programs are increasingly focused on cost, we believe the value proposition for a high quality, rapid oral fluid HCV test will support participation in these programs. Overall, we remain optimistic about our international HCV business model. .

On the domestic side, our HCV business grew 24% compared to the prior year quarter. This growth was driven by expansion of existing programs and the initiation of new testing programs. Growth in the public health and physician offices markets were partially offset by small declines in our hospital business. Despite continued funding challenges domestically, organizations are finding ways to channel resources from other areas into HCV testing and treatment programs.

On past calls, we have mentioned our work with the Southern Cities Initiative. This is a collaboration among OraSure, community-based organizations, advocacy groups and certain pharmaceutical companies. The goal is to expand HCV testing to high prevalence, hard-to-reach populations in urban settings so that diagnosed individuals can be linked to care. The initial cities targeted include Columbia, SC, Birmingham and Tuskegee, AL, and Baton Rouge and New Orleans, LA. During the past 9 months, thousands of individuals have been tested with our product and the results indicate a prevalence of almost 10% in these populations. We are working to expand this program into other cities.

International HIV Self Testing

Our international HIV business turned in a strong performance during Q3, with growth of 176% compared to the prior year quarter. This increase was driven primarily by HIV self-testing orders for Phase II of the STAR project, along with professional product sales in Africa and Asia.

During our last call, we indicated that Phase II of the STAR project is expected to deploy 4 million self-tests and that we expected an additional large order to be shipped prior to year end. I am pleased to report that we received this large order and will be shipping product in the fourth quarter. Outside of the STAR program, we are beginning to see other funding organizations start to fund scale-up of HIV self-testing in non-STAR countries. The apparent trigger for this is the receipt of WHO prequalification for our product, as we previously disclosed. We are also in discussions with an NGO that expects to initiate HIV self-testing in several countries in West Africa. Although orders are not expected until 2018, this is another indication that momentum behind HIV self-testing continues to build following receipt of our WHO prequalification.

Our execution under the Charitable Support Agreement with the Gates Foundation also continues to go very well. The relevant health authorities in 50 countries covered by the agreement have been made aware of our arrangement with Gates and we are beginning to see more sizable orders from countries outside of those covered by the STAR project.

So, our HIV self-testing business continues to grow nicely and we believe this business will be a significant contributor to our infectious disease business in future periods.

Domestic HIV Business

On the domestic front, there has not been much change in the trending for our HIV business. The factors underlying the decline in this business are largely the same as we have seen in prior periods. These include the CDC’s continued movement for use of fourth generation automated laboratory testing equipment, price competition, funding pressures in the public health market and the timing of orders. The recent severe weather conditions also had an impact on the current quarter.

Once again, the decline in our Q3 domestic HIV sales was more than offset by the growth in our HCV and HIV self-test businesses. We expect the challenging market factors will continue to affect our domestic HIV sales in future periods.

Tuberculosis

In prior calls, we indicated that the WHO was expected to issue a report regarding its technical review of sputum transport solutions for tuberculosis, including data for our OMNIgene® ● Sputum product. This guidance report was released this past month and indicated that some data was inconclusive. Consequently, further work is required in order to receive a WHO recommendation for routine use. The report indicated that WHO supports the procurement of OMNIgene® ● Sputum for operational research, which we view as positive. This will allow funding organizations to support interested parties doing pilots of various sizes. Going forward, we will be working with the WHO to define the additional data required to support a recommendation for routine use of OMNIgene® ● Sputum and we will be working with our customers to generate that data.

Emerging Diseases

In the area of emerging diseases, I only have one item to address and that relates to our new Zika test. We previously indicated that we expected to submit for Emergency Use Authorization ("EUA") from the FDA in Q4 of this year. Because of ongoing technical challenges with the test, this submission will likely be pushed into 2018. We remain committed to obtaining EUA approval and successfully commercializing this test.

Operations Update – Doug Michels

A final area I will address is our efforts to expand manufacturing capacity to meet the increasing demand for our products. We have made good progress in a number of areas:

- Our second automated OraQuick® production line is now operational and is running on two shifts.
- Work with the supplier for our third automated OraQuick® line is also progressing nicely. This equipment is now in the design phase and is expected to be installed in mid-2018 with full operation by the end of the year or early 2019.
- The addition of capacity at our Thailand contractor has also progressed, and the new assembly equipment has now been installed. We expect validation of this equipment

to be completed by year-end with regulatory approvals received in early 2018. Our Thailand contractor is used for the supply of non-US and non-CE marked OraQuick® HIV product primarily in developing countries. Given the strength we are seeing in our self-testing business, we are now planning to build two additional lines in Thailand in 2018 to provide for additional capacity.

- A new automated assembly line for Oragene® DNA collection kits was put into operation in mid-October and yet another automated line is being built and is scheduled for delivery in late December or early January with operation expected in March or April of next year.
- We also recently signed a lease for a new warehouse near our Bethlehem facility as part of our capacity expansion project. Construction of the warehouse is expected to be completed by February 1, 2018 and should be fully functional no later than April 1st.

Conclusion – Doug Michels

So, in summary, our Q3 performance was very strong. We will continue to focus on expanding the use of our products around the globe, consistent with our strategic priorities. We are making the necessary investments in our manufacturing capacity to meet future demand and capitalize on the many opportunities before us. We expect the recent trends in our business to continue through the remainder of 2017 and to enter 2018 with solid momentum.

So with that, we can 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, high unemployment levels and poor credit 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 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; history of losses and ability to achieve 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; ability to successfully renew contracts or enter into new contracts with existing customers; 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 OraSure Technologies undertakes no duty to update these statements.