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): August 2, 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 August 2, 2017, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter and six-month period ended June 30, 2017, and providing financial guidance for the third 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 August 2, 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 six-month period ended June 30, 2017, provided financial guidance for the third 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 August 2, 2017, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and six-month period ended June 30, 2017, and providing financial guidance for the third quarter of 2017.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Second Quarter 2017 Analyst/ Investor Conference Call held August 2, 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: August 2, 2017

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

Index to Exhibits

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OraSure Technologies, Inc.

Company Contact:

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

OraSure Announces 2017 Second Quarter Financial Results

BETHLEHEM, PA – August 2, 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 six months ended June 30, 2017.

Financial Highlights

- Consolidated net revenues for the second quarter of 2017 were $40.2 million, a 28% increase from the second quarter of 2016. Net product revenues were $39.1 million, representing a 42% increase over the second quarter of 2016.
- Consolidated net revenues for the six months ended June 30, 2017 were $72.7 million, a 20% increase from the comparable period of 2016. Net product revenues were $70.6 million, representing a 34% increase over the first half of 2016.
- Net molecular collection systems revenues were $16.1 million during the second quarter of 2017, which represents a 90% increase over the second quarter of 2016. Net molecular collection systems revenues during the six months ended June 30, 2017 were $26.8 million, a 75% increase from the comparable period in 2016.
- Total OraQuick® HCV sales of $7.6 million for the second quarter of 2017 increased 138% compared to the second quarter of 2016 and included a 268% increase in international sales of the product from the prior year quarter. OraQuick® HCV sales were $13.7 million in the first six months of 2017, a 125% increase over the first six months of 2016 and included a 298% increase in international sales of the product from the prior year period.

- Net revenues from international sales of the Company's OraQuick® HIV products remained consistent at $2.0 million in the second quarters of 2017 and 2016. Total international OraQuick® HIV sales for the six months ended June 30, 2017 were $4.7 million, a 65% increase over the first six months of 2016.
- Consolidated net income for the second quarter of 2017 was $5.4 million, or $0.09 per share on a fully diluted basis, which compares to consolidated net income of $3.8 million, or $0.07 per share on a fully diluted basis, for the second quarter of 2016. Consolidated net income for the six months ended June 30, 2017 was $17.9 million, or $0.30 per share on a fully-diluted basis, which compares to consolidated net income of $6.3 million, or $0.11 per share, for the comparable period of 2016. Results for the first six 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 short-term investments totaled $162.1 million and working capital amounted to $182.5 million at June 30, 2017.

"Our second quarter results were truly outstanding, driven by strong performances in our molecular collection and infectious disease businesses," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies, Inc. "We are successfully executing against our strategic growth objectives globally. Our existing business momentum is strong, and we believe we are in the early stages of addressing several new large business opportunities. Because of the potential of these opportunities, we are also building additional production capacity to meet the expected strong demand for our products in the coming years."

Financial Results

Consolidated net product revenues for the second quarter of 2017 increased 42% over the comparable period of 2016, primarily as a result of higher sales of the Company's molecular collections and OraQuick® HCV products, partially offset by lower domestic sales of the Company's professional OraQuick® HIV product.

Consolidated net product revenues for the first six months of 2017 increased 34% over the comparable period of 2016, primarily as a 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.

Consolidated other revenues for the second quarter and first six months of 2017 were $1.0 million and $2.1 million, respectively. This compares to consolidated other revenues for the second quarter and first six months of 2016 of $3.8 million and $7.6 million, respectively. Other revenues in 2017 represent funding received from the U.S. Biomedical Advanced Research Development Authority ("BARDA").

Other revenues in the second quarter of 2016 included $417,000 of BARDA funding and $3.4 million of exclusivity revenues recognized under the Company's HCV co-promotion agreement with AbbVie, which terminated effective December 31, 2016. Other revenues in the first six months of 2016 included $899,000 of BARDA funding and $6.7 million of AbbVie exclusivity revenues.

Consolidated gross margin was 63% for both the three and six months ended June 30, 2017. Consolidated gross margin for the three and six months ended June 30, 2016 was 67% and 68%, respectively. Gross margin for the current quarter and for the first six months of 2017 decreased primarily due to the absence of AbbVie exclusivity revenues during these periods. Gross margin in the first six months of 2017 was also negatively impacted by an increase in lower margin product sales and higher scrap and spoilage costs.

Consolidated operating expenses increased to $18.6 million during the second quarter of 2017 compared to $16.7 million in the second quarter of 2016. For the six months ended June 30, 2017, consolidated operating expenses were $23.0 million, an $11.3 million decrease from the $34.4 million reported for the six months ended June 30, 2016. The quarterly increase was largely due to higher staffing costs and increased lab supplies. The decrease in the six-month period was primarily due to the $12.5 million gain on a litigation settlement, the absence of costs associated with the AbbVie HCV co-promotion agreement, and lower legal fees, partially offset by increased staffing costs and higher research and development expenses.

Operating income increased 58% to $6.9 million in the second quarter of 2017 compared to $4.3 million in the second quarter of 2016. Operating income for the six months ended June 30, 2017 was $22.7 million, a 223% increase over the comparable period in 2016.

The Company's cash and short-term investment balance totaled $162.1 million at June 30, 2017, compared to $120.9 million at December 31, 2016. Working capital was $182.5 million at June 30, 2017, compared to $139.1 million at December 31, 2016. For the six months ended June 30, 2017, the Company generated $21.7 million in cash from operations.

Third Quarter 2017 Outlook

The Company expects consolidated net revenues to range from $40.5 million to $41.5 million and is projecting consolidated net income of $0.09 to $0.10 per share for the third quarter of 2017.

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

Unaudited

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Results of Operations				
Net revenues	$40,176	$31,359	$ 72,722	$60,448
Cost of products sold	14,699	10,274	26,935	19,050
Gross profit	25,477	21,085	45,787	41,398
Operating expenses:				
Research and development	3,338	2,985	6,308	5,351
Sales and marketing	7,502	7,397	14,379	16,103
General and administrative	7,750	6,354	14,842	12,896
Gain on litigation settlement	—	—	(12,500)	—
Total operating expenses	18,590	16,736	23,029	34,350
Operating income	6,887	4,349	22,758	7,048
Other income (expense)	96	(340)	563	(532)
Income before income taxes	6,983	4,009	23,321	6,516
Income tax expense	1,555	173	5,452	234
Net income	$ 5,428	$ 3,836	$ 17,869	$ 6,282
Earnings per share:				
Basic	$ 0.09	$ 0.07	$ 0.31	$ 0.11
Diluted	$ 0.09	$ 0.07	$ 0.30	$ 0.11
Weighted average shares:				
Basic	58,478	55,543	57,708	55,497
Diluted	60,728	56,208	59,755	56,144

Summary of Net Revenues by Market and Product (Unaudited)

Market	Three Months Ended June 30, Dollars 2017	2016	% Change	Percentage of Total Net Revenues 2017	2016
Infectious disease testing	$16,663	$12,949	29%	41%	41%
Risk assessment testing	3,238	3,159	3	8	10
Cryosurgical systems	3,174	3,041	4	8	10
Molecular collection systems	16,057	8,433	90	40	27
Net product revenues	39,132	27,582	42	97	88
Other	1,044	3,777	(72)	3	12
Net revenues	$40,176	$31,359	28%	100%	100%

Market	Six Months Ended June 30, Dollars 2017	2016	% Change	Percentage of Total Net Revenues 2017	2016
Infectious disease testing	$31,245	$24,317	28%	43%	40%
Risk assessment testing	6,368	6,265	2	9	10
Cryosurgical systems	6,237	6,922	(10)	8	12
Molecular collection systems	26,764	15,323	75	37	25
Net product revenues	70,614	52,827	34	97	87
Other	2,108	7,621	(72)	3	13
Net revenues	$72,722	$60,448	20%	100%	100%

HIV Revenues	Three Months Ended June 30, 2017	2016	% Change	Six Months Ended June 30, 2017	2016	% Change
Domestic	$4,965	$5,886	(16)%	$ 8,779	$11,588	(24)%
International	2,025	1,969	3	4,669	2,824	65
Domestic OTC	1,894	1,739	9	3,436	3,262	5
Net product revenues	$8,884	$9,594	(7)%	$16,884	$17,674	(4)%

HCV Revenues	Three Months Ended June 30, 2017	2016	% Change	Six Months Ended June 30, 2017	2016	% Change
Domestic	$2,382	$1,788	33%	$ 4,091	$ 3,689	11%
International	5,261	1,428	268	9,664	2,430	298
Net product revenues	7,643	3,216	138	13,755	6,119	125
Amortization of exclusivity payments	—	3,360	(100)	—	6,722	(100)
Net HCV-related revenues	$7,643	$6,576	16%	$13,755	$12,841	7%

Cryosurgical Systems Revenues	Three Months Ended June 30, 2017	2016	% Change	Six Months Ended June 30, 2017	2016	% Change
Domestic professional	$1,445	$1,145	26%	$ 2,941	$ 2,699	9%
International professional	243	211	15	373	446	(16)
Domestic OTC	347	345	1	632	723	(13)
International OTC	1,139	1,340	(15)	2,291	3,054	(25)
Net product revenues	$3,174	$3,041	4%	$ 6,237	$ 6,922	(10)%

Condensed Consolidated Balance Sheets (Unaudited)

	June 30, 2017	December 31, 2016
Assets		
Cash and cash equivalents	$ 106,703	$ 109,790
Short-term investments	55,354	11,160
Accounts receivable, net	26,731	19,827
Inventories	14,548	11,799
Other current assets	2,363	3,865
Property and equipment, net	20,291	20,033
Intangible assets, net	9,343	10,337
Goodwill	19,482	18,793
Other non-current assets	3,536	2,331
Total assets	$ 258,351	$ 207,935
Liabilities and Stockholders' Equity		
Accounts payable	$ 9,623	$ 4,633
Deferred revenue	1,477	1,388
Other current liabilities	12,092	11,314
Other non-current liabilities	3,538	2,304
Deferred income taxes	2,209	2,446
Stockholders' equity	229,412	185,850
Total liabilities and stockholders' equity	$ 258,351	$ 207,935

	Six Months Ended June 30,	
	2017	2016
Additional Financial Data (Unaudited)		
Capital expenditures	$ 1,567	$ 2,729
Depreciation and amortization	$ 2,891	$ 2,738
Stock-based compensation	$ 3,631	$ 2,942
Cash provided by operating activities	$21,704	$16,741

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2017 second quarter financial results, certain business developments and financial guidance for the third 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 #50993000 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 August 9, 2017, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #50993000.

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 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; 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.

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Exhibit 99.2

OraSure Technologies, Inc.

2017 Second Quarter

Analyst/Investor Conference Call

August 2, 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.

It is a pleasure to report that we had an exceptional second quarter. As you can see from our earnings release, we exceeded our published financial guidance and consensus analysts' estimates on both the top and bottom lines by a fairly wide margin. I am delighted with our performance.

Our message to investors since the end of last year has been that OraSure is in the early stages of several large market opportunities and is well positioned to capitalize on them. Our Q2 performance shows that we are doing just that. Many of the countries and customers we serve have only just begun executing on their goals and objectives. And there are many more businesses and countries with which we currently do not transact business, and we think many of these potential customers could benefit from our products. For this reason, we still believe we are in the early stages of our growth potential.

Demand for our molecular collection kits has been extraordinary, primarily because of growth in the personalized medicine market. Our HCV business continues to perform very well, especially in international markets in support of broad-based testing and treatment programs. We are very confident and enthusiastic about the growth of the OraQuick HIV self-test after receipt of WHO prequalification, our new agreement with

the Gates Foundation and the announced expansion of the Self Testing in Africa (“STAR”) project. We are making strategic investments to substantially expand manufacturing capacity in anticipation of continued strong demand for our products. In short, our recent performance demonstrates that we are successfully executing on our strategic growth objectives for both the infectious disease and molecular businesses.

Turning to the quarter -

- Our consolidated net revenues grew 28% compared to the year ago period and topped $40 million for the first time. Product revenue growth was 42%.
- Our molecular business delivered another record performance, as Q2 revenues reached $16 million. This is almost double the revenue generated in Q2 of last year and is by far the best quarter ever for this business.
- Our infectious disease business also performed extremely well, with 29% revenue growth from the year-ago period. Significant increases in international and domestic sales of our HCV product were the primary growth drivers.
- On the bottom line, our consolidated net income also improved nicely from the year-ago quarter and we ended the quarter with over $160 million in cash and cash equivalents.

In short, our Q2 results were outstanding. As Ron will explain, we expect this trend to continue as we are projecting similar performance in Q3.

So with that brief introduction, let me turn the call over to Ron for his detailed financial review. I will then provide some business updates, after which we will take your questions.

Ron...

Second Quarter 2017 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

As you can see in our press release, 2017 continues to be a very successful year. Our second quarter consolidated net revenues increased 28% to $40.2 million, compared to $31.4 million reported in the second quarter of 2016. Notably, our consolidated net product revenues rose 42% to $39.1 million compared to the prior-year period. Higher sales of our molecular products and our OraQuick® HCV product were the primary drivers of this performance.

Our molecular revenues rose 90% to $16.1 million in the second quarter of 2017 compared to $8.4 million in the second quarter of 2016. Sales of our Oragene® product to commercial customers increased 122%, largely due to higher customer demand. Academic sales increased 2% largely due to customer ordering patterns.

International sales of our HCV test in the second quarter of 2017 rose 268% to $5.3 million from $1.4 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 increased 33% in the second quarter of 2017 to $2.4 million from $1.8 million in the prior-year period, primarily due to business growth and customer ordering patterns.

Domestic professional HIV sales decreased 16% to $5.0 million in the second quarter of 2017, compared to $5.9 million in the second quarter of 2016, as result of customer ordering patterns and competition from other products. It should be noted that while domestic HIV sales were down compared to the prior-year period, second quarter 2017 domestic HIV sales increased 30% sequentially over Q1 of 2017.

Other Revenues were $1.0 million in the current quarter, representing funding we received from BARDA for our rapid Ebola and Zika products. Other revenues in the second quarter of 2016 totaled $3.8 million and included $417,000 in BARDA funding and $3.4 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 second quarter of 2017 was 63% compared to 67% reported for the second 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.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the second quarter of 2017 were $18.6 million compared to $16.7 million in the comparable period of 2016. This increase was largely due to higher staffing-related costs and increased spending on lab supplies.

Income Taxes – Ron Spair

Income tax expense was $1.6 million in the second quarter of 2017 compared to $173,000 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 $5.4 million, or $0.09 per share on a fully diluted basis, for the second quarter of 2017, compared to net income of $3.8 million, or $0.07 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 short-term investment balance at June 30, 2017 was $162.1 million compared to $120.9 million at December 31, 2016. Cash generated by operating activities for the first half of 2017 was $21.7 million compared to $16.7 million in the same period of 2016.

Third Quarter 2017 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the third quarter of 2017, we are projecting consolidated net revenues of approximately $40.5 million to $41.5 million. We are also projecting consolidated net income of approximately $0.09 to $0.10 per share for Q3 of 2017.

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

Business Update – Doug Michels

Thanks, Ron. I'll now walk you through some of the progress we are making in our various businesses.

Infectious Disease Testing – Doug Michels

As noted, in the infectious disease area international product sales and domestic sales of our OraQuick HCV test continue to be the primary growth drivers.

HCV Elimination Programs

The largest contribution in Q2 came from international sales growth primarily in support of large-scale HCV testing programs, including in particular the country elimination initiative and related government supply agreement we previously highlighted. Our execution against this contract has gone very well. During Q2, we shipped over one million HCV tests under this agreement and we anticipate continued strong demand from this customer. As discussed previously, this customer has the option to renew the contract and purchase up to 100% of the original quantities of product on the same terms and conditions as provided in the original contract. Discussions around a renewal are progressing well, with conversations occurring on specific volumes and timing of future shipments. Assuming the successful conclusion of these discussions, we expect future volumes will exceed those shipped under the original contract. Negotiations regarding this expanded supply arrangement should be completed during the third quarter.

Apart from this government customer, the level of interest in HCV testing and treatment programs remains strong. We previously mentioned that we fulfilled initial orders from two other countries that have initiated broad HCV testing programs. We anticipate additional orders from these countries later this year, depending of course on continued funding, which in turn will impact the ability of these countries to add needed infrastructure and define the ultimate scope of their programs.

We previously reported that the WHO has announced its goal of eliminating hepatitis C by the year 2030. The list of countries with plans to reach that goal has grown from 36 to 52. While this increase does not guarantee available funding or that large-scale HCV testing programs will occur in all cases, it does show that a growing list of high prevalence countries are focused on reducing the burden of HCV infection.

I would note that a key enabler for large-scale HCV testing and treatment programs is the reduced costs to cure HCV with new generic therapeutics available in certain markets. In many countries that are executing or considering broad testing and elimination programs, the cost to cure HCV is now below $1,000 per patient as a result of the availability of the generic drugs. Our research has identified several countries that have obtained this type of reduced pricing for the new therapeutics, and we are working to understand how these developments may open the door to future broad-scale testing programs.

Finally, our domestic HCV sales provided a nice contribution to the quarter, increasing 33% compared to the prior year. This was driven by an expansion of existing, and the initiation of new, testing programs. Sales to the public health, hospital and physician office markets all contributed to the growth in our domestic business. We expect this trend to continue.

International HIV Self Testing

Our international HIV business grew during Q2 as well, although at a more modest rate than in prior periods. This was largely due to the timing of orders for our OraQuick® HIV self-test by Population International Services (or “PSI”) in connection with the STAR project. We believe this is just a timing issue and that stronger growth will resume in future periods.

There have been a number of recent positive developments in our HIV self-testing business.

- We recently announced a new four-year Charitable Support Agreement with the Bill & Melinda Gates Foundation. Under this agreement, the Gates Foundation will subsidize the price of our HIV self-test in 50 developing countries. The amount of the support payments is tied to the volume of product sold in the covered countries along with the level of costs we incur in connection with regulatory approvals and other investments needed to supply the product. The goal of this agreement is to drive the accelerated adoption of our OraQuick® HIV self-test so that more people can learn their status and receive necessary treatment. Since the agreement was signed, we have worked closely with the Gates Foundation to promote this program. Updates on the program have been provided to major funding organizations, such as the Global Fund, PEPFAR and the Children's Investment Fund Foundation. This was very timely as these organizations are currently preparing their program budgets. In addition, correspondence outlining the program has been sent to the Ministers of Health in the 50 covered countries. Our agreement with the Foundation was also highlighted at the recent International AIDS Conference in Paris and generated significant interest.
- We also recently announced the receipt of prequalification from the WHO for our HIV self-test. We are now offering the only rapid HIV self-test that has received this designation. WHO prequalification allows governmental organizations implementing self-testing pilots and programs to use international donor funding for the purchase of our tests.
- As we have indicated on other calls, our work with PSI on the STAR project has gone well. We recently received another large self-test order from PSI that will ship during the third quarter and we expect more to come. PSI and UNITAID

recently announced Phase II of the STAR program and, importantly, the expansion of the program to additional countries and an increase in test volume from 750,000 to approximately 4 million additional HIV self-tests. We believe that we will supply the vast majority of these tests. We have been notified by PSI to expect an additional large order of tests to be shipped during the fourth quarter of this year under Phase II. This next phase will extend the STAR program beyond Zimbabwe, Malawi and Zambia, to additional countries, including South Africa, Swaziland and Lesotho.

So, we remain very optimistic about HIV self-testing and believe this business will help drive future growth in our infectious disease business.

Domestic Business

On the domestic front, our HIV business was down again compared to the prior-year quarter, although, as Ron noted, this business grew 30% sequentially from Q1. The negative factors affecting our domestic HIV business remain the same and include the CDC's continued push for use of fourth-generation automated laboratory testing equipment, public health budget pressures and price competition. In fact, we have been advised that the CDC is instructing public health jurisdictions to prepare for future possible budget reductions, as the current administration has indicated plans to cut the HHS budget in the coming fiscal year. The timing of several orders from our larger physician's office distributors also had a negative impact on the quarter. The good news is that the Q2 decline in domestic HIV sales was more than offset by the growth in our HCV business.

Tuberculosis

As indicated in our last call, clinical studies using our Tuberculosis product have been completed by the Foundation for Innovative New Diagnostics, or FIND, in support of WHO endorsement of our OMNIgene®• SPUTUM product. FIND has issued its final data dossier on our product and the WHO conducted a technical review of this data along with data for other sputum transport solutions on May 29th. The WHO has not yet issued a final report from its meeting, but is expected to do so in the near future.

Emerging Diseases

Turning briefly to emerging diseases, I want to briefly update you on clinical activities for our new Zika test. We previously indicated that we expected to submit for Emergency Use Authorization ("EUA") from the FDA either in late Q2 or early Q3. Due to some stability challenges with our test, this submission will likely be pushed to Q4. We believe these technical issues will be resolved, and we remain committed to obtaining EUA approval and successfully commercializing this test.

Molecular Business Growth Drivers – Doug Michels

Our molecular business turned in another exceptional performance in Q2, with 90% growth over the prior year quarter and 50% growth sequentially from Q1. We expect this strong growth trend, including sequential quarterly growth, to continue in Q3.

Genomics

These results were partially driven by shipments of Oragene® devices against the $20 million supply agreement we announced last quarter as well as overall strong performance in our commercial business where we saw increases with most of our commercial customers compared to the prior year quarter. Along with the continued acquisition of new customers, we expect strong triple-digit growth in our commercial business in Q3, compared to the prior-year quarter.

On July 24th, Helix launched a range of personalized DNA-powered products as part of its online marketplace offering. Since announcing our supply agreement with Helix last November, we have been shipping Oragene® devices and providing kit fulfillment and logistics services for Helix through our GenoFIND service. We expect their recent launch of a broad set of products and services provided by their partners will drive increased consumption of our products and services under this agreement.

Finally, our GenoFIND fulfillment and logistics service business had a record quarter in Q2 delivering the most kits since we launched the service. We expect this service to continue to grow nicely as we acquire new customers and our existing customers' businesses continue to grow.

Microbiome

Our Microbiome business delivered record revenues of $840,000 in Q2, representing almost a fourfold increase over Q2 2016. This brings first half revenue to $1.6M which exceeds our total 2016 microbiome revenue of $1.1M.

This growth has come from both repeat purchasers and new customers acquired during the quarter. We experienced strong double-digit growth in customer acquisition, both sequentially and over the prior year period. We continue to see strong interest in our microbiome products and services with the number of new testers almost doubling year-over-year.

During Q2, we closed one of the largest sales ever in our microbiome business with a long running academic cohort for the provision of kits, custom packaging and fulfillment services. We will provide additional details on this study when it is publicly announced and we start delivering against this contract, which is expected to be in Q4.

Operations Update – Doug Michels

Turning to operations, as stated earlier, there has been intense focus on the expansion of our manufacturing capacity.

The second automated OraQuick® production line mentioned on prior calls has received all necessary regulatory approvals and is now being used to make saleable product on one shift with a second shift planned for later this year. When fully operational, this line will add additional capacity of up to 10.4 million devices per year.

A supplier has been selected and we have placed an order for a third automated OraQuick® line. Delivery of this line is expected in mid-2018 and should be operational by the end of 2018. This line will also add capacity for up to an additional 10.4 million devices per year.

Cleanroom construction has begun to add capacity at our contractor in Thailand, which we use to assemble and supply non-US and non-CE marked OraQuick® HIV product primarily in developing countries. We expect installation and validation of an additional semi-automated assembly line to be completed in 2017, with related regulatory approvals obtained in early 2018. An additional line in Thailand is also planned for 2018.

We have also ordered two additional automated assembly lines for our saliva DNA collection kits and expect the first line to become operational by the end of 2017 and the second in early 2018. These new lines will more than double our capacity.

In addition to increased automated assembly, we have begun the process to add manufacturing capacity here in Bethlehem to meet expected increased demand for our OraQuick® HCV product. A new warehouse, new cleanroom, new manufacturing area, and new QC labs, will be put in place by Q2 2018 to provide additional capacity for this product.

Lastly, as noted on the prior call, we were working with a consulting firm to help us optimize the global footprint for the manufacture of our products. The initial engagement concluded last quarter and resulted in recommendations for the location of additional manufacturing capacity to meet global demand in 2020 and beyond. The second phase of the engagement will begin this quarter and will include the identification and sourcing of qualified contract manufacturers and raw material suppliers for our OraQuick® and Oragene® products. This second engagement is expected to be completed by the end of 2017.

New Director – Doug Michels

A final item I would like to mention is the recent appointment of Mara Aspinall as a member of our Board of Directors. Mara's extensive experience in both the molecular and diagnostics fields makes her an ideal addition to the Board. In fact, her background in the molecular field will be especially valuable given the strategic importance of this area to our business. Mara currently serves as Executive Chairman of GenePeeks, a computational genomics company, and she also spent a number of years serving as President of the Genetics Division of Genzyme Corporation, which is a leading provider of genetic tests for the reproductive, oncology and personalized medicine markets. We are delighted that Mara has joined the Board and we look forward to working with her.

Conclusion – Doug Michels

So, in summary, our Q2 performance exemplifies the tremendous momentum in our business and our ability to execute on our key strategic priorities. We remain excited about our future prospects. This optimism is based on our discussions with both existing and potential new customers, as well as the recent addition of a new funding vehicle and the potential for additional funding channels in international markets. As evidenced by our Q3 guidance, we are confident that our international HCV and HIV products and our molecular business will continue to drive strong growth. We are making the necessary investments in our manufacturing capacity to capitalize on these opportunities. We believe the recent trends in our business will continue through the remainder of 2017 and I look forward to reporting on our progress and continued growth in future calls.

Before we open the floor to your questions, I would like to recognize and sincerely thank my OraSure colleagues for all their contributions in making this such a successful quarter.

And with that, we are ready for 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 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; 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 our 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.