# 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): May 3, 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**<br>**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 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 l2b-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 May 3, 2017, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended March 31, 2017, and providing financial guidance for the second 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 May 3, 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 ended March 31, 2017, provided financial guidance for the second 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 May 3, 2017, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2017, and providing financial guidance for the second quarter of 2017. |
| 99.2 | Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. First Quarter 2017 Analyst/ Investor Conference Call held May 3, 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: May 3, 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 First Quarter Financial Results**

**BETHLEHEM, PA** – May 3, 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 first quarter ended March 31, 2017.

**Financial Highlights**

- Consolidated net revenues for the first quarter of 2017 were $32.5 million, a 12% increase from the first quarter of 2016. Net product revenues were $31.5 million, representing a 25% increase over the first quarter of 2016.
- Net molecular collection systems revenues were $10.7 million during the first quarter of 2017, which represents a 55% increase over the first quarter of 2016.
- Total OraQuick® HCV sales of $6.1 million for the first quarter of 2017 increased 111% compared to the first quarter of 2016 and included a 340% increase in international sales of the product from the prior year quarter.
- Net revenues from international sales of the Company's OraQuick® HIV products were $2.6 million in the first quarter of 2017, representing a 210% increase over the first quarter of 2016.
- First quarter 2017 results include a $12.5 million pre-tax gain related to the settlement of litigation against Ancestry.com DNA LLC and its contract manufacturer, which was accounted for as a reduction of operating expenses.
- The Company entered into a contract to supply more than $20 million of its saliva DNA collection devices, which represents the largest supply contract in the history of the Company's molecular business.

- Consolidated net income for the first quarter of 2017 was $12.4 million, or $0.21 per share on a fully diluted basis, which compares to consolidated net income of $2.4 million, or $0.04 per share on a fully diluted basis, for the first quarter of 2016.
- Cash and short-term investments totaled $141.5 million and working capital amounted to $162.2 million at March 31, 2017.

“We are extremely pleased with our financial performance and the progress made on our growth objectives during the first quarter,” said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies, Inc. “Product sales increased 25% over the prior year, led by strong results from our molecular business. International sales of our OraQuick® HIV self-test and OraQuick® HCV product were also significant contributors in the quarter. Our business momentum remains strong and we are well positioned to further capitalize on the exciting market opportunities we are pursuing.”

**Financial Results**

Consolidated net product revenues for the first quarter of 2017 increased 25% over the comparable period of 2016, primarily as a result of higher sales of the Company’s molecular products and higher international sales of the OraQuick® HIV self-test and OraQuick® HCV product, partially offset by lower domestic sales of the Company’s professional OraQuick® HIV product and lower cryosurgical systems sales.

Consolidated other revenues were $1.1 million and $3.8 million for the first quarter of 2017 and 2016, respectively. Other revenues in the first quarter of 2017 included $1.1 million of funding received from the U.S. Biomedical Advanced Research Development Authority (“BARDA”). Other revenues in the first quarter of 2016 included $482,000 of funding received from BARDA and $3.4 million of exclusivity revenues recognized under the Company’s HCV co-promotion agreement with AbbVie, which terminated effective December 31, 2016.

Consolidated gross margin for the three months ended March 31, 2017 was 62% compared to 70% for the three months ended March 31, 2016. Gross margin for the current quarter decreased due to the absence of exclusivity revenues, increased scrap and spoilage costs, and a less favorable product mix.

Consolidated operating expenses decreased to $4.4 million during the first quarter of 2017 compared to $17.6 million in the first quarter of 2016. The decrease was primarily due to the $12.5 million gain on the litigation settlement, the absence of costs associated with the AbbVie HCV co-promotion agreement and lower legal fees. These decreases were partially offset by higher research and development expenses and increased general and administrative costs.

The Company’s cash and short-term investment balance totaled $141.5 million at March 31, 2017, compared to $120.9 million at December 31, 2016. Working capital was $162.2 million at March 31, 2017, compared to $139.1 million at December 31, 2016. For the three months ended March 31, 2017, the Company generated $12.6 million in cash from operations.

**Second Quarter 2017 Outlook**

The Company expects consolidated net revenues to range from $36.5 to $37.0 million and is projecting consolidated net income of $0.07 to $0.08 per share for the second quarter of 2017.

**Financial Data**

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

**Unaudited**

| | Three months ended March 31, | |
|---|---|---|
| | **2017** | **2016** |
| **Results of Operations** | | |
| Net revenues | $ 32,546 | $29,089 |
| Cost of products sold | 12,236 | 8,776 |
| Gross profit | 20,310 | 20,313 |
| Operating expenses: | | |
| Research and development | 2,970 | 2,366 |
| Sales and marketing | 6,877 | 8,706 |
| General and administrative | 7,092 | 6,542 |
| Gain on litigation settlement | (12,500) | — |
| Total operating expenses | 4,439 | 17,614 |
| Operating income | 15,871 | 2,699 |
| Other income (expense) | 467 | (192) |
| Income before income taxes | 16,338 | 2,507 |
| Income tax expense | 3,897 | 61 |
| Net income | $ 12,441 | $ 2,446 |
| Earnings per share: | | |
| Basic | $ 0.22 | $ 0.04 |
| Diluted | $ 0.21 | $ 0.04 |
| Weighted average shares: | | |
| Basic | 56,929 | 55,451 |
| Diluted | 58,772 | 56,079 |

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

| | Three Months Ended March 31, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| Market | 2017 | 2016 | % Change | 2017 | 2016 |
| Infectious disease testing | $14,583 | $11,368 | 28% | 45% | 39% |
| Risk assessment testing | 3,130 | 3,105 | 1 | 10 | 11 |
| Cryosurgical systems | 3,063 | 3,882 | (21) | 9 | 13 |
| Molecular collection systems | 10,706 | 6,890 | 55 | 33 | 24 |
| Net product revenues | 31,482 | 25,245 | 25 | 97 | 87 |
| Other | 1,064 | 3,844 | (72) | 3 | 13 |
| Net revenues | $32,546 | $29,089 | 12% | 100% | 100% |

| | Three Months Ended March 31, | | |
|---|---|---|---|
| HIV Revenues | 2017 | 2016 | % Change |
| Domestic | $3,812 | $5,703 | (33)% |
| International | 2,644 | 854 | 210 |
| Domestic OTC | 1,542 | 1,523 | 1 |
| Net product revenues | $7,998 | $8,080 | (1)% |

| | Three Months Ended March 31, | | |
|---|---|---|---|
| HCV Revenues | 2017 | 2016 | % Change |
| Domestic | $1,709 | $1,900 | (10)% |
| International | 4,402 | 1,001 | 340 |
| Net product revenues | 6,111 | 2,901 | 111 |
| Amortization of exclusivity payments | — | 3,362 | (100) |
| Net HCV-related revenues | $6,111 | $6,263 | (2)% |

| Cryosurgical Systems Revenues | Three Months Ended March 31, 2017 | 2016 | % Change |
|---|---|---|---|
| Domestic professional | $1,496 | $1,554 | (4)% |
| International professional | 130 | 235 | (45) |
| Domestic OTC | 285 | 378 | (25) |
| International OTC | 1,152 | 1,715 | (33) |
| Net product revenues | $3,063 | $3,882 | (21)% |

**Condensed Consolidated Balance Sheets (Unaudited)**

| | March 31, 2017 | December 31, 2016 |
|---|---|---|
| Assets | | |
| Cash and cash equivalents | $ 122,682 | $ 109,790 |
| Short-term investments | 18,776 | 11,160 |
| Accounts receivable, net | 24,005 | 19,827 |
| Inventories | 12,707 | 11,799 |
| Other current assets | 2,365 | 3,865 |
| Property and equipment, net | 20,134 | 20,033 |
| Intangible assets, net | 9,779 | 10,337 |
| Goodwill | 18,971 | 18,793 |
| Other non-current assets | 3,173 | 2,331 |
| Total assets | $ 232,592 | $ 207,935 |
| Liabilities and Stockholders' Equity | | |
| Accounts payable | $ 7,286 | $ 4,633 |
| Deferred revenue | 1,306 | 1,388 |
| Other current liabilities | 9,685 | 11,314 |
| Other non-current liabilities | 3,160 | 2,304 |
| Deferred income taxes | 2,330 | 2,446 |
| Stockholders' equity | 208,825 | 185,850 |
| Total liabilities and stockholders' equity | $ 232,592 | $ 207,935 |

| Additional Financial Data (Unaudited) | Three months ended March 31, 2017 | 2016 |
|---|---|---|
| Capital expenditures | $ 878 | $1,593 |
| Depreciation and amortization | $ 1,408 | $1,354 |
| Stock-based compensation | $ 1,518 | $1,452 |
| Cash provided by operating activities | $12,619 | $4,744 |

**Conference Call**

The Company will host a conference call and audio webcast to discuss the Company's 2017 first quarter financial results, certain business developments and financial guidance for the second 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 #3133897 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 May 10, 2017, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #3133897.

**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; 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.

# # #

**OraSure Technologies, Inc.**
**2017 First Quarter**
**Analyst/Investor Conference Call**
**May 3, 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 Michelle. Good afternoon everyone and welcome to our call.

I am very pleased to report that we delivered another strong quarter and the year is off to a terrific start. Demand for our products is strong and we are excited about the future prospects for our business.

On last quarters' call, I encouraged those who missed our Analyst Day in November 2016 to consider reviewing our commentary from that day. It provides a helpful roadmap of the numerous opportunities available in our various businesses. As you will hear today, we are making great progress on the opportunities we highlighted at the Analyst Day. One of our goals was to communicate to the investment community why we believe OraSure is in the early stages of several large market opportunities and very well positioned to capitalize on them. One example which I am happy to share this afternoon, is the recent signing of, another large contract, this time with a genomics customer, to supply them with over $20 million of our molecular collection devices over a period greater than 12 months. This is the largest contract in the history of our molecular business. There is no shortage of potential opportunities and we are pursuing them across our business.

So, moving on to the quarter, as indicated in our earnings release, we delivered a strong first quarter.

- Both our top and bottom lines exceeded expectations, with 12% revenue growth and a $10.0 million improvement in net income compared to the year-ago quarter. Product revenue growth was 25%. Truly outstanding.
- We achieved these results despite the absence of AbbVie exclusivity revenues, which as you know ended in 2016. These revenues were $3.4 million in Q1 of last year.
- Leading the way in Q1 was a record performance by our molecular business, where revenues grew 55% and topped $10 million for the first time.
- Our infectious disease business also performed very well, with 28% revenue growth from the year-ago period. Significant increases in international sales of our HIV self-test and HCV product were the primary growth drivers.
- Not surprisingly, our balance sheet improved, with over $20 million in cash added during the quarter. We ended the quarter with more than $140 million in cash on hand.

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

Ron...

***First Quarter 2017 Financial Results – Ron Spair***

Thanks Doug, and good afternoon everyone.

***Revenues – Ron Spair***

We certainly are off to a great start for 2017. Our first quarter consolidated net revenues increased 12% to $32.5 million, compared to $29.1 million reported in the first quarter of 2016. Notably, our consolidated net product revenues rose 25% to $31.4 million compared to the prior year period. Higher sales of our molecular products along with higher international sales of our OraQuick® HIV self-test and OraQuick® HCV product were partially offset by a decline in domestic sales of our OraQuick® HIV and HCV products and lower cryosurgical sales.

Other Revenues were $1.1 million in the current quarter, representing funding we received from BARDA for our rapid Ebola and Zika products. Other revenues in the first quarter of 2016 totaled $3.8 million and included $482,000 in BARDA funding and $3.4 million of exclusivity revenues under the AbbVie HCV co-promotion agreement which terminated effective December 31, 2016.

Our molecular revenues rose 55% to $10.7 million in the first quarter of 2017 compared to $6.9 million in the first quarter of 2016. Sales of our Oragene® product to commercial customers increased 119%, largely due to higher customer demand and the increased sales from new customer accounts won in the second half of 2016. Academic sales decreased 20% largely due to customer ordering patterns and the absence of a one-time order of almost $400,000 by the WHO for an epidemiology study which occurred in the first quarter of 2016 and will not repeat in 2017.

International sales of our HCV test in the first quarter of 2017 rose 340% to $4.4 million from $1.0 million in the same period of 2016, primarily due to the continued shipments of product to a foreign government pursuant to a previously announced countrywide elimination program as well as increased shipments for large-scale screening programs. Domestic OraQuick® HCV product sales decreased 10% in the first quarter of 2017 to $1.7 million from $1.9 million in the prior year period, primarily due to customer ordering patterns.

International sales of our HIV products increased 210% to $2.6 million in the first quarter of 2017, compared to $854,000 in the first quarter of 2017. This increase was due to the continued shipment of product in support of an HIV self-testing program in Africa and higher sales in the Middle East.

Domestic professional HIV sales decreased 33% to $3.8 million in the first quarter of 2017, compared to $5.7 million in the first quarter of 2016, as result of customer ordering patterns and competition from other products.

Sales of our cryosurgical products decreased 21% to $3.1 million in the first quarter of 2017 from $3.9 million in the first quarter of 2016 largely due to lower sales of our international OTC products.

***Gross Margin – Ron Spair***

Gross margin for the first quarter of 2017 was 62% compared to 70% reported for the first 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, a less favorable product mix, and increased scrap and spoilage costs.

***Operating Expenses – Ron Spair***

Our consolidated operating expenses for the first quarter of 2017 were $4.4 million compared to $17.6 million in the comparable period of 2016. This decrease was largely due to the inclusion of a $12.5 million pre-tax gain related to our Ancestry litigation settlement, the absence of costs associated with our terminated HCV co-promotion agreement with AbbVie, and lower legal fees.

***Income Taxes – Ron Spair***

Income tax expense was $3.9 million in the first quarter of 2017 compared to $61,000 in the same period last year. Taxes for the current period included the additional Canadian taxes due as a result of the litigation settlement gain of $12.5 million.

***Net Income – Ron Spair***

From a bottom line perspective, we reported net income of $12.4 million, or $0.21 per share on a fully diluted basis, for the first quarter of 2017, compared to net income of $2.4 million, or $0.04 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 March 31, 2017 was $141.5 million compared to $120.9 million at December 31, 2016. Cash generated by operating activities for the first three months of 2017 was $12.6 million compared to $4.7 million in the same period of 2016.

***Second Quarter 2017 Consolidated Financial Guidance – Ron Spair***

Turning to guidance for the second quarter of 2017, we are projecting consolidated net revenues of approximately $36.5 million to $37.0 million. We are also projecting consolidated net income of approximately $0.07 to $0.08 per share for Q2 of 2017.

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

***Business Update – Doug Michels***

Thanks, Ron. As you know, our growth strategy is focused on our infectious disease business, which includes our HCV, HIV, Ebola, Zika and TB programs, and our molecular business, which includes our genomics and microbiome programs.

***Infectious Disease Testing – Doug Michels***

The storyline in infectious disease continues to be strong international growth.

*HCV Elimination Programs*

The largest Q1 revenue increases came from international HCV sales in support of large-scale HCV elimination or testing programs, including the large government supply contract we previously highlighted. That initiative has been going well and we expect to continue supplying product to this government customer throughout the remainder of 2017. In addition, this customer has an 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. We are starting discussions on a potential renewal this week.

The level of interest in foreign HCV testing and treatment programs continues to be strong. Orders have been received from two other countries that have indicated an intent to start testing programs. These orders have been filled and we anticipate additional orders from these countries later this year. As we reported during our Analyst Day last November, the WHO has announced its goal of eliminating Hepatitis C by the year 2030. To date, 36 countries have developed national programs to combat hepatitis and 33 additional countries are developing similar plans. While this does not guarantee available funding or that large-scale HCV testing programs will occur in all cases, it does evidence the increased focus by high prevalence countries on the need to take action with respect to hepatitis. We believe this bodes well for the future of our HCV business.

*HIV Self Testing*

The other main growth driver internationally was our OraQuick® HIV self-test. We indicated on the last call that an additional order had been received from Population Services International, or "PSI," in support of the "Self-Testing in Africa," or STAR project. This additional order was for approximately 350,000 tests and we filled that order during Q1.

To date, we have shipped over 700,000 tests as part of the initial phase of the STAR project. Field reports remain positive on the use and performance of our test and a second phase of this program is now being discussed with PSI and its funding source, UNITAID. We expect more details on the timing and scope of phase II in the next few months, and we expect additional orders throughout 2017 and beyond.

The international focus on HIV self-testing is increasing and the STAR program is just part of the story. In November 2016, UNITAID issued a "call for proposals" for the purpose of accelerating the demand for and widespread adoption of HIV self-testing programs in low and middle income countries. As part of this request, UNITAID specifically mentioned the success of the STAR project that has been using our product. The closing date for submissions to UNITAID was March 31st. These additional programs, assuming they are approved and funded, are expected to be incremental to the STAR program.

In addition, we continue to see high interest levels from a number of public health departments or ministries and NGO's in numerous countries. We are currently engaged with approximately 20 countries that have taken or are planning concrete steps to begin implementation of self-testing. These include many countries outside the current STAR pilot program.

During the first quarter, we announced that our HIV self-test was designated as eligible for procurement by purchasing entities entitled to access Global Fund resources. Our product was classified by the Global Fund's Expert Review Panel for Diagnostics (ERPD) as Category 2, which permits product procurement for 12 months with Global Fund monies. This designation is important in that it permits funded purchases even though our product has not yet received WHO pre-qualification.

On that front, our efforts to obtain pre-qualification have also progressed. During our last call, we indicated that our submission was under active review and we expected to receive feedback during the first quarter. We did receive that feedback and are now in the process of completing additional data collection that we expect to submit to the WHO in early June. WHO pre-qualification is important in that it will enable countries to purchase our test with monies from large funding organizations such as UNITAID, PEPFAR and the Global Fund.

So, we remain very optimistic about HIV self-testing and believe this business will be an important source of future growth for the infectious disease market.

*Domestic Business*

The strong international sales during the first quarter more than offset declines in our domestic businesses.

The magnitude of the Q1 decline in HIV sales was driven primarily by the timing of customer orders, including in particular a very large order from a public health jurisdiction, and by competition. In the past, this jurisdiction has placed their orders during the first quarter. However, beginning in 2017, the customer decided to spread its orders out more evenly throughout the year. While the pressure on our HIV domestic business is expected to continue, we do not anticipate the steep decline in Q1 to repeat in future periods.

Timing of purchases was a key factor in the performance of our domestic HCV business. We remain confident in the future growth of our domestic HCV sales. As public health budgets continue to be pressured, a number of jurisdictions are shifting funding to HCV from other areas of their budget and one of our largest customers recently provided a forecast doubling their deployment of HCV tests in 2017. In addition, as you may know, public health jurisdictions are attempting to respond to the opioid epidemic. Since injection drug use remains the most common risk factor for HCV infection in the United States and, in fact, accounts for more than 50% of all new infections, we are beginning to see drug treatment centers increase deployment of HCV testing programs. As a result, we expect our domestic HCV business to resume more normal revenue patterns and return to year-over-year quarterly growth beginning in Q2.

*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 has indicated it will review the FIND data and issue a broader review of all commercial sputum transport reagents later this year. In the meantime, commercial discussions with foreign ministries of health for deployment of our product are progressing, as are discussions with a National Tuberculosis and Leprosy Control Program in Africa. These initiatives and other activities are expected to generate expanded sales in 2018.

*Emerging Diseases*

Turning briefly to emerging diseases, there have been a number of activities that continue to progress.

With respect to our OraQuick® Ebola test, the CDC is currently assessing its product needs for 2017 and we should have better visibility of future orders once that assessment is completed. Our clinical work for this product also continues. We have had further dialog with the FDA and we received input on the additional clinical work needed for 510(k) clearance. We expect this work will result in a mid-year 2018 submission to the FDA.

Finally, our efforts to progress clinical activities for our new Zika test continue. We are still planning to submit for Emergency Use Authorization from the FDA later this year. Zika remains an important public health risk and we believe our new test can play an important role in combatting this disease.

***Molecular Business Growth Drivers – Doug Michels***

As Ron explained, our molecular business turned in an exceptional Q1 performance, with 55% growth over the prior year quarter and 25% growth sequentially from Q4 of last year. We expect continued strong performance from this part of the business with strong double-digit growth in Q2 from the prior-year quarter.

*Genomics*

During Q1, there were a number of developments in the genomics market.

- Revenues from our top 20 genomics accounts more than doubled compared to the year ago quarter.
- Our top 5 commercial accounts contributed significant growth in Q1, both sequentially and from the year-ago quarter with numerous repeat orders.
- Our business in China continues to grow, with a 100% increase in Q1 revenues compared to the year-ago quarter. During the last call, we discussed a new multi-year supply agreement with WeGene, a company that offers genetic testing and personalized health care services in Asia. We will continue shipping against the WeGene contract in Q2.

- Overall, we are now seeing a record level of product orders in our molecular business.
- Additionally, you may have seen the recent announcement that 23andMe has received FDA clearance to begin marketing their health risk test for 10 diseases or conditions using our ORAgene® collection device. We congratulate 23andMe and believe this is a very positive development for their business and hopefully ours as well.

*Microbiome*

Turning to our Microbiome business, we recorded almost $800,000 in revenues in Q1, a 373% increase over Q1 of last year. We recorded approximately $1.1 million in microbiome revenues for the full-year 2016, and we expect to exceed that total by the end of Q2.

The majority of our microbiome revenues continue to be derived from our Oragene® gut or fecal sample collection kits and related services. We acquired 135 new microbiome testers in Q1, a 65% increase over Q1 2016, with the majority of Q1 microbiome revenues coming from academic or research customers.

Not all of the new testers are new customers as we are also seeing increased cross selling of microbiome solutions to existing genomics customers who are expanding their research to include microbiome data. For example, during the quarter, we closed a sale for both gut microbiome kits and our oral microbiome collection kits with a world-renowned research institute which has been an Oragene® customer for over ten years. We believe our ability to provide trusted solutions for both genomics and microbiome research is a meaningful differentiator for our business. While gut microbiome remains the primary area of interest in this market, we are starting to see more and more interest in other microbiomes, allowing us to deliver increasing value with our portfolio of microbiome collection devices and services.

*Litigation Settlement*

Finally, in February we announced the settlement of our litigation against Ancestry.com and its contract manufacturer. As part of this settlement, Ancestry paid us $12.5 million and we granted Ancestry a royalty bearing, non-exclusive worldwide license to certain of our patents. The license is specifically limited to the saliva DNA collection kits sold or used as part of Ancestry's genetic testing service offerings and does not cover the sale or use of product outside of its business. We are pleased with the terms of this settlement and are happy to have this matter resolved.

***Operations Update – Doug Michels***

A final area I will address is operations.

The second automated OraQuick® production line mentioned on prior calls has been installed and validated and the related regulatory submissions have been made. We expect to begin producing product later in Q2 with this equipment. This will add additional capacity of up to 10.4 million devices per year when this equipment becomes fully operational.

We also plan to order a third automated line this quarter. We estimate this third line will become operational in the back half of 2018 and would add up to an additional 10.4 million devices of annual capacity.

We are also expanding capacity at our OraQuick® assembly contractor in Thailand. We use this firm to assemble and supply non-US and non-CE marked OraQuick® 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 is also planned for 2018.

Given the growth in our molecular business, we are also expanding production capacity. Two additional automated assembly lines have been ordered, which will more than double our capacity. We expect the first line to become operational by the end of 2017 and the second in early 2018.

These changes will help ensure that we have more than enough capacity to meet forecasted global demand for our HIV, HCV and molecular products through at least 2019.

Lastly, as noted on the prior call, we are working with a consulting firm to help us optimize the global footprint for the manufacture of our products. We expect this engagement will conclude in the next several months.

***Conclusion***

So, in summary, there is much for which to be excited. Our business has more opportunity than at any time since I have been with OraSure. That opportunity is translating into strong financial results as evidenced by our recent quarters. Our international HCV and HIV products and our molecular business continue to fuel strong growth and we are taking the necessary steps to ensure we can meet future demand for our products on a worldwide basis. We believe the recent trends in our businesses will continue and should make 2017 a very successful year for OraSure.

And with that, I will now open the floor to 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; 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.