
**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 6, 2019

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

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16537
(Commission
File Number)

36-4370966
(I.R.S. Employer
Identification No.)

220 East First Street
Bethlehem, Pennsylvania
(Address of Principal Executive Offices)

18015-1360
(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.

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|--|------------------------------|--|
| Common Stock, \$0.000001 par value per share | OSUR | The NASDAQ Stock Market LLC |

Item 2.02 – Results of Operations and Financial Condition.

On May 8, 2019, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended March 31, 2019 and updated financial guidance. 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 5.02 – Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

2019 Incentive Plan

On May 6, 2019, the Board of Directors (the “Board”) of OraSure Technologies, Inc. (the “Company”) approved the terms of the Company’s 2019 Incentive Plan (the “2019 Incentive Plan”), with input from the Compensation Committee of the Board (the “Committee”). The 2019 Incentive Plan provides for the payment of incentive cash bonuses to the management of the Company and its subsidiary, DNA Genotek, Inc. (“DNAG”), based on performance during 2019.

Bonus Pool Funding. Pursuant to the 2019 Incentive Plan, incentive cash bonuses may be paid out of a cash pool to be funded based on the Company’s achievement of certain financial and strategic objectives. Specific financial objectives were established for consolidated revenues and operating income. The Board also established four strategic initiatives for purposes of pool funding. These initiatives focus on either the advancement of strategic transactions or significant commercial milestones that the Board believes will help drive growth in the Company’s business.

In early 2019, the Company disclosed that a large consumer genetics customer had changed its promotional strategy and, as a result, reduced its projected purchases for 2019, thereby lowering the Company’s projected revenues for the year. The Board structured the financial objectives and added the strategic initiatives to take account of this unexpected event while at the same time providing an appropriate incentive for management to take steps necessary to drive growth in the remainder of the Company’s business.

Under the 2019 Incentive Plan, Threshold, Target, High and Maximum/Breakthrough performance levels have been established for each of the financial objectives to be used to fund the bonus pool. In past years, the Threshold levels represented the Company’s actual performance for the prior year and the Target levels represented performance reflected in the Company’s operating plan, or budget, as adopted by the Board for the plan year. In order to recognize the impact of the large customer’s change in purchasing strategy and still provide a reasonable incentive for management, the Board adopted a Target performance level that represents modest growth from 2018, and a Threshold level somewhat below the Target. Consistent with past practice, the High and Maximum/Breakthrough performance levels were set at 105% and 110%, respectively, of the Target performance levels.

In past years, the objectives for consolidated revenue and operating income were weighted equally for purposes of determining bonus pool funding. However, based on feedback from our stockholders, the Board decided that it would be appropriate to provide a greater incentive for revenue growth in the current plan. Accordingly, under the 2019 Incentive Plan the financial objectives were given equal weight for performance at the Threshold and Target performance levels, and a higher weight was given to the revenue objective for performance at the High and Maximum/Breakthrough performance levels. The relative weighting assigned to the performance objectives is expressed as a percentage of the maximum pool funding amount, which would equal 200% of the aggregate target bonuses for all participants in the 2019 Incentive Plan (the “Maximum Funding Amount”), assuming a historically normal range or mix of individual performance assessments for those participants (i.e. Outstanding, Exceeds, Meets or Does Not Meet). The Board also decided that at least one strategic objective must be achieved in order for the pool to receive 100% of the funding amount for a specific financial performance level. If no strategic objectives are achieved, the funding for a performance level will be discounted to 90%.

The following sets forth the relative weighting of the financial objectives as described above for purposes of pool funding, expressed as a percentage of the Maximum Funding Amount:

| | Performance Level | | | |
|--------------------------------|-------------------|---------------|-------------|----------------|
| | <u>Threshold</u> | <u>Target</u> | <u>High</u> | <u>Maximum</u> |
| Consolidated Revenue Objective | 12.5% | 25% | 50% | 75% |

Based on the foregoing, preliminary pool funding under the 2019 Incentive Plan could be as follows, depending on the performance level for each financial objective and whether at least one strategic initiative is achieved (dollars in thousands):

| | Performance Level | | | |
|--------------------------------|-------------------|---------------|-------------|-----------------------------|
| | <u>Threshold</u> | <u>Target</u> | <u>High</u> | <u>Maximum/Breakthrough</u> |
| Consolidated Revenue Objective | \$ 989 | \$2,000 | \$4,000 | \$5,900 |
| Operating Income Objective | \$1,000 | \$2,000 | \$2,000 | \$2,000 |
| Total with Strategic (100%) | \$1,989 | \$4,000 | \$6,000 | \$7,900 |
| Total without Strategic (90%) | \$1,780 | \$3,600 | \$5,400 | \$7,110 |

Performance below Threshold will accrue no bonus pool funding for the applicable objective. Performance between Threshold and Target, Target and High, and High and Maximum/Breakthrough performance levels, will result in pro-rated funding on a linear basis for the applicable objectives.

The Committee and the Board have the discretion to approve bonus pool funding less than or in excess of amounts generated by the formula set forth in the 2019 Incentive Plan; provided that any such discretionary adjustments to pool funding shall be limited to +/- 10% of the aggregate pool amount otherwise determined by the plan's self-funding formula.

Payments from the Bonus Pool. Specific bonus payments from the pool to the Company's senior management (other than the CEO) will generally depend on an evaluation of the participant's achievement of individual performance objectives for 2019. The bonus payment for the CEO will be based on an assessment of the Company's overall performance. Bonus payments will be based on target bonus amounts, which are expressed as a percentage of annual base salary. Targets for the company's named executive officers are set forth below, were established with input from an independent executive compensation consultant engaged by the Committee, and are similar to bonus targets offered at medical diagnostic and healthcare companies comparable to the Company.

| <u>Title</u> | <u>Target Payouts</u> <u>(% of Base Salary)</u> |
|--------------------------|--|
| President and CEO | 85% |
| CFO | 50% |
| Executive Vice President | 40% |
| Senior Vice President | 35% |

Based on an assessment of performance, as described above, bonus payments of 100% of target may be awarded for a "Meets Requirements" assessment, bonus payments of 101% - 125% of target may be awarded for an "Exceeds Requirements" assessment and bonus payments of 125% - 150% of target may be awarded for an "Outstanding" assessment. Awards may be adjusted on a pro rata basis as determined in the Committee's or Board's discretion to the extent any participant is employed for only a portion of the year.

The Committee recommends for Board approval any bonus awards for the CEO. The CEO recommends individual awards for the other executive officers for approval by the Committee. The Committee and the Board shall have the right, in their sole discretion, to reject any or all of the recommended bonus awards or approve different bonus awards, even if the bonus pool has been funded and any and all applicable performance criteria have or have not been satisfied, based on the business conditions of the Company or other factors deemed relevant by the Committee or Board. All bonus awards under the 2019 Incentive Plan are subject to the Company's Compensation Recoupment Policy (i.e. clawback policy).

Item 7.01 – Regulation FD Disclosure.

On May 8, 2019, the Company held a webcast conference call with analysts and investors, during which Stephen S. Tang, Ph.D., the Company's President and Chief Executive Officer, and Roberto Cuca, the Company's Chief Financial Officer, discussed the Company's consolidated financial results for the quarter ended March 31, 2019, provided updated financial guidance and described certain business developments. A copy of the prepared remarks of Dr. Tang and Mr. Cuca is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

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

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

| Exhibit Number | Description |
|-------------------|---|
| 99.1 | <u>Press Release, dated May 8, 2019, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2019 and updated financial guidance.</u> |
| 99.2 | <u>Prepared Remarks of Stephen S. Tang, Ph.D. and Roberto Cuca for OraSure Technologies, Inc. First Quarter 2019 Analyst/ Investor Conference Call Held May 8, 2019.</u> |

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 8, 2019

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary



OraSure Technologies, Inc.

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OraSure Announces 2019 First Quarter Financial Results

BETHLEHEM, PA – May 8, 2019 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its financial results for the quarter ended March 31, 2019.

“Our first quarter 2019 performance was in line with our expectations for both the top and bottom lines,” said Stephen S. Tang, Ph.D., President and CEO of OraSure Technologies. “We are optimistic about the second quarter and full-year performance of our underlying businesses, despite the impact of a previously announced change in market approach by a large consumer genetics customer. The foundations of our business are strong, and we believe we are on the right path with our innovation-driven growth strategy.”

“We continue to diversify our molecular collections business and are seeing opportunity in key segments of the genomics market. Our microbiome business has continued to grow year-over-year in every quarter since we first began breaking out its revenues in 2016. Our HCV business grew both domestically and internationally, and we expect our OraQuick® HIV sales to show solid growth for the full year. Our recent acquisitions are just the first examples of implementation of our growth strategy and we remain committed to making additional strategic growth investments.”

Financial and Business Highlights

- In January 2019, the Company acquired innovation growth companies Novosanis NV and CoreBiome, Inc. for an aggregate purchase price of approximately \$13.3 million. Novosanis is a leader in urine sample collection devices targeted primarily at the liquid biopsy, sexually transmitted infection screening, and urological cancer markets, and CoreBiome is an early-stage microbiome services provider that accelerates discovery for customers in the pharmaceutical, agricultural and research communities. The sales generated by these new subsidiaries are included in the revenues of the Company’s molecular collection systems segment.
 - The Company’s financial performance during the first quarter of 2019 was in line with expectations. Net revenues for the first quarter of 2019 were \$30.1 million, a 28% decrease from the first quarter of 2018. Net product revenues were \$28.3 million, representing a 26% decrease from the first quarter of 2018. These decreases were primarily the result of a previously-disclosed change in marketing strategy by a large consumer genetics customer.
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- International sales of the Company's OraQuick® HCV product of \$1.5 million increased 119% for the first quarter of 2019 compared to the first quarter of 2018. Domestic sales of the Company's OraQuick® HCV product of \$1.8 million increased 12% over the comparable period of the prior year.
- International sales of the Company's OraQuick® HIV products of \$4.0 million in the first quarter of 2019 decreased 30% compared to the first quarter of 2018. Domestic sales of the Company's OraQuick® HIV products of \$4.3 million decreased 14% compared to the comparable period of the prior year.
- Molecular collection systems revenues including royalty income and other revenues were \$11.9 million during the first quarter of 2019, a decline of 40% from the first quarter of 2018. Molecular collection systems product and service revenues were \$10.6 million during the first quarter of 2019, which represents a 42% decrease from the first quarter of 2018.
- Net loss for the first quarter of 2019 was \$3.3 million, or \$0.05 per share, which compares to a net loss of \$2.1 million, or \$0.03 per share, for the first quarter of 2018. Net loss for the first quarter of 2019 included acquisition-related charges of \$1.3 million for the change in fair value of contingent consideration and \$597,000 of transaction costs. These charges had a combined impact of approximately \$0.03 per share. The net loss for the first quarter of 2018 included \$6.4 million of pre-tax transition costs, or \$0.10 per share, associated with executive management changes which occurred in 2018. These transition costs primarily consisted of non-cash stock compensation charges.
- Cash and investments totaled \$183.6 million at March 31, 2019.

Financial Results

Net product revenues for the first quarter of 2019 decreased 26% from the comparable period of 2018, primarily as a result of lower sales of the Company's molecular collections products and OraQuick® HIV tests, partially offset by higher OraQuick® HCV test sales.

International sales of the OraQuick® HIV Self-Test for the three months ended March 31, 2019 and 2018 included \$709,000 and \$985,000 respectively of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation").

Royalty income from a litigation settlement associated with a molecular collection device was \$1.1 million and \$1.6 million for the first quarters of 2019 and 2018, respectively. Other revenues, excluding royalty income, were \$706,000 and \$2.1 million for the first quarters of 2019 and 2018, respectively. Other revenues decreased due to lower funding received from the U.S. Biomedical Advanced Research Development Authority and lower cost reimbursement from the Gates Foundation.

Gross profit percentage was 60% and 58% for the three months ended March 31, 2019 and 2018, respectively. Gross profit percentage in 2019 benefited from improved product mix associated with an increase in sales of higher gross profit products and lower royalty expense, partially offset by lower royalty income.

For the three months ended March 31, 2019, operating expenses were \$21.9 million, a decrease of \$3.1 million from the \$25.0 million reported for the three months ended March 31, 2018. This decrease was largely due to the absence of \$6.4 million of transition costs associated with executive management changes that occurred in the first quarter of 2018, partially offset by a non-cash charge of \$1.3 million for the change in fair value of contingent consideration associated with the recent acquisition of CoreBiome and Novosanis, the incremental operating expenses of CoreBiome and Novosanis, and \$597,000 of transaction

costs associated with the recent acquisitions. There were no similar acquisition costs in the first quarter of 2018.

The Company reported an operating loss of \$3.8 million in the first quarter of 2019, compared to an operating loss of \$498,000 in the first quarter of 2018.

During the first quarter of 2019, the Company recorded an income tax benefit of \$29,000 compared to income tax expense of \$2.0 million recorded in the first quarter of 2018. The decrease in income tax expense reflects the lower pre-tax income generated by the Company's Canadian subsidiary in the current period and includes an income tax benefit generated by Novosanis.

The Company's cash and investment balance totaled \$183.6 million at March 31, 2019, compared to \$201.3 million at December 31, 2018. For the three months ended March 31, 2019, the Company generated \$528,000 in cash from operations.

Second Quarter and Full Year 2019 Outlook

The Company expects second quarter 2019 net revenues to range from \$40.0 million to \$42.0 million and is projecting net income of approximately \$0.02 per share. For the full year of 2019, the Company is expecting net revenues to range from \$170.0 million to \$175.0 million and is projecting net income of \$0.22 to \$0.24 per share. These projections do not account for the impact of changes in the fair value of acquisition-related contingent consideration or any potential transaction costs related to future business development activity since those items cannot be fully determined at this time.

“As in prior years, we expect the Company's financial performance will progress and grow from our solid first quarter driven by both our core infectious disease and molecular collection businesses. Our results also reflect performance by CoreBiome and Novosanis and the seasonality of certain parts of our business,” Dr. Tang said. “It should be clear from our second quarter and full-year guidance that we anticipate a very strong second half of the year, reflecting full-year growth in all of our core strategic product lines, when the effect of the large consumer genetics customer's change in market strategy is excluded.”

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

| | Three Months Ended March 31, | |
|--|---------------------------------|------------|
| | 2019 | 2018 |
| Results of Operations | | |
| Net revenues | \$ 30,122 | \$ 41,987 |
| Cost of products sold | 12,042 | 17,520 |
| Gross profit | 18,080 | 24,467 |
| Operating expenses: | | |
| Research and development | 4,371 | 4,075 |
| Sales and marketing | 7,295 | 7,499 |
| General and administrative | 8,930 | 13,391 |
| Change in fair value of acquisition-related contingent consideration | 1,295 | — |
| Total operating expenses | 21,891 | 24,965 |
| Operating loss | (3,811) | (498) |
| Other income | 524 | 412 |
| Loss before income taxes | (3,287) | (86) |
| Income tax expense (benefit) | (29) | 2,033 |
| Net loss | \$ (3,258) | \$ (2,119) |
| Loss per share: | | |
| Basic | \$ (0.05) | \$ (0.03) |
| Diluted | \$ (0.05) | \$ (0.03) |
| Weighted average shares: | | |
| Basic | 61,531 | 60,865 |
| Diluted | 61,531 | 60,865 |

| | Three Months Ended March 31, | | | | |
|----------------------------------|------------------------------|-----------|-------------|-------------------------------------|-------|
| | Dollars | | % Change | Percentage of Total Net Revenues | |
| | 2019 | 2018 | | 2019 | 2018 |
| Market | | | | | |
| Infectious disease testing | \$ 12,338 | \$ 14,170 | (13) % | 41 % | 34 % |
| Risk assessment testing | 2,836 | 3,002 | (6) | 9 | 7 |
| Cryosurgical systems | 2,575 | 2,785 | (8) | 9 | 6 |
| Molecular collection systems | 10,583 | 18,361 | (42) | 35 | 44 |
| Net product and service revenues | 28,332 | 38,318 | (26) | 94 | 91 |
| Royalty income | 1,084 | 1,602 | (32) | 4 | 4 |
| Other | 706 | 2,067 | (66) | 2 | 5 |
| Net revenues | \$ 30,122 | \$ 41,987 | (28) % | 100 % | 100 % |

| | Three Months Ended March 31, | | |
|----------------------------------|---------------------------------|-----------|-------------|
| | 2019 | 2018 | % Change |
| <u>OraQuick® Revenues</u> | | | |
| Domestic HIV | \$ 4,304 | \$ 4,976 | (14) % |
| International HIV | 4,001 | 5,737 | (30) |
| Net HIV revenues | 8,305 | 10,713 | (22) |
| Domestic HCV | 1,828 | 1,627 | 12 |
| International HCV | 1,457 | 665 | 119 |
| Net HCV revenues | 3,285 | 2,292 | 43 |
| Net product revenues | \$ 11,590 | \$ 13,005 | (11) % |

| | Three Months Ended March 31, | | |
|---|---------------------------------|-----------|-------------|
| | 2019 | 2018 | % Change |
| <u>Molecular Collection Systems Revenues</u> | | | |
| Genomics | \$ 8,047 | \$ 17,088 | (53) % |
| Microbiome | 2,326 | 1,273 | 83 |
| Other | 210 | - | 100 |
| Net product and service revenues | 10,583 | \$ 18,361 | (42) |
| Royalty income | 1,084 | 1,602 | (32) |
| Other | 222 | - | 100 |
| Total Molecular Collection Systems Revenues | \$ 11,889 | \$ 19,963 | (40) % |

Condensed Consolidated Balance Sheets (Unaudited)

| | March 31, 2019 | December 31, 2018 |
|---|-------------------|-------------------|
| <u>Assets</u> | | |
| Cash and cash equivalents | \$ 69,516 | \$ 88,438 |
| Short-term investments | 77,474 | 68,134 |
| Accounts receivable, net | 24,909 | 34,842 |
| Inventories | 26,213 | 22,888 |
| Other current assets | 7,226 | 5,010 |
| Property, plant and equipment, net | 25,970 | 24,299 |
| Right of use assets, net | 5,265 | - |
| Intangible assets, net | 12,929 | 5,137 |
| Goodwill | 28,903 | 18,521 |
| Long-term investments | 36,585 | 44,752 |
| Other non-current assets | 3,935 | 3,550 |
| Total assets | \$ 318,925 | \$ 315,571 |
| <u>Liabilities and Stockholders' Equity</u> | | |
| Accounts payable | \$ 10,638 | \$ 10,598 |
| Deferred revenue | 4,234 | 3,521 |
| Contingent consideration obligation | 3,638 | - |
| Other current liabilities | 8,798 | 13,861 |
| Long-term lease liabilities | 4,375 | - |
| Long-term contingent consideration obligation | 1,987 | - |
| Other non-current liabilities | 4,748 | 4,213 |
| Stockholders' equity | 280,507 | 283,378 |
| Total liabilities and stockholders' equity | \$ 318,925 | \$ 315,571 |

| Additional Financial Data (Unaudited) | Three Months Ended | |
|--|--------------------|----------|
| | March 31, | |
| | 2019 | 2018 |
| Capital expenditures | \$ 2,628 | \$ 1,897 |
| Depreciation and amortization | \$ 1,726 | \$ 1,868 |
| Stock-based compensation | \$ 1,231 | \$ 7,483 |
| Cash provided by operating activities | \$ 528 | \$ 7,636 |

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2019 first quarter results, certain business developments and updated financial guidance, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Dr. Stephen S. Tang, President and Chief Executive Officer, and Roberto Cuca, Chief Financial Officer. The call will include prepared remarks by management and a question and answer session.

In order to listen to the conference call, please either dial 844-831-3030 (Domestic) or 315-625-6887 (International) and reference Conference ID #5270658 or go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Relations page. Please click on the webcast link and follow the prompts for registration and access 10 minutes prior to the call. A replay of the call will be archived on

OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until midnight, May 15, 2019, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #5270658.

About OraSure Technologies

OraSure Technologies is empowering the global community to improve health and wellness by providing access to accurate essential information. OraSure is a leader in the development, manufacture and distribution of point-of-care diagnostic tests, molecular 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 Hepatitis C (HCV) on the OraQuick® platform, sample self-collection and stabilization products for molecular applications, and oral fluid laboratory tests for detecting various drugs of abuse. Together with its wholly-owned subsidiaries (DNA Genotek, CoreBiome and Novosanis), OraSure provides its customers with value-added, end-to-end solutions that encompass tools, diagnostics and services. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research institutions, distributors, government agencies, physicians' offices, commercial and industrial entities and consumers.

For more information on OraSure Technologies, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: successfully managing and integrating acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration ("FDA") or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company's products; impact of significant customer concentration in the genomics business; impact of increased reliance on U.S. government contracts; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions;

reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention (“CDC”) or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company’s stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could affect our results are discussed more fully in the Company’s Securities and Exchange Commission (“SEC”) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2018, 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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OraSure Technologies, Inc.
2019 First Quarter
Analyst/Investor Conference Call
May 8, 2019

Prepared Remarks of Dr. Stephen S. Tang and Roberto Cuca

Please see “Important Information” at the conclusion of the following prepared remarks

Introduction – Steve Tang

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

I'm pleased to report that our first quarter revenues and bottom line performance fell within the financial guidance we announced during our last earnings call and represent a good starting point for the second quarter and full-year 2019. Our innovation-driven growth strategy is working and delivered many positive developments, during the quarter, that we will detail later in the call. We remain confident in our strategy and our ability to execute against our strategic priorities.

During our last call, we reported that a large consumer genetics customer had recently adopted a new promotional strategy and, as a result, reduced its purchase forecast for the year. While that unfortunate development had a measurable effect on our Q1 results, it is important that we not let that event obscure the significant positive progress underlying our business. For example:

- Apart from that large customer, our genomics business showed year-over-year growth in Q1, and we expect this growth to continue for the foreseeable future. Looking at accounts other than this one customer, we expect the genomics business to grow by healthy double digits in 2019.
 - Genetic testing is at a much earlier stage in the Asia-Pacific market and we are well positioned to serve the needs of this market. We see it as a significant growth opportunity which is already contributing to our financial results.
 - The microbiome market is also at an early stage and the potential is enormous for a company with our position in the market. Our microbiome sales are growing robustly
-

each quarter and should also contribute double-digit growth for the year. The addition of CoreBiome has enabled us to expand and strengthen our microbiome offerings with cutting-edge laboratory and bio-informatics analysis and services.

- Multiomics is an emerging approach to evaluating health that also offers significant growth potential. This relatively new field provides a multifactorial examination of health. Our ability to provide customers both genomic and microbiome products and services is an important foundation for OraSure to become a leading source for multiomics tools and analytics.
- In our infectious disease testing business, we expect another strong year of growth, particularly for our HIV Self-Test, although this growth may not be distributed evenly over the year due to timing of orders. Despite this choppiness, we project double-digit revenue growth for our global HIV franchise this year.
- Our HCV business also grew during the quarter on both the domestic and international fronts. We believe that additional funding is driving this growth, and that funding will continue to be available.
- Finally, we demonstrated our ability to execute against our acquisition growth strategy with the CoreBiome and Novosanis transactions in Q1. After only a few months, these acquisitions are already expanding our market reach with new products and services. We see these acquisitions as just the beginning, and we plan to remain very active pursuing additional transactions. So, there is more to come because of our very strong balance sheet and our considerable focus on business development.

As you can see, we are enthusiastic about this quarter and our future. The foundations of our business are strong, and we are seeing growth in the areas in which we have targeted and invested. Importantly, we are on the right path with our innovation-growth strategy despite the negative effect on near-term revenue by the new market approach of a large customer.

Looking ahead, we expect the underlying strength of our infectious disease testing and molecular solutions segments will be more fully demonstrated as the year progresses.

Turning briefly to the quarter, the decline in our revenues compared to the first quarter of 2018 was primarily the result of the reduced purchases by that large customer I mentioned earlier and some unevenness in the timing of customer orders for our OraQuick® HIV Self-Test in international markets. Nonetheless, we delivered Q1 results within our expectations.

Beyond the first quarter, we expect strong molecular growth outside of the one large consumer genetics customer. We expect sales to this customer will be consistent with its annual minimum contractual purchase obligation. This, combined with continued growth in our global infectious disease testing business, will drive solid financial results and gives us the confidence to issue full-year guidance. Our guidance for Q2 and the full year reflects the continued success we anticipate as we further execute our growth strategy.

With that, let me now turn things over to Roberto for his financial review. I will then follow up with some additional insight into the trends and factors that help validate our strategy and that are expected to benefit our business for the remainder of 2019 and beyond.

First Quarter 2019 Financial Results – Roberto Cuca

Thanks Steve, and good afternoon everyone.

Our first quarter net revenues decreased 28% to \$30.1 million from \$41.9 million reported in the first quarter of 2018. Our net product revenues decreased 26% to \$28.3 million compared to the prior-year period. As Steve just described much of this decrease was driven by the changed market approach of a single large consumer genetics customer and the uneven distribution of the strong international HIV sales we expect over the course of the year due to ordering patterns.

Our molecular net revenues including other revenues decreased 40% to \$11.9 million in the first quarter compared to \$20.0 million in 2018. Royalty income declined 32% to \$1.1 million in the first quarter of 2019, from \$1.6 million in the same period of 2018. Molecular product revenues decreased 42% to \$10.6 million in the first quarter of 2019 compared to \$18.4 million in the first quarter of 2018. Sales of our genomic products declined 53% to \$8.1 million largely due to the lower sales to a large consumer genetics customer as previously described. Microbiome sales

increased 83% to \$2.3 million from \$1.3 million in the first quarter of last year due both to organic growth as well as the inclusion of lab service revenues generated by our newly-acquired subsidiary CoreBiome.

Domestic HIV sales decreased 14% to \$4.3 million in the first quarter of 2019 compared to \$5.0 million in the first quarter of 2018 largely due to decreased sales of our OraQuick® In-Home test and lower sales of our professional product as a result of continued product and price competition.

International HIV sales decreased 30% to \$4.0 million from \$5.7 million in the first quarter of 2018 due to customer ordering patterns partially offset by higher sales of our HIV Self-Test into Asia. Quarter-over-quarter variability in volume is expected as the programs utilizing our Self-Test continue to create awareness and assess on-going demand.

Domestic HCV sales increased 12% in the first quarter of 2019 to \$1.8 million from \$1.6 million in the prior-year period largely due to increased government funding that is allowing for the expansion of existing HCV testing and treatment programs and the addition of new programs.

International HCV sales in the first quarter of 2019 increased 119% to \$1.5 million from \$665,000 in the same period of 2018 primarily due to continued growth in Asia as well as customer ordering patterns.

Other revenues were \$1.8 million in the current quarter compared to \$3.7 million in the prior year. The decrease is largely due to lower royalty income and decreases in BARDA funding and cost reimbursement under our charitable support agreement with the Gates Foundation. The reduced BARDA funding is an indication that we are wrapping up the work under this program and rotating R&D resources to projects that are aligned with our long-term growth strategy.

Gross profit percentage for the first quarter of 2019 was 60% compared to 58% reported for the first quarter of 2018. Gross profit percentage for the current quarter benefited from improved product mix associated with an increase in higher gross profit percentage product sales and lower royalty expense partially offset by the decrease in other revenues which contribute 100% to the gross profit percentage.

Our operating expenses for the first quarter of 2019 were \$21.9 million compared to \$25.0 million in the comparable period of 2018. Operating expense in the first quarter of 2019 included \$1.3 million of non-cash acquisition-related contingent consideration costs, incremental operating expenses generated by CoreBiome and Novosanis, and \$597,000 of acquisition-related transaction costs. There were no similar acquisition-related costs in the first quarter of 2018. The first quarter of 2018 included \$6.4 million of transition costs associated with executive management changes that occurred during that period. There were no material transition costs in the first quarter of 2019.

In the first quarter of 2019 we recorded an income tax benefit of \$29,000 compared to income tax expense of \$2.0 million in the same period last year. The decline in tax expense reflects the lower pre-tax earnings generated by our Canadian subsidiary and the results generated by Novosanis.

We reported a net loss of \$3.3 million, or \$0.05 per share, for the first quarter of 2019 compared to a net loss of \$2.1 million, or \$0.03 per share, for Q1 2018.

We continue to maintain a solid cash and liquidity position. Our cash and investments balance at March 31, 2019 was \$183.6 million compared to \$201.3 million at December 31, 2018. During the first quarter of 2019 we used \$13.3 million of cash to acquire CoreBiome and Novosanis. Cash generated by operating activities during the first quarter of 2019 was \$528,000 compared to \$7.6 million in the same period of 2018.

Turning to guidance: For the second quarter of 2019, we are projecting revenues of \$40.0 to \$42.0 million and net income of approximately \$0.02 per share. For the full year of 2019, we are projecting revenues of \$170 to \$175 million and net income of \$0.22 to \$0.24 per share. These projections do not account for the impact of changes in the fair value of acquisition-related contingent consideration or potential business development transaction costs since the full extent of those items cannot be determined at this time.

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

Business Update – Steve Tang

Thanks Roberto. I'd now like to share with you some key market trends in our Molecular and Infectious Disease businesses that substantiate our strategy and support our guidance. Let me first discuss our Molecular business, which will continue to be a key driver of our overall business.

Molecular Solutions – Steve Tang

Human Genomics

The genetic testing market has been the largest component of our overall molecular business for some time, and continues to evolve. Given the importance of the genetic testing market to our business, I would like to describe some of the trends we are seeing based on a combination of data analysis, customer feedback and market research we recently conducted. Of most interest are the market dynamics affecting two areas within genetic testing. They are ancestry and disease risk management.

Ancestry testing consists primarily of genetic tests that provide consumers with genealogical information. This is the largest and most developed component of the genetic testing market. Historically, the growth in ancestry testing seems to have been strongly tied to advertising spend and promotional pricing offered by the leading direct-to-consumer companies. It appears that the ancestry market in the United States is maturing. As such, we expect to see the growth rate of that subsector of the overall genetic testing market slowing, and likely leveling off in the next couple of years.

Outside of the U.S., however, we are seeing, and expect to continue to see, significant growth in genetic testing. As previously noted, the Asia-Pacific market is at a much earlier stage than the U.S. market. Our market analysis suggests that it may be as much as five years behind the domestic market, so there is much room for us to grow. In Q1, although the dollar amount is relatively low, we saw our sales increase 231% in Asia when compared to the first quarter of 2018. This type of growth reflects increased product offerings, new market entrants and the expansion of existing customers, like WeGene, into new geographies in Asia. Given the early stage of this market, we expect continued robust growth for the foreseeable future.

The other key submarket of genetic testing is disease risk management, which encompasses genetic tests that provide information about an individual's genetic health risk. Examples include an individual's predisposition to diseases such as cancer and carrier status. Pharmacogenomics

and companion diagnostics are also included in this submarket. We are seeing a steady increase in the number of new customers in this area and consistent growth as companies are adding to their test menus and increasing their test volumes. We believe that uptake in this market will be highly dependent on practitioner awareness and consumer awareness of emerging patient-initiated testing models. Given the increasing focus on personalized medicine, we see much potential for growth in disease risk management.

We currently count several pioneering companies in this space as customers. One example of such a customer is Helix which recently announced an increased focus on enabling population-based health studies such as the Healthy Nevada project. This study, which has enrolled over 35,000 participants since its launch two years ago, has just been expanded to the entire state of Nevada, with a goal of becoming a nationwide model. We are proud of our relationship with Helix and believe we are uniquely qualified to serve this market thanks to our leadership position in DNA collection, our focus on high quality products, and our FDA and other global regulatory clearances.

Moreover, with the addition of Novosanis' Colli-Pee™ collection device, which is designed to collect first-void urine samples, we are now able to expand the types of specimen collection kits we offer to serve new markets including the sexually transmitted infection and cancer screening markets. An increasing number of testing guidelines are including first-void urine as a recommended specimen type. In particular, urinary Human Papilloma Virus (HPV) detection is an alternate sampling method to improve cervical cancer screening participation.

These trends are already positively impacting our genomics business. For example:

- We added more than 40 new genetic testing customers in the first quarter, continuing the trend of new customer additions seen in prior periods;
- Our collection device unit sales to customers other than the large consumer genetics customer grew 72% in Q1 compared to the comparable quarter of 2018;
- There are now two customers in Asia and 12 disease risk management customers in our list of top 20 customers, based on trailing 12-month sales; and

- Sales to the disease risk management accounts within our top 20 accounts for the last 12 months were up over 505% compared to the prior 12-month period.

Finally, there are other parts of the consumer genetic testing market that are expected to grow, but today are only small contributors to our business. These include lifestyle testing, which uses genetic tests to provide lifestyle information around metabolism, fitness, health traits and entertainment, and companion animal genetic testing. We believe these areas, as well as others that will undoubtedly emerge, could become meaningful contributors to our business.

Microbiome

If you have been following OraSure, you know that we have highlighted the similarities between trends in the microbiome research market and the early days of genetic testing. That similarity continues.

In the microbiome market we delivered another record performance with first quarter revenues up 83% when compared to 2018. This reflects a 30% increase in sample collection kits shipped and a 56% increase in first-time purchasers of our kits when compared to the prior year quarter. Both of these metrics support our view that the recent strong growth in this market is likely to continue for the foreseeable future. As we have learned from our human genomics experience, new customers tend to start with small volumes of devices as they validate their study and lab protocols, and then expand their studies as new funding becomes available.

Diversification of our microbiome offerings remains a key focus. We intend to continue expanding our collection kit offerings to include different specimen types, such as skin, in addition to stool, for microbiome analysis. With the acquisition of CoreBiome, additional opportunities are also opening for microbiome analysis, including not just human microbiome tests but also environmental and agricultural testing. Approximately 60% of CoreBiome's customers are currently in the area of pharmaceutical discovery and clinical trials. We expect that pharmaceutical customers will continue to be important, early adopters of advanced multiomic data analysis. In fact, during the first quarter CoreBiome entered into a contract with a significant new customer to provide advanced machine learning for biomarker discovery. This type of discovery is expected to help advance our understanding for optimal disease treatments.

We are also thrilled with the recent addition of Dr. Rob Knight to CoreBiome's scientific advisory board. Dr. Knight is Professor and Director for the Center for Microbiome Innovation at the University of California, San Diego, and one of the most widely cited scientists in the microbiome field. He was a key contributor to the National Institutes of Health Human Microbiome Project, and is also a thought leader who developed many of the foundational tools underlying microbiome science. His involvement as an advisor to our business exemplifies how we are working with field experts in our key growth areas, and further demonstrates our commitment to driving innovation in the microbiome community.

Multiomics

As previously noted, we continue to see nice synergies within our molecular business, as more of our existing human genomics customers start to move towards multiomics, by introducing a microbiome component to their studies and offerings. In particular, we saw a 33% increase in customers who are using both genomics and microbiome kits during the first quarter of 2019, compared to the prior year quarter. We see this trend continuing and will continue to evolve our multiomics strategy in order to maximize the potential for this emerging area in human health.

Infectious Disease Testing – Steve Tang

Turning now to infectious disease:

Our global HIV revenues were down in Q1 compared to 2018, primarily as a result of the timing of orders for our OraQuick® HIV Self-Test. In particular, lower sales into Africa were only partially offset by growth in Asia. As indicated in prior calls, the quarterly volume of self-test sales can be a bit choppy as individual countries determine their utilization of product. This is part of the normal development cycle within this market that involves the start-up of new testing programs where awareness needs to be created and routine utilization is being determined.

However, we expect that our HIV global business will show solid double-digit growth for the full year, once again primarily driven by increased self-test revenues in subsequent quarters. We are continuing to see the HIV self-test market develop, as countries with existing programs reorder product, additional countries move from a pilot stage to full scale up for their programs, and the

number of country registrations for our product continues to increase. As previously noted, phase II of the STAR, or Self-Testing Africa, program has largely ended, and a majority of our volumes are now coming from non-STAR countries. We expect that trend to continue.

We have also had numerous discussions with major funders of testing programs. Although these discussions do not guarantee additional purchases, these funding organizations have signaled their intention of beginning or increasing their investment into the self-testing market. As you may recall, we previously mentioned that UNITAID would be funding another self-testing project involving the Ivory Coast and other nearby countries. This funding has begun and initial shipments of our test for that program occurred in Q1. Although this program will be much smaller than the STAR program, it is a concrete example of how and where additional funding is driving growth in HIV self-testing.

Our activities under the support agreement with the Gates Foundation also continue, as expected. We now have product registrations in 15 countries, submissions pending in an additional 17 countries and other registration applications being prepared. We are gradually expanding our access to the 50 countries covered by the Gates Agreement, and our strategy for regulatory submissions and approvals reflects how this market is developing and growing.

All of this continues to lend support to the robust projections previously announced in a report by UNITAID and the World Health Organization, or WHO, which we discussed on prior calls. That report suggested self-test demand would increase from 1 million tests in 2017 to an average range of 16 million tests by the end of 2020, with the higher end of that range reaching just over 19 million tests. Along these lines, in March of this year, the Journal of the International AIDS Society published a comprehensive review entitled, “Realizing the potential of HIV self-testing for Africa: lessons learned from the STAR project.” This report concluded that HIV self-testing has substantially developed in recent years and is now considered a critical HIV response strategy in controlling the epidemic. The report also concluded that a new testing paradigm based in part on HIV self-testing is a key part of HIV response over the next decade and will be critical to achieving 95% diagnosis in broad geographic markets during that period. As the first WHO-prequalified HIV self-test, we are leading the way in self-testing.

So with what we're seeing in our own business, coupled with the market developments I have outlined, we are quite optimistic about the continuing growth potential for our global HIV franchise.

Turning briefly to our OraQuick® HCV business, global revenues grew 43%, with international sales increasing 119% compared to the first quarter of 2018. We are seeing growth primarily in Asia and Eastern Europe with the expansion of existing programs and new customers and new testing and treatment programs emerging.

Our domestic HCV business is growing as well, with revenues up 12% for the quarter. This growth was generally derived from the initiation of new programs and the expansion of existing programs. Funding for this growth is coming from a combination of the Centers for Disease Control and Prevention and state jurisdictions that are finding additional funds within their existing budgets.

As you may know, the current Federal budget included an additional \$5 million in funding to manage the impact of the opioid epidemic on infectious disease, with HCV being one of the diseases specifically mentioned. In the proposed 2020 Federal budget, an additional \$291 million is being requested in order to end the HIV epidemic, and another \$58 million is being requested to address the infectious disease consequences of the opioid epidemic. So we believe more funding is likely to continue for both HIV and HCV, and will help enable the HCV franchise to continue as a growth driver and help stabilize our HIV franchise.

Conclusion - Steve Tang

So, in closing, despite the head wind from that large consumer genetics customer, our overall business is performing as we would have expected -- and even better in certain areas. Our innovation-driven growth strategy is working and we expect to continue to benefit from the large and growing markets we serve. It should be clear from our second quarter and full-year guidance, that we anticipate a strong second half of the year. Our business is well positioned to deliver strong growth in future periods, both through acquisition and strategic execution. We are particularly excited about the prospects for the international genomics market, the growth of the disease risk management submarket of genetic testing, particularly around population studies, and

our microbiome products and services, as well as our unique ability to support the emerging multiomics market.

Our infectious disease segment is on track and we expect significant growth from our global HIV franchise. In addition, we see our HCV product as an ongoing contributor.

Based on our extensive market research and discussions with customers, we are confident that our best days are ahead. We believe that we have the right products, leadership team, balance sheet and business strategy in place to capitalize on the opportunities before us. It's exciting that many of the key markets we serve are very large for a company our size, and these opportunities are still mostly in their infancy. I would also emphasize that we are not only adding new customers, due to our expanded offerings, but we are also increasing the size of our existing relationships. Importantly, we do not have another customer close to the size of the one that changed its purchasing expectations. Therefore, it is safe to assume that another disruption to our top line coming from a single customer is unlikely going forward. Lastly, we are confident we can deliver on our full-year guidance and we are committed to using our balance sheet to enhance our already attractive long-term growth prospects.

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

* * *

[Q&A session]

Final Conclusion – Steve Tang

Thank you for participating on today's call and for your continued interest in OraSure. Have a good afternoon and evening.

Important Information

This document contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or

results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration ("FDA") or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company's products; impact of 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 increased reliance on U.S. government contracts; impact of negative economic conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms

or other recommendations by the Centers for Disease Control and Prevention (“CDC”) or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company’s stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could affect our results are discussed more fully in the Company’s Securities and Exchange Commission (“SEC”) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2018, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this call, and OraSure Technologies undertakes no duty to update these statements.