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

FORM 8-K

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

Date of Report (Date of earliest event reported): August 6, 2019

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

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

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

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

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

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

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

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

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

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

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

Emerging growth company ☐

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

Item 2.02 – Results of Operations and Financial Condition.

On August 6, 2019, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended June 30, 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 7.01 – Regulation FD Disclosure.

On August 6, 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 June 30, 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	Press Release, dated August 6, 2019 announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2019 and updated financial guidance.
99.2	Prepared Remarks of Stephen S. Tang, Ph.D. and Roberto Cuca for OraSure Technologies, Inc. Second Quarter 2019 Analyst/ Investor Conference Call Held August 6, 2019.

Signatures

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

ORASURE TECHNOLOGIES, INC.

Date: August 6, 2019

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

Exhibit 99.1

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OraSure Announces 2019 Second Quarter Financial Results

BETHLEHEM, PA – August 6, 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 three and six months ended June 30, 2019.

"Second quarter revenues were not what we had targeted due to a three-day delayed shipment of HIV Self-Tests and ongoing softness in the consumer genomics markets. However, our earnings were strong and we continue to expect to deliver on and exceed our original profit targets for the year notwithstanding market headwinds," said Stephen S. Tang, Ph.D., OraSure President and CEO. "We are encouraged by the continued, annual double-digit growth in our Microbiome line of business, as well as growth in the Disease Risk Management sector of Consumer Genomics. On the Infectious Disease side, we continue to expect annual double-digit growth in global HIV testing revenues, driven by expanding international usage of our HIV Self-Test product."

Financial and Business Highlights

- Net revenues for the second quarter of 2019 were $38.8 million, an 11% decrease from the second quarter of 2018. Net product revenues were $37.3 million, representing a 4% decrease from the second quarter of 2018.
- Net revenues for the six months ended June 30, 2019 were $68.9 million, a 19% decrease from the comparable period of 2018. Net product revenues were $65.6 million, representing a 15% decrease from the first half of 2018.
- Molecular collection systems revenues including royalty income and other revenues were $18.5 million during the second quarter of 2019, a decline of 4% from the second quarter of 2018. Molecular collection systems revenues including royalty income and other revenues were $30.3 million during the first half of 2019, a decline of 23% from the same period in the prior year.
- Molecular collection systems product and service revenues were $17.3 million and $27.9 million during the second quarter and first half of 2019, respectively, which represents a 1% increase from the second quarter of 2018 and a 22% decrease from the first six months of 2018.

- Domestic and international sales of the Company's OraQuick® HIV products of $9.9 million in the second quarter of 2019 decreased 21% compared to the second quarter of 2018. Domestic and international sales of the Company's OraQuick® HIV products for the six months ended June 30, 2019 of $18.2 million decreased 22% compared to the comparable period of the prior year.
- Domestic sales of the Company's OraQuick® HCV product of $2.1 million increased 22% over the second quarter of 2018. OraQuick® HCV domestic sales for the six months ended June 30, 2019 were $3.9 million, a 17% increase from the comparable period of 2018.
- International sales of the Company's OraQuick® HCV product of $1.0 million decreased 33% for the second quarter of 2019 compared to the second quarter of 2018. OraQuick® HCV international sales for the six months ended June 30, 2019 were $2.4 million, a 14% increase from the comparable period of 2018.
- Net income for the second quarter of 2019 was $4.4 million, or $0.07 per share on a fully-diluted basis, which compares to net income of $4.1 million, or $0.07 per share on a fully-diluted basis, for the second quarter of 2018. Net income for the six months ended June 30, 2019 was $1.1 million, or $0.02 per share on a fully-diluted basis, which compares to net income of $2.0 million, or $0.03 per share on a fully-diluted basis, for the comparable period of 2018. Net income for the current three and six month periods included acquisition-related charges of $249,000 and $1.5 million, respectively, representing the change in fair value of contingent consideration associated with two recent acquisitions. The current six month period also included $597,000 of transaction costs. These acquisition-related charges were negligible for the current quarter on a per share basis and approximated $0.03 per share for the first six months of 2019. Net income for the second quarter and first six months of 2018 included $2.2 million and $8.6 million, respectively, of transition costs associated with executive management changes which occurred in 2018. These transition costs approximated $0.04 and $0.14 per share, respectively, for the second quarter and first six months of 2018, and primarily consisted of non-cash stock compensation charges.
- Cash and investments totaled $186.6 million at June 30, 2019.

Financial Results

Net product revenues for the second quarter of 2019 decreased 4% from the comparable period of 2018, primarily as a result of lower sales of the Company's OraQuick® HIV and genomics products and lower international sales of the Company's OraQuick® HCV test, partially offset by higher sales of the Company's microbiome, cryosurgical, and domestic HCV products.

Net product revenues for the first six months of 2019 decreased 15% from the comparable period of 2018, primarily as a result of lower sales of the Company's genomics and OraQuick® HIV products, partially offset by increases in microbiome, cryosurgical systems, and OraQuick® HCV sales.

International sales of the OraQuick® HIV Self-Test for the three months ended June 30, 2019 and 2018 included $1.1 million and $1.7 million, respectively, of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation"). International sales of the OraQuick® HIV Self-Test for the six months ended June 30, 2019 and 2018 included $1.8 million and $2.7 million, respectively, of support payments.

Royalty income from a litigation settlement associated with a molecular collection device was $1.1 million and $2.1 million for the second quarters of 2019 and 2018, respectively, and $2.2 million and $3.7 million for the first six months of 2019 and 2018, respectively. Other revenues, excluding royalty income, were

$445,000 and $2.7 million for the second quarters of 2019 and 2018, respectively, and $1.1 million and $4.8 million for the first six months of 2019 and 2018, respectively. Other revenues in both periods decreased due to lower funding received from the U.S. Biomedical Advanced Research Development Authority (BARDA) and lower cost reimbursement from the Gates Foundation.

Gross profit percentage was 64% and 63% for the three and six months ended June 30, 2019. Gross profit percentage for the three and six months ended June 30, 2018 was 59% in both periods. Gross profit percentage in both periods of 2019 benefited from improved product mix associated with higher sales of higher gross profit products and lower royalty expense, partially offset by lower other revenues, and the lower margins generated by the Company's newly acquired subsidiaries, Novosanis and CoreBiome.

For the three months ended June 30, 2019, operating expenses were $19.7 million, a decrease of $604,000 from the $20.3 million reported for the three months ended June 30, 2018. The decrease was due in part to the absence of $2.2 million of transition costs associated with executive management changes that occurred in the second quarter of 2018, partially offset by a non-cash charge of $249,000 in the current quarter for the change in fair value of contingent consideration associated with the recent acquisition of CoreBiome and Novosanis, as well as by the incremental operating expenses of CoreBiome and Novosanis. For the six months ended June 30, 2019, operating expenses were $41.6 million, a decrease of $3.7 million from the $45.3 million reported for the six months ended June 30, 2018. This decrease was due in part to the absence of $8.6 million of transition costs associated with executive management changes that occurred in the first half of 2018, partially offset by a non-cash charge of $1.5 million in the first half of 2019 for the change in fair value of contingent consideration associated with the recent acquisition of CoreBiome and Novosanis as well as by the incremental operating expenses of CoreBiome and Novosanis. During the first six months of 2019, the Company also incurred $597,000 of transaction costs associated with the recent acquisitions. There were no similar acquisition costs in either period of 2018.

The Company reported operating income of $5.3 million and $1.5 million in the second quarter and first six months of 2019, respectively, compared to operating income of $5.6 million and $5.1 million in the second quarter and first six months of 2018, respectively.

During the second quarter of 2019, the Company recorded income tax expense of $1.4 million compared to $2.2 million recorded in the second quarter of 2018. During the six months ended June 30, 2019, the Company recorded income tax expense of $1.4 million compared to $4.2 million in the six months ended June 30, 2018. The decrease in income tax expense in both periods reflects the lower pre-tax income generated by the Company's Canadian subsidiary, DNA Genotek, and includes an income tax benefit generated by Novosanis.

The Company's cash and investment balance totaled $186.6 million at June 30, 2019, compared to $201.3 million at December 31, 2018. For the six months ended June 30 2019, the Company generated $4.7 million in cash from operations.

Third Quarter and Updated Full-Year 2019 Guidance

The Company expects third quarter 2019 net revenues to range from $39.0 million to $40.5 million and is projecting net income of approximately $0.04 per share to $0.05 per share. For full-year 2019, the Company is expecting net revenues to range from $165.0 million to $170.0 million and is projecting net income of $0.24 to $0.26 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. The downward revision to full-year revenue expectations from $170.0 to $175.0 million for 2019 reflects continued softness in the consumer genomics market and lower royalties associated with that market. Nonetheless,

the Company continues to expect that genomics revenues excluding the single largest customer, microbiome revenues, and global HIV testing revenues will all grow by double digits in 2019 compared to 2018.

Financial Data

Condensed Consolidated Financial Data

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Results of Operations				
Net revenues	$ 38,826	$ 43,625	$ 68,948	$ 85,612
Cost of products sold	13,808	17,730	25,850	35,250
Gross profit	25,018	25,895	43,098	50,362
Operating expenses:				
Research and development	4,535	4,261	8,906	8,336
Sales and marketing	7,687	7,429	14,982	14,928
General and administrative	7,262	8,647	16,192	22,038
Change in fair value of acquisition-related contingent consideration	249	—	1,544	—
Total operating expenses	19,733	20,337	41,624	45,302
Operating income	5,285	5,558	1,474	5,060
Other income	524	736	1,048	1,148
Income before income taxes	5,809	6,294	2,522	6,208
Income tax expense	1,411	2,173	1,382	4,206
Net income	$ 4,398	$ 4,121	$ 1,140	$ 2,002
Earnings per share:				
Basic	$ 0.07	$ 0.07	$ 0.02	$ 0.03
Diluted	$ 0.07	$ 0.07	$ 0.02	$ 0.03
Weighted average shares:				
Basic	61,709	61,100	61,621	60,983
Diluted	62,128	62,244	62,191	62,379

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2019	2018	% Change	2019	2018
Market					
Infectious disease testing	$ 13,348	$ 15,919	(16) %	34 %	36 %
Risk assessment testing	3,097	3,315	(7)	8	8
Cryosurgical systems	3,518	2,392	47	9	6
Molecular collection systems	17,304	17,192	1	45	39
Net product and service revenues	37,267	38,818	(4)	96	89
Royalty income	1,114	2,092	(47)	3	5
Other	445	2,715	(84)	1	6
Net revenues	$ 38,826	$ 43,625	(11) %	100 %	100 %

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2019	2018	% Change	2019	2018
Market					
Infectious disease testing	$ 25,686	$ 30,090	(15) %	37 %	35 %
Risk assessment testing	5,934	6,316	(6)	9	7
Cryosurgical systems	6,093	5,177	18	9	6
Molecular collection systems	27,886	35,553	(22)	40	42
Net product revenues	65,599	77,136	(15)	95	90
Royalty income	2,198	3,694	(40)	3	4
Other	1,151	4,782	(76)	2	6
Net revenues	$ 68,948	$ 85,612	(19) %	100 %	100 %

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	% Change	2019	2018	% Change
OraQuick® Revenues						
Domestic HIV	$ 4,460	$ 5,189	(14) %	$ 8,765	$ 10,234	(14) %
International HIV	5,422	7,397	(27)	9,423	13,067	(28)
Net HIV revenues	9,882	12,586	(21)	18,188	23,301	(22)
Domestic HCV	2,102	1,730	22	3,930	3,358	17
International HCV	983	1,473	(33)	2,440	2,138	14
Net HCV revenues	3,085	3,203	(4)	6,370	5,496	16
Net product revenues	$ 12,967	$ 15,789	(18) %	$ 24,558	$ 28,797	(15) %

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	% Change	2019	2018	% Change
Molecular Collection Systems Revenues						
Genomics	$ 14,221	$ 15,368	(7) %	$ 22,269	$ 32,456	(31) %
Microbiome	2,975	1,824	63	5,300	3,097	71
Other	108	—	100	317	—	100
Net product and service revenues	17,304	$ 17,192	1	27,886	$ 35,553	(22)
Royalty income	1,114	2,092	(47)	2,198	3,694	(40)
Other	36	—	100	259	—	100
Total Molecular Collection Systems Revenues	$ 18,454	$ 19,284	(4) %	$ 30,343	$ 39,247	(23) %

Condensed Consolidated Balance Sheets (Unaudited)

	June 30, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 72,567	$ 88,438
Short-term investments	74,446	68,134
Accounts receivable, net	29,390	34,842
Inventories	25,670	22,888
Other current assets	7,185	5,010
Property, plant and equipment, net	27,793	24,299
Right of use assets, net	5,147	—
Intangible assets, net	12,472	5,137
Goodwill	29,280	18,521
Long-term investments	39,555	44,752
Other non-current assets	3,960	3,550
Total assets	$ 327,465	$ 315,571
Liabilities and Stockholders' Equity		
Accounts payable	$ 10,956	$ 10,598
Deferred revenue	3,914	3,521
Contingent consideration obligation	5,249	—
Other current liabilities	9,832	13,861
Long-term lease liabilities	4,196	—
Long-term contingent consideration obligation	649	—
Other non-current liabilities	4,448	4,213
Stockholders' equity	288,221	283,378
Total liabilities and stockholders' equity	$ 327,465	$ 315,571

	Six Months Ended June 30,	
Additional Financial Data (Unaudited)	2019	2018
Capital expenditures	$ 5,513	$ 4,484
Depreciation and amortization	$ 3,610	$ 3,746
Stock-based compensation	$ 1,848	$ 11,262
Cash provided by operating activities	$ 4,661	$ 13,928

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2019 second 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 dial 844-831-3030 (Domestic) or 315-625-6887 (International) and reference Conference ID #9973117 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, August 13, 2019, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #9973117.

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: 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; 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; impact of increased reliance on U.S. government contracts; impact of negative economic conditions; 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 our 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.

# # #

Exhibit 99.2

OraSure Technologies, Inc.

2019 Second Quarter

Analyst/Investor Conference Call

August 6, 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.

Our second quarter revenues were lower than expected due in part to the changing dynamics of the consumer genomics market, and to the transient effect of an approximately $1.0 million delayed HIV Self-Test shipment that slipped into the third quarter. Nonetheless, we delivered a very strong bottom line for the second quarter of 2019. In addition, we continued to execute against our innovation-driven growth strategy with much attention focused on evaluating potential business development opportunities. Overall, and despite some headwinds in the consumer genomics market, we remain confident in our business. The opportunities before us are abundant, and we are well positioned to execute against our strategic priorities.

In past calls, we have described the market changes that are affecting the consumer genomics business as companies in that market are changing their approach to direct-to-consumer testing. These trends impacted our Q2 performance and will likely continue to evolve over the near term. Nevertheless, the rest of our business remains largely on track.

- Outside of the single large customer, our consumer genomics business is healthy. It grew by strong double digits in the second quarter excluding that customer, and we still expect it to grow by double digits for the full year 2019, again excluding that customer.
- The microbiome market remains a very bright spot with robust growth and enormous potential. We expect this revenue line to grow at double digits in both organic sales and including the acquisition of CoreBiome over the full year.

- The integration of our recent acquisitions, Novosanis and CoreBiome, also continues to go well. CoreBiome, in particular, is helping to strengthen our microbiome business with recent customer wins for its cutting-edge laboratory and bio-informatics services.
- We have previously mentioned multiomics as an emerging approach to evaluating health that offers significant growth potential. We continue to achieve success in cross-selling our genomic and microbiome products as we stake out a leadership position in this important and emerging market.
- In infectious disease, our HIV Self-Test business remains strong, although our Q2 performance was negatively affected by the slippage of the $1.0 million order I just mentioned, from the last week of June to the first days of July. Notwithstanding inter-quarter variability of ordering patterns in the international markets that can change from year to year, we continue to project double-digit revenue growth for our global HIV franchise in 2019, primarily due to our Self-Test business.
- Our HCV business grew domestically during the quarter as the result of additional funding that we expect will likely continue in future periods. While international revenues were down for the quarter, this was largely a timing issue and the entire global HCV business showed strong growth for the first six months of the year compared to the prior year period.
- Our balance sheet is very strong with nearly $187.0 million in cash which equates to over $3.00 per share of our stock price.

So, despite some challenges, our overall business remains strong and we are growing in our strategically targeted areas. We continue to believe in the strength of our businesses and the prospects for both our infectious disease testing and molecular solutions segments. And we remain committed to bringing our customers, and the people they serve, the tools, services and data-driven insights they need to get reliable, actionable answers to their most critical scientific and healthcare questions.

With that, I will now turn the call over to Roberto for his financial review. I will then provide some additional commentary on our business and some of the trends likely to affect the remainder of this year and beyond.

Second Quarter 2019 Financial Results – Roberto Cuca

Thanks Steve, and good afternoon everyone.

Our second quarter net revenues decreased 11% to $38.8 million from $43.6 million reported in the second quarter of 2018. Our net product and services revenues decreased 4% to $37.3 million compared to the prior-year period.

Our molecular net revenues including other revenues decreased 4% to $18.5 million in the second quarter compared to $19.3 million in 2018. Royalty income declined 47% to $1.1 million in the second quarter of 2019, from $2.1 million in the same period of 2018 and showed only 3% growth from the immediately preceding quarter versus 31% growth sequentially from the first quarter to second quarter of 2018. Molecular product revenues increased 1% to $17.3 million in the second quarter of 2019 compared to $17.2 million in the second quarter of 2018. Sales of our genomic products declined 7% to $14.2 million largely due to lower customer demand, primarily from a large consumer genomics customer that changed its promotional strategy which impacted its purchasing patterns. Notably, excluding this single customer, genomic product revenues grew over 20% compared to the second quarter of 2018. Microbiome sales increased 63% to $3.0 million from $1.8 million in the second quarter of last year primarily due the inclusion of lab service revenues generated by our newly-acquired subsidiary CoreBiome as well as healthy double digit organic growth.

Domestic HIV sales decreased 14% to $4.5 million in the second quarter of 2019 compared to $5.2 million in the second quarter of 2018, largely due to lower sales of our professional product as a result of previously reported continued product and price competition and customer ordering patterns within the quarter.

International HIV sales decreased 27% to $5.4 million from $7.4 million in the second quarter of 2018 due to customer ordering patterns and the slippage of an approximately $1.0 million order from the last week of June to the first days of July, partially offset by higher sales of our HIV Self-Test into Asia and Europe.

Domestic HCV sales increased 22% in the second quarter of 2019 to $2.1 million from $1.7 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. Customer ordering patterns also contributed to this increase.

International HCV sales in the second quarter of 2019 decreased 33% to $1.0 million from $1.5 million in the same period of 2018 primarily due to the timing of customer orders.

Other revenues were $1.6 million in the current quarter compared to $4.8 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 reflects the conclusion of our projects under this program and our rotation of R&D resources to projects that are aligned with our long-term growth strategy.

Gross profit percentage for the second quarter of 2019 was 64% compared to 59% reported for the second quarter of 2018. Improved product mix associated with an increase in higher gross profit percentage product sales and lower royalty expense was partially offset by the decrease in other revenues which contribute 100% to the gross profit percentage and by the lower margins generated by CoreBiome and Novosanis.

Our operating expenses for the second quarter of 2019 were $19.7 million compared to $20.3 million in the comparable period of 2018. Operating expense in the second quarter of 2019 included $249,000 of non-cash acquisition-related contingent consideration costs and incremental operating expenses generated by CoreBiome and Novosanis. There were no similar acquisition-related costs in the second quarter of 2018. The second quarter of 2018 included $2.2 million of transition costs associated with executive management changes that occurred during that period. There were no material transition costs in the second quarter of 2019.

In the second quarter of 2019 we recorded income tax expense of $1.4 million compared to $2.2 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 net income of $4.4 million, or $0.07 per share, for the second quarter of 2019 compared to net income of $4.1 million, or $0.07 per share, for Q2 2018.

We continue to maintain a solid cash and liquidity position. Our cash and investments balance at June 30, 2019 was $186.6 million compared to $201.3 million at December 31, 2018. During the first quarter of 2019, we used $13.2 million of cash to acquire CoreBiome and Novosanis. Cash generated by operating activities during the first six months of 2019 was $4.7 million compared to $13.9 million in the same period of 2018.

Turning to guidance: For the third quarter of 2019, we are projecting revenues of $39.0 to $40.5 million and net income of $0.04 to $0.05 per share. For the full year of 2019, we are projecting revenues of $165.0 to $170.0 million and net income of $0.24 to $0.26 per share, up from our previous expectation 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. The downward revision to our full-year revenue guidance from $170.0 to $175.0 million for 2019 reflects continued softness in the consumer genomics market, including our expectations for royalties associated with this market. Despite that, and as Steve mentioned earlier, we continue to expect that our global HIV testing revenues, our microbiome revenues, and our genomics revenues, excluding the one big genomics customer, will all grow by double digits this year compared to 2018.

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

Business Update – Steve Tang

Thanks Roberto. I'd like to continue with some further comments on our Molecular business, and then I will turn to Infectious Disease.

Molecular Solutions – Steve Tang

Human Genomics

The human genomics market has continued to moderate since our last earnings call. Historically, ancestry testing has been the largest part of the human genomics market and a key driver of our business. Some of the larger players in this area have reduced their promotional support and

changed their business models to focus either on health offerings or therapeutic discovery and development. The high cost to compete in the consumer market has also, in our view, negatively impacted this submarket.

Although our business was specifically impacted by lower revenues from a large consumer genomics customer changing its promotional strategy and ordering patterns, we are now seeing additional consumer genomics customers re-evaluating their business models in an effort to be more competitive. We see these ancestry sub-market trends continuing for the foreseeable future. Nevertheless, other subsets of the genomics market are more robust with higher growth prospects, primarily in the areas of disease risk management, and companion animal and lifestyle testing.

Disease risk management encompasses genetic tests that provide information about an individual's health risk, including an individual's predisposition to diseases such as cancer and carrier status. We continue to see a steady increase in the number of customers in this area and believe the growth potential in future periods is significant. In fact, during the second quarter, 15 of our top 20 customers based on trailing 12-month revenues were in the disease risk management submarket. And more than half of the 45 new commercial genomics customers added during the second quarter were in this category. We are seeing more customers in the disease risk space moving to a patient-initiated model where the test results are given back to the patient through a medical practitioner. For example, one customer recently announced a patient-initiated service to provide consumers with genetic testing along with telemedicine-enabled clinical guidance and the ability to share test results with the consumer's personal physician. We expect other customers to pursue similar patient-initiated offerings.

Another significant part of disease risk management relates to population-based health studies. These large cohort studies provide disease risk information back to the participants, and are an important opportunity for OraSure. They generally require the use of an FDA-cleared collection device, which is significant since our Oragene® and OraCollect® devices are the only FDA-cleared devices for the collection of DNA in saliva.

Our customer Helix is one example. As mentioned on our call in May, Helix's Healthy Nevada Project has enrolled over 35,000 participants since its launch two years ago and has expanded to the entire state of Nevada. Helix is also involved in the recent Florida Health System Project through AdventHealth, which will extend to nine other states following its successful launch in Florida. Another population study is the recently launched Sequence Bio Canada New Foundland Genome Project. This project will leverage New Foundland's founder population to study disease in order to generate data for drug development. The current research plan anticipates the collection of more than 100,000 saliva samples.

We are also seeing increased demand in the animal testing and lifestyle submarkets, with several new customers in these categories added during the second quarter. In animal testing, a larger existing customer recently entered into a new agreement for the use of our Performagene™ devices. We also have new customers that are offering lifestyle genetic testing. They are focusing on genetic sensitivity to cannabis strains; nutri-genomics, which studies the effects of food on gene expression; and how genetic variations affect the nutritional environment and vitamin/supplement genetic testing.

In fact, we now have several customers in the emerging cannabis market, who are conducting research or providing genetic testing that will ultimately lead to individual recommendations on the optimal strain and amount of cannabis for health benefits. We are working with several other companies who are also exploring this area. While these submarkets are still in their early days, we are excited about their growth potential and our current market position.

Demand for academic researchers in the genomics market is also strong. In the second quarter, we saw almost 60 new studies initiated in the academic research market by our customers, with 40% of those studies outside of North America.

Outside of the United States, genomics represents an important opportunity. However, as in the U.S., we have noted changes in market approaches by our customers. We intend to continue our focus on developing the Asia-Pacific and other foreign markets and expect they will be important growth contributors to our business going forward.

The underlying strength in our genomics business was clearly evident during the second quarter:

- We added more than 250 new genomics customers in Q2, continuing the prior pattern of new customer additions;
- Our collection device unit sales to customers other than the large consumer genomics customer grew 22% in Q2 compared to the comparable quarter of 2018, and 20% from Q1 this year;
- Sales to the disease risk management accounts for Q2 were up over 64% compared to Q2 of 2018.

In summary, despite the challenges in the genomics market, which were exacerbated by the impact of a large consumer genomics customer, we believe that our overall genomics business is healthy, and excluding that large customer, should generate double-digit revenue growth during the remainder of the year.

Microbiome

Consistent with prior periods, the microbiome business delivered another strong quarter. Q2 revenues were up 63% when compared to 2018, due to increased service revenues and higher kit sales. Of our top 30 microbiome accounts, which are largely commercial customers, 16 have purchased in both Q1 and Q2 of this year, demonstrating momentum and consistency in this market. Clinical trials continue to be a source of growth in our microbiome business. Total revenue derived from clinical trials was up 26% in Q2 versus the second quarter of 2018. Two of our largest microbiome accounts now have programs transitioning from Phase I to Phase II clinical trials, thereby demonstrating the value of our microbiome products and services for the pharmaceutical industry.

Academic interest in our microbiome offerings is also continuing with research customers showing interest in observational and interventional studies at scale. One example is an academic customer that is exploring the gut microbiome and the impact of probiotic interventions in a malnourished population in Kenya. This customer is also running an industry-sponsored trial assessing the gut microbiome in connection with inflammatory bowel disease. Another study,

called the Michigan Microbiome Project, is now in its third year and continues to recruit subjects for a multiomic study of dietary fiber and butyrate production in the gut through the study of DNA and metabolites.

Additionally, CoreBiome is increasing its contribution to our microbiome business. CoreBiome signed its first ever direct-to-consumer, or DTC customer, and is now officially offering services as a back-end diagnostics lab for the DTC microbiome market. CoreBiome is also providing shotgun metagenomics testing service for a large government sponsored study. Finally, CoreBiome's first academic collaboration publication was recently published in *Cell Host and Microbe* and received coverage in the mainstream media such as Discover Magazine. This study showed the value of the shallow shotgun sequencing services provided by CoreBiome when analyzing the impact of diet on the gut microbiome.

Multiomics

We continue to see growth potential in new products and services focused on the microbiome and the broader field of multiomics. This emerging area of life science and data analytics provides a multifactorial examination of an individual's health. As we move towards becoming a leader in this field, we continue to see nice synergies within our current molecular business, as more of our existing human genomics customers are introducing a microbiome component to their studies and offerings. We saw a 100% increase in customers who are using both genomics and microbiome kits during the second quarter of 2019, compared to the prior year quarter. This trend will enable us to advance our multiomics strategy in order to maximize the potential for this important and emerging area in human health.

Urine Collection

Finally, the acquisition of Novosanis has expanded our collection capability to other specimen types, in this case urine. Novosanis' Colli-Pee® urine collection device is designed to allow the collection of first-void urine, which due to its analyte-rich content can be used in a number of applications.

Since the acquisition, Novosanis entered into a worldwide, non-exclusive agreement with Fujirebio for the distribution of the Colli-Pee® collection device for use with Fujirebio's INNO-LiPA HPV genotyping EXTRA II assay. Recent feasibility studies with the Fujirebio assay, which can identify up to 32 HPV-genotypes, showed promising results on samples of self-collected first void urine. Use of Colli-Pee's volumetric and standardized urine collection device can help ensure more accurate detection with the Fujirebio assay because first-void urine contains higher amounts of HPV DNA when compared to random or mid-stream urine samples.

The Colli-Pee® device is also being used with lab developed test (LDT) applications here in the U.S. In one application, the Colli-Pee® device may be used with the Exosome Dx (which was recently acquired by Bio-Techne) ExDx® Prostate Intelliscore (EPI) test, which allows a physician to predict if a patient presenting for internal biopsy does not have high-grade prostate cancer. This assay was recently included as a recommended test in the National Comprehensive Cancer Network clinical practice guidelines in oncology for prostate cancer early detection. In addition, the National Government Services, which is the Medicare administrative contractor for Exosome Dx, posted a draft local coverage decision for biomarker testing prior to initial biopsy for prostate cancer diagnosis which includes proposed coverage for the EPI assay. We believe this and other LDT applications represent potential significant opportunities for the Colli-Pee® business.

Infectious Disease Testing – Steve Tang

Turning now to infectious disease:

Our global HIV revenues were down in Q2 compared to 2018, primarily as a result of the timing of orders for our OraQuick® HIV Self-Test. We experienced lower sales into Africa that were only partially offset by growth in Asia and Europe. As I have mentioned previously, our Self-Test sales can be a bit choppy on a quarter-to-quarter basis as individual countries deal with factors such as funding issues and uncertainty around product utilization. This is part of the normal development cycle within a country-based market that involves the start-up of new testing programs where awareness needs to be created and ongoing demand needs to be assessed so that routine utilization can be determined. In this case, the deployment of self-tests occurred more slowly in Q2 as countries work through these issues. We still support the projections issued by

WHO that Self-Test demand will 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.

As we've shared in pervious calls, Phase II of the STAR, or Self-Testing Africa, program has largely ended. Yet, there is still much opportunity for HIV self testing. In addition to the STAR countries deploying tests, we continue to see new country registrations and demand that we expect to materialize into new orders.

The HIV Self-Test market is continuing to develop as countries achieve scale in their programs and begin to reorder product, as more countries move from pilot to full scale up and as the number of country registrations for our product continues to increase. We are focused on helping improve efficiency in countries already deploying our Self-Test. Specifically, we are working with customers to develop methods to deploy the test faster and more efficiently than has been occurring in the past. We have had discussions with some of the major stakeholders, such as PEPFAR, UNITAID and PSI, on ways to improve test deployment through additional training and implementation of best practices.

There continues to be strong support for HIV Self-Testing in the public health community. In addition to the WHO report I just mentioned, the Journal of the International AIDS Society recently published a comprehensive review that supports HIV self testing as a critical response strategy in controlling the epidemic. More recently:

- In July, we attended the International AIDS Conference in Mexico City, where HIV Self-Testing had significant visibility. In particular, presentations were made by the WHO and USAID that expressed continued support for HIV self testing as a key tool to help identify new positive patients.
- There was also a recent report published by PSI that presented data indicating that HIV self testing is more cost effective in identifying new positives than traditional rapid testing in clinics.

Based on what we're seeing in our own business, combined with information from our actual and potential customers and continued recent market developments, we remain optimistic about the overall, long-term growth potential for our global HIV franchise. As a result, we still project double-digit growth in global HIV revenue for the full year.

Turning briefly to HCV, this part of the business continues to perform as it has in recent quarters. Domestic revenues increased for the quarter as a result of the initiation of new programs and expansion of existing programs funded primarily by the Centers for Disease Control and Prevention and state jurisdictions that are finding additional funds within their existing budgets. Internationally, revenues were down for the second quarter, primarily due to the timing of orders. We expect to see ongoing international demand in future quarters. As noted at the beginning of the call, our global HCV business performed quite well for the first six months of the year and is expected to contribute growth to our infectious disease business going forward.

Conclusion - Steve Tang

So, in closing, despite some continuing disruption in the consumer genomics market, our overall business is well positioned to compete and succeed. Our innovation-driven growth strategy will serve us well in the coming years as we have targeted significant nascent opportunities that have yet to blossom. Disease risk management, microbiome and multiomics research are expected to require an enormous amount of genetic testing and we intend to capitalize on those opportunities. Moreover, our strong balance sheet affords us the ability to execute on our steadfast commitment to acquire additional products and services to augment our current capabilities. Our pipeline of acquisition candidates is replete and robust.

We expect continued growth from our global HIV and HCV franchises in the future and expect those who can best serve the market for molecular solutions will be handsomely rewarded. These growth platforms give us confidence that our best days are still ahead.

As I noted at the outset of this call, we remain committed to bringing our customers, and the people they serve, the tools, services and data-driven insights they need to get reliable, actionable answers to their most critical scientific and healthcare questions. And we are confident in the future success of our Company.

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; 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; impact of increased reliance on U.S. government contracts; impact of negative economic conditions; 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**.**