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): February 19, 2020

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 February 19, 2020, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the full year and quarter ended December 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 7.01 – Regulation FD Disclosure.

On February 19, 2020, 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 full year and quarter ended December 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	Press Release, dated February 19, 2020, announcing consolidated financial results of OraSure Technologies, Inc. for the full year and quarter ended December 31, 2019 and updated financial guidance.
99.2	Prepared Remarks of Stephen S. Tang, Ph.D. and Roberto Cuca for OraSure Technologies, Inc. Full Year and Fourth Quarter 2019 Analyst/ Investor Conference Call Held February 19, 2020.
Exhibit 104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: February 19, 2020

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 Full Year and Fourth Quarter Financial Results

BETHLEHEM, PA – February 19, 2020 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests, specimen collection devices and microbiome laboratory and analytical services, today announced its financial results for the three months and year ended December 31, 2019.

Financial and Business Highlights

- Net revenues for the fourth quarter of 2019 were $49.7 million, a 1% decrease from the fourth quarter of 2018. Net product revenues were $47.2 million, a 5% increase from the fourth quarter of 2018. Net product and service revenues in the fourth quarter of 2019 increased 12% over the comparable period of 2018 if revenues from the Company's cryosurgical systems business, which was sold in 2019, are excluded from the year ago period.
- Other revenue highlights include:
  - International sales of the Company's OraQuick® HIV products increased 123% compared to the fourth quarter of 2018. This increase was primarily the result of higher sales of the Company's OraQuick® HIV Self-Test.
  - Total microbiome product and service revenues in the fourth quarter of 2019 were $4.4 million compared to $1.9 million in the fourth quarter of 2018. Microbiome revenues in 2019 include the service revenues generated by the Company's subsidiaries, CoreBiome, Inc. and Diversigen, Inc.
  - Total molecular collection systems revenues including royalty income and other revenues were $27.8 million during the fourth quarter of 2019, a decline of 8% from the fourth quarter of 2018. Molecular collection systems product and service revenues were $25.5 million during the fourth quarter of 2019, and were flat compared to the fourth quarter of 2018.
- Net income for the fourth quarter of 2019 was $2.4 million, or $0.04 per share on a fully-diluted basis, compared to net income of $10.3 million, or $0.16 per share on a fully-diluted basis, for the fourth quarter of 2018. Net income for the fourth quarter of 2019 included $797,000 of acquisition-related transaction costs and a non-cash charge of $179,000 representing the change

in fair value of contingent consideration associated with two acquisitions that closed at the beginning of the year. The net impact of the additional transaction costs and the change in the fair value of contingent consideration in the current quarter was approximately $0.02 per share on a fully-diluted basis. Net income for the fourth quarter of 2018 included $1.2 million of expense for activities in support of the early January 2019 acquisitions and $974,000 of transition costs associated with the Company's executive management changes during that period. The transaction and transition costs together represent $0.04 per share for the fourth quarter of 2018. The transition costs in the fourth quarter consisted of non-cash stock compensation charges.

- Cash and investments totaled $189.8 million at December 31, 2019.

"We had a strong close to 2019. Our fourth quarter revenue performance was primarily driven by triple-digit growth in our international HIV sales and an impressive showing by our microbiome product and services business," said OraSure President and CEO, Stephen S. Tang. "Through our acquisitions and investment in our core businesses, we have built on our leadership in sample collection and infectious disease diagnostics and bolstered our services capabilities in the burgeoning field of microbiome analysis. In 2020, we expect to increase our investment in these core areas to provide our customers with the information and data they need to understand health, wellness and disease states. Looking further ahead, we believe these activities will empower us to advance our innovation strategy at an ever faster rate."

Financial Results

Net product and service revenues for the fourth quarter of 2019 increased 5% from the comparable period of 2018, primarily as a result of higher international HIV product sales and higher sales of the Company's microbiome products and services. The increased sales were partially offset by the absence of cryosurgical sales in the quarter, as the cryosurgical systems business was divested in mid-August, and by lower genomics product sales.

International sales of the OraQuick® HIV Self-Test for the three months ended December 31, 2019 and 2018 included $966,000 and $855,000, respectively, of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation.
Royalty income from a litigation settlement associated with a molecular collection device was $2.2 million and $4.8 million for the fourth quarter of 2019 and 2018, respectively. Other revenues were $334,000 and $578,000 for the fourth quarter of 2019 and 2018, respectively.

Gross profit percentage was 60% and 69% for the three months ended December 31, 2019 and 2018, respectively. Gross profit percentage in 2019 was negatively affected by a less favorable product mix as a result of higher sales of lower gross profit products and services and the decline in other revenues.

For the three months ended December 31, 2019, operating expenses were $25.8 million, an increase of $3.6 million from the $22.2 million reported for the three months ended December 31, 2018. This increase was due primarily to the contribution of $2.0 million of operating expenses incurred by our newly acquired subsidiaries, higher research and development costs associated with the development of automated drug testing assays, and increased professional fees associated with business development work including $797,000 associated with the Diversigen acquisition, partially offset by a decline in employee bonus accruals and stock compensation expense, the amount of which is directly related to Company and individual performance. Fourth quarter 2018 operating expenses included $1.2 million of transaction costs associated with the Company's acquisitions of CoreBiome and Novosanis.

The Company generated operating income of $4.1 million in the fourth quarter of 2019 compared to operating income of $12.5 million in the fourth quarter of 2018.

During the fourth quarter of 2019, the Company recorded income tax expense of $2.1 million compared to $3.8 million recorded in the fourth quarter of 2018. This decrease largely reflects the lower pre-tax income generated by the Company's Canadian subsidiary.

The Company's cash and investment balance totaled $189.8 million at December 31, 2019, compared to $201.3 million at December 31, 2018. For the year ended December 31, 2019, the Company generated $9.8 million in cash from operations compared with $39.1 million in the same period of 2018.

Full-Year 2020 Guidance

The Company expects consolidated net revenues for the year ended December 31, 2020 to range from $145.0 million to $155.0 million and is projecting a net loss of $0.07 to $0.10 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. "We expect 2020 to be a building year for the OraSure family of companies as we focus on revenue growth by continuing to invest in our core businesses and leveraging our balance sheet to accelerate our innovation growth strategy," added Dr. Tang.

Financial Data

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

(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Results of Operations				
Net revenues	$ 49,668	$ 50,246	$ 154,605	$ 181,743
Cost of products sold	19,829	15,540	60,022	68,130
Gross profit	29,839	34,706	94,583	113,613
Operating expenses:				
Research and development	6,104	4,059	19,629	16,250
Sales and marketing	7,932	8,377	31,869	30,609
General and administrative	11,539	9,758	35,287	38,325
Change in fair value of acquisition-related contingent consideration	179	—	(664)	—
Gain on sale of business	—	—	(10,149)	—
Total operating expenses	25,754	22,194	75,972	85,184
Operating income	4,085	12,512	18,611	28,429
Other income	477	1,629	2,720	3,287
Income before income taxes	4,562	14,141	21,331	31,716
Income tax expense	2,124	3,843	4,675	11,320
Net income	$ 2,438	$ 10,298	$ 16,656	$ 20,396
Earnings per share:				
Basic	$ 0.04	$ 0.17	$ 0.27	$ 0.33
Diluted	$ 0.04	$ 0.16	$ 0.27	$ 0.33
Weighted average shares:				
Basic	61,729	61,268	61,675	61,112
Diluted	62,199	62,511	62,170	62,532

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2019	2018	% Change	2019	2018
Market					
Infectious disease testing	$ 18,743	$ 13,643	37 %	38 %	27 %
Risk assessment testing	2,944	2,898	2	6	6
Cryosurgical systems	—	2,894	(100)	—	6
Molecular collection systems	25,487	25,407	—	51	50
Net product and service revenues	47,174	44,842	5	95	89
Royalty income	2,160	4,826	(55)	4	10
Other	334	578	(42)	1	1
Net revenues	$ 49,668	$ 50,246	(1) %	100 %	100 %

	Year Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2019	2018	% Change	2019	2018
Market					
Infectious disease testing	$ 58,016	$ 56,148	3 %	38 %	31 %
Risk assessment testing	12,189	12,058	1	8	7
Cryosurgical systems	7,054	10,767	(34)	5	6
Molecular collection systems	70,814	86,455	(18)	45	47
Net product and service revenues	148,073	165,428	(10)	96	91
Royalty income	5,116	9,653	(47)	3	5
Other	1,416	6,662	(79)	1	4
Net revenues	$ 154,605	$ 181,743	(15) %	100 %	100 %

	Three Months Ended December 31,			Year Ended December 31,		
	2019	2018	% Change	2019	2018	% Change
OraQuick® Revenues						
Domestic HIV	$ 4,960	$ 4,974	— %	$ 17,984	$ 19,663	(9) %
International HIV	9,795	4,399	123	25,108	21,794	15
Net HIV revenues	14,755	9,373	57	43,092	41,457	4
Domestic HCV	2,202	2,066	7	8,108	7,490	8
International HCV	1,295	1,598	(19)	4,864	4,904	(1)
Net HCV revenues	3,497	3,664	(5)	12,972	12,394	5
Net product revenues	$ 18,252	$ 13,037	40 %	$ 56,064	$ 53,851	4 %

	Three Months Ended December 31,			Year Ended December 31,		
	2019	2018	% Change	2019	2018	% Change
Molecular Collection Systems Revenues						
Genomics	$ 21,005	$ 23,505	(11) %	$ 57,365	$ 79,765	(28) %
Microbiome	4,423	1,902	133	12,786	6,690	91
Other	59	—	100	663	—	100
Net product and service revenues	25,487	25,407	—	70,814	$ 86,455	(18)
Royalty income	2,160	4,826	(55)	5,116	9,653	(47)
Other	129	—	100	450	—	100
Net revenues	$ 27,776	$ 30,233	(8) %	$ 76,380	$ 96,108	(21) %

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 75,715	$ 88,438
Short-term investments	80,623	68,134
Accounts receivable, net	36,948	34,842
Inventories	23,155	22,888
Other current assets	8,109	5,010
Property, plant and equipment, net	30,339	24,299
Right of use assets, net	6,947	—
Intangible assets, net	14,674	5,137
Goodwill	36,201	18,521
Long-term investments	33,420	44,752
Other non-current assets	3,164	3,550
Total assets	$ 349,295	$ 315,571
Liabilities and Stockholders' Equity		
Accounts payable	$ 9,567	$ 10,598
Deferred revenue	3,713	3,521
Contingent consideration obligation	3,500	—
Other current liabilities	15,933	13,861
Long-term lease liabilities	5,578	—
Other non-current liabilities	3,859	4,213
Stockholders' equity	307,145	283,378
Total liabilities and stockholders' equity	$ 349,295	$ 315,571

Additional Financial Data (Unaudited)

	Year Ended December 31,	
	2019	2018
Capital expenditures	$ 9,314	$ 6,344
Depreciation and amortization	$ 7,730	$ 7,222
Stock-based compensation	$ 4,057	$ 15,237
Cash provided by operating activities	$ 9,804	$ 39,090

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2019 fourth 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 #5381869 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, February 26, 2020, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #5381869.

About OraSure Technologies

OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate essential information. Together with its wholly-owned subsidiaries (DNA Genotek, CoreBiome, Diversigen and Novosanis), OraSure provides its customers with end-to-end solutions that encompass tools, services and diagnostics. The OraSure family of companies is a leader in the development, manufacture and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular product and services solutions designed to discover and detect critical medical conditions. OraSure's portfolio of products is sold globally to clinical laboratories, hospitals, physician's offices, clinics, public health and community-based organizations, research institutions, distributors, government agencies, pharma, commercial entities and direct to 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; impact of increased or different risks arising from the acquisition of companies located in foreign countries; 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 contracting with the U.S. government; 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. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this press release and we undertake no duty to update these statements.

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Exhibit 99.2

OraSure Technologies, Inc.

2019 Full Year and Fourth Quarter

Analyst/Investor Conference Call

February 19, 2020

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 evening everyone and welcome to our call.

We are pleased to report solid financial performance for the fourth quarter of 2019. These results are evidence of the momentum that our innovation-driven growth strategy continues to generate. Revenues were the third highest of any quarter in the Company's history and brought to a close a very productive year for OraSure.

I'd like to take a minute to mention a few highlights from 2019:

- We advanced our innovation-growth strategy with the acquisitions of two leading microbiome laboratory service pioneers, CoreBiome and Diversigen; and Novosanis with its first-void urine collection technology. These acquisitions increase our product and service offerings to capture and expand new market opportunities, which will contribute to future growth.
- We divested our cryosurgical systems product line in order to better align with our strategy and focus our efforts on higher priority growth opportunities.
- We received several important regulatory approvals, including a generic 510(k) clearance of our Oragene® family of molecular collectors, 510(k) clearance of our Rapid Ebola test, and approval to use our WHO prequalified OraQuick® HIV professional and Self-Test products for pediatric testing. These approvals will substantially improve the competitive positioning of these products.

- During Q4 and throughout the year we saw continued strong growth in international sales of our OraQuick® HIV Self-Test and dramatic growth in our microbiome business, including both products and services. We expect these trends to continue in 2020.

Despite the challenges we have seen in the consumer genomics market, and particularly in the ancestry testing market, our overall business remains strong as demonstrated by our Q4 financial performance:

- Q4 net revenues came in at $49.7 million and marked the third highest revenue quarter in the Company's history. We achieved these revenues despite the absence of our cryosurgical product line, which we sold in August of 2019. Our cryosurgical systems business generated revenues of $2.9 million in Q4 2018.
- International HIV sales showed robust growth of 123% for the fourth quarter compared to 2018, showing the ongoing strength of our HIV Self-Test. This performance continued a trend we saw throughout 2019, and is a key driver of the 37% increase in Q4 infectious disease testing revenues compared to 2018.
- Our microbiome business continued to be a stellar performer during the fourth quarter. Including contributions from our new laboratory services subsidiaries, CoreBiome and Diversigen, our microbiome revenues more than doubled in Q4 compared to 2018.
- Our molecular collection systems product and services revenues for Q4 were flat when compared to the fourth quarter of 2018, despite the continued decline in the consumer genomics market. Looking at it from a different perspective, these results show the underlying strength in other parts of our molecular business, which offset the challenges in the consumer ancestry market.
- Our GAAP EPS for the quarter of $0.04 included $1.0 million, or $0.02 of acquisition-related transaction costs and change in value of contingent consideration for two transactions we completed in January of 2019. We continue to prioritize the identification and pursuit of external growth opportunities consistent with our long-term innovation growth strategy.
- Finally, our cash balances at the end of the year were almost $190 million, and should provide sufficient fire power to continue funding our growth priorities.

So we are pleased with the way 2019 closed and are confident we are on the right track. While some ongoing challenges remain, we are encouraged that our infectious disease and molecular segments are well positioned to capitalize on their respective growth opportunities. Our recent acquisitions are generally lining up with expectations, and we are especially excited about the future prospects for our emerging microbiome laboratory services business.

With that, I will now ask Roberto to provide a financial review of the quarter. I will then share some additional thoughts on our business and take your questions.

Fourth Quarter 2019 Financial Results – Roberto Cuca

Thanks Steve, and good evening everyone.

Our fourth quarter net revenues decreased 1% to $49.7 million from $50.2 million reported in the fourth quarter of 2018. Our net product and services revenues increased 5% to $47.2 million compared to the prior-year period. Notably, the fourth quarter of 2018 included cryosurgical revenue of $2.9 million which did not reoccur in 2019 since we sold this line of business in August 2019. Excluding these sales dollars from Q4 2018 revenues would result in an aggregate product and service revenue increase of 12% in the fourth quarter of 2019.

As Steve mentioned, international HIV sales increased 123% to $9.8 million from $4.4 million in the fourth quarter of 2018 due to higher sales of our HIV Self-Test into Africa and Latin America and increased sales of our professional HIV product into Asia, partially offset by lower sales in Europe.

Domestic HCV sales increased 7% in the fourth quarter of 2019 to $2.2 million from $2.1 million in the prior-year period largely due to higher sales into the public health and physician offices markets principally caused by the ongoing opioid crisis and its impact on HCV infections.

International HCV sales in the fourth quarter of 2019 decreased 19% to $1.3 million from $1.6 million in the same period of 2018, primarily due to lower sales into Africa partially offset by sales growth in Asia.

Our total molecular revenues including other revenues decreased 8% to $27.8 million in the fourth quarter compared to $30.2 million in 2018. Royalty income declined 55% to $2.2 million in the fourth quarter of 2019, from $4.8 million in the same period of 2018. This reflects the continuing challenges faced in the consumer genomics ancestry market. Molecular product revenues remained largely flat at $25.5 million in the fourth quarter of 2019 compared to $25.4 million in the fourth quarter of 2018. Sales of our genomic products declined 11% to $21.0 million largely due to a large order shipped in the fourth quarter of 2018 that did not recur in 2019 and due to the purchase ordering patterns of two other large genomics customers. Microbiome sales increased 133% to $4.4 million from $1.9 million in the fourth quarter of last year primarily due the inclusion of lab service revenues generated by our newly-acquired subsidiaries, CoreBiome and Diversigen.

Gross profit percentage for the fourth quarter of 2019 was 60% compared to 69% reported for the fourth quarter of 2018. The decline in gross profit percentage is related to a product mix of higher sales of lower margin products including the absence of higher margin cryosurgical product sales and a decline in other revenues which contribute 100% to the gross profit percentage.

Our operating expenses for the fourth quarter of 2019 were $25.8 million compared to $22.2 million in the comparable period of 2018. Operating expense in the fourth quarter of 2019 included the incremental operating expenses generated by our subsidiaries acquired in 2019, increased spending on the development of automated oral fluid drug assays, $797,000 of transaction costs related to completed acquisitions, and $179,000 of non-cash acquisition-related contingent consideration, partially offset by a decline in bonus and stock compensation costs that are directly tied to company performance. Operating expense in the fourth quarter of 2018 included $1.2 million of transaction costs associated with the acquisitions which occurred in January 2019, and $973,000 of additional transition costs associated with executive management changes that occurred earlier in that year.

In the fourth quarter of 2019, we recorded income tax expense of $2.1 million compared to $3.8 million in the same period last year. The decline in tax expense reflects the lower pre-tax earnings generated by our Canadian subsidiary, DNA Genotek.

We reported net income of $2.4 million, or $0.04 per share on a fully-diluted basis, for the fourth quarter of 2019, compared to net income of $10.3 million, or $0.16 per share, for Q4 2018. The transaction and transition related expenses amounted to approximately $0.02 and $0.04 in the fourth quarters of 2019 and 2018, respectively.

We continue to maintain a solid cash and liquidity position. Our cash and investments balance at December 31, 2019 was $189.8 million compared to $201.3 million at December 31, 2018. During the year, we used $23.8 million of cash to acquire CoreBiome, Novosanis, and Diversigen and we received $12.0 million in proceeds from the sale of our cryosurgical systems business. Cash generated by operating activities during the year ended December 31, 2019 was $9.8 million compared to $39.1 million in the same period of 2018.

Turning to guidance: For full year 2020, we are projecting revenues of $145 million to $155 million and a net loss of $0.07 to $0.10 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. These estimates reflect two developments about which Steve will provide additional detail shortly.

With that, I will now turn the call back over to Steve for further business updates.

Business Update – Steve Tang

Thanks Roberto. Starting first with on our Molecular Solutions business segment –

Molecular Solutions – Steve Tang

Human Genomics

As we have shared in previous calls, the commercial genomics market has been undergoing a major evolution that has created headwinds for our molecular business. We see this trend continuing into 2020. However, we are optimistic that opportunities in other critical growth areas within the genomics market will help offset this trend.

We have always categorized our primary genomic markets as either academic or commercial. In 2019, we started to more closely examine the sub-markets within our commercial category and are classifying our opportunities into ancestry, animal, lifestyle and disease risk management testing. Typically the ancestry, animal and lifestyle sub-markets are consumer led with vendors offering services directly via the web. In contrast, the disease risk management sub-market currently requires some form of medical practitioner or genetic counsellor support.

We expect that the ancestry or genealogy testing sub-market will continue to decline, as we have seen in prior periods. The primary factors driving this are the changing promotional and business strategies of the major players in this market. As you will recall, we first started to see the impact of this trend in early 2019 when a large consumer genomics customer unexpectedly told us of a change in promotional strategy and a reduction in forecasted purchases. We took several actions in 2019 to respond to these marketplace changes.

First, we reduced our expectations regarding royalty payments from a third party as well as orders from our largest customer in this area. In 2019, this large customer accounted for 15% of overall revenue.

Second, towards the end of the year we re-negotiated and amended our contract with the large customer that has most affected our performance by extending the agreement for an additional two years.

This had the effect of reducing the annual minimum requirements to reflect the new marketplace dynamics, but did not change the overall aggregate financial commitment of this customer for the life of the contract. The amendment also aligned the contract years and their respective minimums with calendar years. We believe these actions will improve predictability for this part of our business. To this end, we expect that the customer will order at the annual minimum this year which is approximately half of what it ordered last year. The annual minimums increase over the remainder of the contract term, so we expect the customer to be a contributor to growth again in 2021.

As we’ve mentioned on previous calls, we expect disease risk management, the next largest sub-market within commercial genomics, to continue to grow, and to eventually eclipse ancestry

testing. Disease risk management includes pharmacogenomics testing, hereditary disease screening, prenatal or carrier screening, population health initiatives and other molecular diagnostic tests using microbial DNA or human RNA for diagnosis of acute disease.

This emerging sub-market experienced some volatility in 2019, when the Department of Justice, or DOJ, pursued indictments related to alleged fraudulent Medicare billing against several companies that offered screening and pharmacogenomics testing. A fallout from these events has been lab closures and uncertainty regarding FDA regulatory scrutiny of this area. Both of these factors had a negative impact on demand in this space.

We believe that the DOJ actions were a one-time event and expect that the demand for screening and pharmacogenomics will continue to grow at a rate of 7-10% a year. When added to the strong ongoing growth and diversification within disease risk management, we project robust growth in the overall disease risk management market for 2020 and beyond.

We also believe we are well positioned to capitalize on this growth opportunity. We secured a unique regulatory advantage when the FDA granted a generic 510(k) clearance for our Oragene®•Dx product, making our product the first and only saliva collection device that can be used for prescription or over-the-counter use. This clearance simplifies FDA approvals for genetic test manufacturers who want to add saliva as a sample collection method for their offering. We expect this clearance to enable broader use of our devices in the growing disease risk management arena and potentially other markets.

We have also secured long-term customer contracts with several of the largest players in the disease risk management space, including those with patient-initiated testing programs and large-scale population programs. The number of companies offering these applications continues to increase, and we are also seeing continued growth within most accounts. These contracts will provide a good foundation for continued growth in this part of the genetic testing market.

Microbiome

Our microbiome business is also in a strong position, as evidenced by our Q4 performance. Thanks to our acquisitions of CoreBiome and Diversigen, we are now effectively the leader in end-to-end solutions for the microbiome, from sample collection through analysis.

We continued to grow our customer base within the microbiome space, with double-digit sales growth from our microbiome product portfolio for the year. The number of first-time kit purchasers in Q4 grew 13% quarter-over-quarter, and revenue from first-time purchasers increased 33% for the full-year 2019 compared to 2018.

As you would expect, we are excited about the outlook for our laboratory services business, with several trends supporting robust growth expectations, including continued expansion of microbiome services as an endpoint in clinical trials, and our growing relationships with both established bio-pharma and innovative biotech start-up companies. We also see direct-to-consumer wellness applications as a future growth driver as the market matures and leads toward actionable insights and clinical applications.

We recently won a request for proposals for shotgun metagenomics and analysis in a large epidemiology study. Under this study, we expect to provide services for both prospective and retrospective clinical trial projects. We also have a robust and growing pipeline of proposals across commercial and academic opportunities for our service offerings.

Perhaps the best bellweather of the microbiome market's health and potential is the growing number of scientific studies. There have been many new seminal studies within the last year demonstrating that the microbiome field is continuing to move toward clinical applications. One study offers new evidence that a person's microbiome may determine how well a common drug for treating Parkinson's Disease will work. Another found evidence that levels of certain microbes can predict graft-versus-host disease in stem-cell transplant patients. These two studies are among over 14,000 research articles published about the microbiome in 2019, a 29% increase over 2018, and a sign of the rapid acceleration of discovery within this field.

We also continue to make good progress on the integration of CoreBiome and Diversigen into our operations. Our plan is to consolidate the CoreBiome and Diversigen businesses into one unified premier science-led services company, offering validated protocols for best-in-class lab offerings and superior data analytics. While both brand names carry equity in the marketplace, we will unify our service offerings under the Diversigen name. We will consolidate lab operations in the Minneapolis-St. Paul area where CoreBiome is located. Construction on a new state-of-the-art lab facility is expected to be complete by the end of 2020. We have restructured the team to support

this stronger, unified vision for the Company and are investing in expert resources to grow the business.

Multiomics

As we look further into the future, we continue to see opportunity beyond our genomic and microbiome businesses with significant growth potential in the broader field of multiomics. This emerging area of life science and data analytics provides a multifactorial examination of an individual's health by examining the different "omes" in a person, including the microbiome and the genome. We are seeing continued growth in the number of our existing human genomics customers who are also purchasing microbiome products and services for their studies and offerings. For both the fourth quarter and full year 2019, the number of customers who are using both genomics and microbiome kits increased by more than 30%. We expect this trend to continue. We are also exploring other development opportunities to expand our product portfolio to additional sample types and analytes that are of interest to our customers.

Urine Collection

We continue to be optimistic about the Novosanis Colli-Pee® urine collection device, which is increasingly being used in clinical trials and validated for use through key studies. This foundational work is imperative in demonstrating effectiveness of the product and utility of first-void urine for key applications within high growth screening opportunities.

A paper presented at the Eurogin conference in 2019 demonstrated that samples collected with Colli-Pee provided non-inferior clinical sensitivity when compared to performance with cervical samples. These preliminary results from the ongoing VALHUDES study provide a starting point for validating Colli-Pee for human papillomavirus assays. Similarly, Sciensano (The Belgian Institute for Health) is performing a study using the Colli-Pee device to guide Chlamydia prevention in Belgium. These and other similar studies will be important for the development of this part of the business.

Infectious Disease Testing – Steve Tang

Turning now to Infectious Disease-

HIV and HCV Businesses

The fourth quarter was another strong performance for our infectious disease business, with revenues increasing 37% compared to Q4 2018. The major driver was our HIV franchise, which reported a 57% increase in global revenues when compared to the prior year, driven principally by a 123% increase in revenues from our international HIV business. We shipped 2.9 million HIV Self-Tests in Q4, an all-time record for this product. We expect the recent growth trends in HIV Self-Test sales to continue in 2020 resulting in high-teens growth in global revenues for the year.

Our product registration strategy for the Self-Test continues to progress with 20 registrations currently in place and 15 more in process. The latest registration we received was for the Ivory Coast. Each registration opens a new market for us and expands the opportunity for growth. We now have all the registrations in place we need to support our 2020 business plan for Self-Test sales. Importantly, we have continued to grow our Self-Test business and maintain our strong market share position, even though two blood-based rapid HIV self-tests have received WHO prequalification.

One cautionary note is that our quarterly international revenues will likely continue to be a bit choppy as individual countries determine their ongoing utilization of our product. This is the natural way these markets have developed with order sizes varying as specific in-country programs create awareness and assess ongoing demand for HIV self-testing.

Our domestic HIV professional business also turned in a strong fourth quarter, with revenues up 17%, reflecting sales growth to public health, hospitals and physicians' offices. This growth was primarily driven by the timing of orders as discussed on our last earnings call, some product issues experienced by our competitors, and competitive wins in certain jurisdictions. This double-digit growth is likely to moderate to single digits in future quarters as the competitor issues and competitive wins are absorbed into our ongoing revenue stream.

In prior calls, I have mentioned the U.S. Department of Health and Human Services' initiative, called "Ending the HIV Epidemic: A Plan for America," which has a goal of ending HIV in the U.S. within 10 years. A total of $291 million in funding for the Plan of America was approved in late December of 2020, and the CDC and state jurisdictions are moving ahead with implementation. We expect specific testing plans to be approved in various jurisdictions as the year progresses, which should help drive sales of our HIV testing products.

We are currently working closely with the CDC on implementation with 57 targeted jurisdictions, many of which are recognizing in-home or self-testing as an important tool for achieving plan goals. We expect the opportunities under the Plan for America to continue beyond this year as additional funding for this multi-year initiative becomes available. The recent budget proposed by the Administration includes $716 million in funding for a second year of the initiative which, if approved, would represent a significant increase in funding for the next fiscal year.

Finally, there have been several recent studies demonstrating the benefits of HIV self-testing with our In-Home HIV test. One of the most recent reports came from a state Department of Health which is a long-term customer of ours. This report included data indicating that HIV Self-Testing:

- Reaches those people who are not accessing HIV testing through the normal channels;
- Reaches those people whose behaviors put them at an elevated risk for HIV infection;
- Empowers individuals to know their HIV status by testing more frequently and talking with their peer groups about HIV testing more often;
- Is popular because it's easy to use, provides a sense of confidentiality, and puts the user in firm control of his/her own health; and
- Successfully allows HIV positive individuals to be linked to care and begin receiving treatment in a timely manner.

For all these reasons, we remain optimistic about the overall long-term potential for our HIV franchise.

Turning briefly to HCV, our performance for the fourth quarter was a bit mixed with overall global revenues down 5% compared to the prior year quarter. Domestic sales for the quarter increased 7% primarily due to new programs and program expansions, as we are seeing increased rates of

HCV infection resulting from opioid use. International revenues were down largely as a result of timing issues, as two larger purchases that occurred in 2018 did not repeat in 2019.

Risk Assessment Testing

The announcement of oral fluid drug testing guidelines by the Substance Abuse and Mental Health Services Administration, or SAMHSA, last year is impacting the risk assessment testing portion of our infectious disease business. As mentioned on prior calls, these guidelines will give us access to businesses where employee drug testing is regulated by the federal government. This is a large untapped market for us. In the second half of 2019, we amended our development agreement with Thermo Fisher and are optimizing our Intercept® collection device and the Thermo assays in order to meet these new federal guidelines. This development work will be a priority throughout 2020 and is expected to drive growth in subsequent years after the appropriate regulatory clearances are obtained.

Ancestry Arbitration

A final topic I want to address is the recent arbitration proceeding against Ancestry.comDNA ("Ancestry"). As you may recall, we settled patent infringement and breach of contract litigation with Ancestry back in late 2017. Under the Settlement Agreement from that litigation, a process was established to evaluate new DNA collection products developed by Ancestry to determine whether they fall within the royalty provisions of the Agreement. Because we disagreed with Ancestry's view of its new collection device, we engaged in arbitration to resolve the dispute. To our surprise, the arbitration panel's recently issued decision found that the new Ancestry product does not infringe the patents we asserted in the arbitration. As a result, the product will not be subject to royalties under the Settlement Agreement once it is commercialized.

Although this decision is final and binding on the parties with respect to the patents asserted in the arbitration, it does not cover any patent continuations that we may obtain or new patents that we may acquire in this area. Our strategy has always been to build a strong patent portfolio for DNA collection devices, to expand that portfolio where possible and to aggressively defend our intellectual property rights. And that is exactly the strategy we have been following and will continue to follow.

Conclusion - Steve Tang

In conclusion, we ended 2019 in a good position with solid financial results for the fourth quarter. During 2019, we had to deal with our fair share of challenges as we worked to replace a significant amount of revenue that was lost due to a dramatic slowdown in our consumer genomics business. I want to thank all those at OraSure who helped navigate that significant headwind to get us back on track and finish the year on solid footing. We made great progress executing against our long-term innovation growth strategy that calls for us to invest in emerging technologies and become a leading provider of end-to-end solutions for our molecular customers that takes them all the way from sample to answers. To that end, we improved our competitive profile and expanded our addressable markets with the completion of three acquisitions and a divestiture of a non-strategic business line. Our strong balance sheet affords us the ability to acquire additional products and services to augment our current capabilities. Our focus on finding and closing such acquisitions will continue with a robust pipeline of acquisition candidates under review.

Our global HIV and HCV franchises and molecular solutions business will likely continue to be primary drivers of revenue growth in the near term, with risk assessment testing picking up again in the near future.

Through our acquisitions and investment in our core businesses, we have assembled a company that drives access to multiple layers of information and data to understand health, wellness, and disease states. We will build on that foundation as we continue to advance our innovation-driven strategy into 2020 and beyond.

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; impact of increased or different risks arising from the acquisition of companies located in foreign countries, 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 contracting with the U.S. government; 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, 2019, 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. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this call, and we undertake no duty to update these statements**.**