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

FORM 8-K

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

Date of Report (Date of earliest event reported): May 6, 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 May 6, 2020, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended March 31, 2020 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 May 6, 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 quarter ended March 31, 2020, 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 May 6, 2020, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2020 and updated financial guidance.
99.2	Prepared Remarks of Stephen S. Tang, Ph.D. and Roberto Cuca for OraSure Technologies, Inc. First Quarter 2020 Analyst/ Investor Conference Call Held May 6, 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: May 6, 2020

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

Exhibit 99.1

OraSure Technologies, Inc.

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OraSure Announces 2020 First Quarter Financial Results and Provides COVID-19 Update

BETHLEHEM, PA – May 6, 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 ended March 31, 2020 and provided an update on COVID-19 activities.

Financial and Business Highlights

- Net revenues for the first quarter of 2020 were $31.6 million, a 5% increase from the first quarter of 2019. Net product and services revenues were $30.9 million, a 9% increase from the first quarter of 2019. Excluding cryosurgical revenues, the line of business the Company sold in August 2019, and Diversigen revenues, which the Company acquired in November 2019, net revenues and product and services revenues grew 8% and 13%, respectively, from the first quarter of 2019.
- Other revenue highlights include:
  - International sales of the Company's OraQuick® HIV products increased 74% compared to the first quarter of 2019. This increase was primarily the result of higher sales of the Company's OraQuick® HIV Self-Test.
  - Total genomics revenues were $9.1 million during the first quarter of 2020, an increase of 14% from the first quarter of 2019.
  - Total laboratory service revenues in the first quarter of 2020 were $2.4 million compared to $717,000 in the first quarter of 2019. Laboratory services in 2020 include the service revenues generated by the Company's subsidiaries, CoreBiome, Inc. and Diversigen, Inc.
- Net loss for the first quarter of 2020 was $7.3 million, or $0.12 per share on a fully-diluted basis, compared to a net loss of $3.3 million, or $0.05 per share on a fully-diluted basis, for the first quarter of 2019. Net loss for the first quarter of 2020 included a $1.1 million non-cash pre-tax charge associated with the change in fair value of acquisition-related contingent consideration. The net impact of 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 loss in the first quarter of 2019 included a $1.3 million non-cash pre-tax charge associated with the change in the fair value of acquisition-related contingent consideration and $597,000 of acquisition-related transaction costs. The combined impact of these charges reduced fully diluted earnings per share by approximately $0.03.
- Cash and investments totaled $176.2 million at March 31, 2020.

COVID-19 Update

OraSure is working in several ways to improve and increase testing for the novel coronavirus ("COVID-19"):

- The Company was awarded a $710,310 contract from the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services (HHS), to develop a pan-SARS-coronavirus rapid antigen in-home self-test that uses oral fluid samples. This support from BARDA will enable OraSure to file for U.S. food and Drug Administration (FDA) Emergency Use Authorization (EUA), potentially allowing for an in-home self-test to debut into the U.S. market. The Company anticipates having the test on the market by Fall 2020, if its development efforts are successful.
- The Company is also developing an Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of human anti-SARS-CoV-2 antibodies in oral fluid specimens. The oral fluid ELISA could dramatically increase the throughput of COVID-19 antibody testing. The Company expects to file for FDA EUA for the ELISA test in June 2020.
- The Company believes that oral samples collected using its currently marketed liquid saliva collection kits or oral swab collectors could be a suitable alternative to nasopharyngeal or oropharyngeal swabs for COVID-19 testing. The Company's molecular business unit is working with several labs and researchers to determine if its sample collection technologies can be used to safely collect and transport COVID-19 samples. In addition, several customers are currently validating various OraSure/DNA Genotek products for COVID-19 testing. If the data supports it, the Company will explore these avenues for COVID-19 sample collection and testing.
- The Company is also seeing increased demand for its molecular collection products from customers who conduct both saliva and blood-based testing. As it becomes increasingly difficult to collect blood in clinics or healthcare settings, these customers are increasingly relying on the saliva collection alternative, presenting another opportunity for OraSure's product lines.

"Our underlying business was strong in the first quarter as evidenced by year over year double-digit growth in both Infectious Disease Testing and Molecular Collection Systems. We are encouraged by the continued strength of our International HIV Self-test franchise as well as our genomics business," said Stephen S. Tang, Ph.D., President and Chief Executive Officer.

"Nevertheless, we do expect downward revenue pressure in certain parts of the business as customers repurpose funding and testing and research projects are deferred as a result of the pandemic. The good news is that we also see potentially significant opportunity from COVID-19 across our business which may more than offset any revenue declines. For example, public health customers in the U.S. are buying more of our In-Home HIV tests to allow continued HIV testing by individuals while adhering to social distancing requirements. A number of our molecular customers are already placing increased orders for our saliva collection and oral swab products as they move from blood collection to saliva collection as a result of the difficulties in collecting blood samples due to the stay-at-home and social distancing restrictions. In addition, with the massive amount of testing likely required to get the COVID-19 pandemic under control and restart our economy, we believe our pan-SARS coronavirus rapid antigen in-home self-test and ELISA antibody test, once developed and approved by the FDA, as well as expanded use of our saliva collection products once validated, could play significant roles in helping end the pandemic," Dr. Tang continued.

Financial Results

Net product and service revenues for the first quarter of 2020 increased 9% from the comparable period of 2019, primarily as a result of higher international HIV Self-Test sales, higher sales of the Company's genomics products, and increased laboratory services revenues. The increased sales were partially offset by the absence of cryosurgical sales in the quarter, as the cryosurgical systems business was sold in August 2019 and by lower world-wide HCV product sales.

Royalty income from a litigation settlement associated with a molecular collection device was $446,000 and $1.1 million for the first quarter of 2020 and 2019, respectively. Other revenues were $264,000 and $706,000 for the first quarter of 2020 and 2019 respectively.

Gross profit percentage was 51% and 60% for the three months ended March 31, 2020 and 2019, respectively. Gross profit percentage in the first quarter of 2020 was negatively affected by a less favorable product mix as a result of higher sales of lower gross profit products and services, increased international freight costs, higher scrap and spoilage expense, and the decline in other revenues which contribute 100% to our gross profit percentage.

For the three months ended March 31, 2020, operating expenses were $24.2 million, an increase of $2.3 million from the $21.9 million reported for the three months ended March 31, 2019. This increase was due primarily to increased staffing costs, higher lab supply and consulting costs in support of bioinformatics and new product initiatives, higher legal fees, and the inclusion of operating expenses incurred by Diversigen.

The Company generated an operating loss of $8.0 million in the first quarter of 2020 compared to an operating loss of $3.8 million in the first quarter of 2019.

During the first quarter of 2020, the Company recorded income tax expense of $712,000 compared to an income tax benefit of $29,000 recorded in the first quarter of 2019. This tax increase largely reflects the higher pre-tax income generated by the Company's Canadian subsidiary.

The Company's cash and investment balance totaled $176.2 million at March 31, 2020, compared to $189.8 million at December 31, 2019. For the year ended March 31, 2020, the Company generated $2.5 million in cash from operations compared with $528,000 in the same period of 2019.

Full- Year 2020 Guidance

The Company is withdrawing its previously announced full-year 2020 financial guidance because of the unpredictable impact of the COVID-19 global pandemic on its results of operations. Although the Company may be able to capture new revenue opportunities from the initiatives described above, the pandemic is also likely to affect certain business lines negatively, and the extent of either effect is impossible to estimate reliably at this time.

Financial Data

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

(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Results of Operations		
Net revenues	$ 31,596	$ 30,122
Cost of products sold	15,465	12,042
Gross profit	16,131	18,080
Operating expenses:		
Research and development	5,644	4,371
Sales and marketing	7,369	7,295
General and administrative	10,054	8,930
Change in fair value of acquisition-related contingent consideration	1,110	1,295
Total operating expenses	24,177	21,891
Operating loss	(8,046)	(3,811)
Other income	1,430	524
Loss before income taxes	(6,616)	(3,287)
Income tax expense (benefit)	712	(29)
Net loss	$ (7,328)	$ (3,258)
Loss per share:		
Basic	$ (0.12)	$ (0.05)
Diluted	$ (0.12)	$ (0.05)
Weighted average shares:		
Basic	61,937	61,531
Diluted	61,927	61,531

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended March 31,				
	Dollars			Percentage of Total Net Revenues	
	2020	2019	% Change	2020	2019
Market					
Infectious disease testing	$ 14,664	$ 12,338	19 %	46 %	41 %
Risk assessment testing	3,000	2,836	6	9	9
Cryosurgical systems	—	2,575	(100)	—	9
Molecular collection systems	13,222	10,583	25	43	35
Net product and service revenues	30,886	28,332	9	98	94
Royalty income	446	1,084	(59)	1	4
Other	264	706	(63)	1	2
Net revenues	$ 31,596	$ 30,122	5 %	100 %	100 %

* Note cryosurgical systems business divested in August 2019.

	Three Months Ended March 31,		
	2020	2019	% Change
OraQuick® Revenues			
Domestic HIV	$ 4,216	$ 4,304	(2) %
International HIV	6,949	4,001	74
Net HIV revenues	11,165	8,305	34
Domestic HCV	1,494	1,828	(18)
International HCV	1,097	1,457	(25)
Net HCV revenues	2,591	3,285	(21)
Net product revenues	$ 13,756	$ 11,590	19 %

	Three Months Ended March 31,		
	2020	2019	% Change
Molecular Collection Systems Revenues			
Genomics	$ 9,135	$ 8,047	14 %
Microbiome	1,645	1,609	2
Other product revenues	27	210	(87)
Laboratory services	2,415	717	237
Net product and service revenues	13,222	10,583	25
Other	582	1,306	(55)
Net revenues	$ 13,804	$ 11,889	16 %

Condensed Consolidated Balance Sheets (Unaudited)

	March 31, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 83,365	$ 75,715
Short-term investments	82,735	80,623
Accounts receivable, net	27,861	36,948
Inventories	22,694	23,155
Other current assets	6,790	8,109
Property, plant and equipment, net	31,829	30,339
Intangible assets, net	15,746	14,674
Goodwill	34,544	36,201
Long-term investments	10,070	33,420
Other non-current assets	9,438	10,111
Total assets	$ 325,072	$ 349,295
Liabilities and Stockholders' Equity		
Accounts payable	$ 6,881	$ 9,567
Deferred revenue	4,312	3,713
Contingent consideration obligation	1,220	3,500
Other current liabilities	13,926	15,933
Other non-current liabilities	8,581	9,437
Stockholders' equity	290,152	307,145
Total liabilities and stockholders' equity	$ 325,072	$ 349,295

Additional Financial Data (Unaudited)

	Three Months Ended March 31,	
	2020	2019
Capital expenditures	$ 2,595	$ 2,628
Depreciation and amortization	$ 2,197	$ 1,726
Stock-based compensation	$ 1,376	$ 1,231
Cash provided by operating activities	$ 2,499	$ 528

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2020 first quarter results, updated financial guidance, and certain business developments, 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 #5498040 or go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Relations page. Please click on the webcast link and follow the prompts for registration and access 10 minutes prior to the call. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until midnight, May 13, 2020, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #5498040.

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; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collector products and commercialize such products for COVID-19 tests; 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 press release and we undertake no duty to update these statements.

# # #

Exhibit 99.2

OraSure Technologies, Inc.

2020 First Quarter

Analyst-Investor Conference Call

May 6, 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.

Before we begin, on behalf of all of us at OraSure, I would like to express our sincere gratitude to the healthcare providers on the front lines fighting the COVID-19 pandemic. We would also like to acknowledge all those workers who are performing jobs that keep our country and society functioning. Your dedication, bravery and importance are vital to us. I also must thank all of our employees. Your outstanding efforts play an important role in helping people around the world. Our employees are being put to the test every day and they are responding with tenacity and excellence. I have never been prouder to lead our exceptional Company.

OraSure has a storied history of rising to the occasion of challenging health circumstances, having developed high quality diagnostic tests for HIV, HCV and Ebola. As you can imagine, we are doing everything we can to bring our expertise with infectious disease diagnostics and sample collection to the battle against COVID-19. On the testing front, we are developing a pan-SARS-coronavirus rapid antigen in-home self-test that uses oral fluid samples, and an ELISA-based test for the detection of human anti-SARS-CoV-2 antibodies in oral fluid specimens. Our molecular solutions business unit is working with laboratories and researchers to demonstrate the effectiveness of its sample collection technologies for coronavirus testing. Later in the call, I will update you on our progress on these items.

Turning to the first quarter, I'm pleased to report that OraSure is off to a good start in 2020, with solid financial results. The coronavirus pandemic is certainly affecting our business, and I will

discuss that in a minute. But it is important to note that any negative impact from COVID-19 in Q1 was largely offset by additional product uptake in response to the pandemic. As a result, the Company's sales were in line with our own expectations from before the onset of the pandemic.

Because our Company is considered an essential business, we are permitted to continue operating in the various states and countries where our employees are located. A large number of our employees can fulfill their job functions remotely and are working from home, in accordance with local stay-at-home requirements. A key group of employees who must be on site are primarily manufacturing, warehouse, laboratory and R&D personnel. We have implemented enhanced hygiene and social distancing protocols to ensure their safety. Fortunately, we have had only one instance of COVID-19 infection reported among the more than 470 employees Company-wide. That employee, who is field-based, is recovering well. For that, we are very grateful.

The COVID-19 pandemic is having a mixed impact on OraSure. We saw some downward pressure from COVID-19 on revenues in our domestic professional HIV and HCV businesses and in our molecular sales to the academic market in Q1, as HIV and HCV testing programs and molecular research programs have been delayed or terminated because of COVID-19. In our services business, revenues were also impacted as customers could not access samples housed at academic or medical facilities that were to be sent into our Microbiome services lab for processing. We see these trends continuing with a likely bigger impact on future quarters. However, sales of our In-Home HIV test are rising as public health HIV testing programs in the U.S. are increasingly using our over-the-counter product as they adjust testing strategies in response to COVID-19. We are also seeing increased sales of our existing molecular saliva collection kits and oral swabs as some customers move from blood to saliva collection due to difficulties collecting blood samples under current circumstances.

Assuming we are successful in our development and regulatory efforts, we anticipate that the new coronavirus testing products we are working on, and the expanded use of some existing molecular collection products, could make significant contributions later this year, especially as the need for COVID-19 testing increases.

Our manufacturing operations have been unaffected by the pandemic and we have not had any significant disruptions from our suppliers. Importantly, we expect that to continue. With respect to logistics, we have seen additional challenges for international shipments, particularly by our Thailand contract supplier, largely due to a reduction in the availability of air freight, the closing of customs offices in certain countries and transport congestion. We have generally been able to work around these issues by using more sea freight. Accordingly our shipping costs are and will continue to be a bit higher for certain destinations. We are considering several options to expand current capacity to make sufficient quantities to support the growing demand for existing products as well as demand for COVID-19 products in development. We will share more information about these options, once relevant and timely.

So despite the many moving parts and uncertainty surrounding the impact of COVID-19, we believe OraSure is well positioned to maintain its base business and to play an important role in fighting the pandemic.

Turning briefly to the highlights from Q1:

- Net revenues of $31.6 million represented a 5% increase from the year-ago period. We achieved this increase despite the absence of our cryosurgical product line, which we sold in 2019. Excluding revenues from our cryosurgical business, which we sold in August 2019, and revenues from our newest subsidiary, Diversigen, which we acquired in November 2019, net revenues grew 8%.
- International HIV sales increased a robust 74% for the first quarter compared to 2019, largely due to the strength of our HIV Self-Test. This performance continues a trend we saw throughout 2019, and we expect that to continue in future periods.
- Our molecular collection systems product and services revenues for Q1 grew 25%, largely due to renewed genomic sales growth and a strong performance by our laboratory services business.
- Our genomic business grew 14% during the first quarter compared to last year. This was largely due to the shift from blood to saliva testing by certain customers, as I mentioned earlier.

- We saw a 237% increase in laboratory services revenues for Q1 primarily due to the addition of Diversigen, which we acquired in late 2019.
- Net loss for the first quarter was higher than the prior year as a result of greater costs of goods sold, increased R&D spend, and charges and costs associated with our business development activity as we continue to prioritize the identification and pursuit of external acquisition opportunities consistent with our long-term innovation growth strategy, all partly offset by higher foreign exchange gains.
- Finally, our cash balances at the end of the quarter totaled $176 million. This significant cash balance, coupled with the absence of debt on our balance sheet, will enable us to weather the type of uncertainties presented by the COVID-19 pandemic while still pursuing our innovation growth strategy.

So, we are pleased with the way 2020 has started and we look forward to delivering a successful rest of the year despite the challenges that may arise from COVID-19.

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

First Quarter 2020 Financial Results – Roberto Cuca

Thanks Steve, and good evening everyone.

Our first quarter net revenues increased 5% to $31.6 million from the $30.1 million reported in the first quarter of 2019. Our net product and services revenues increased to $30.9 million or 9% compared to the prior-year period. Notably, the first quarter of 2019 included cryosurgical revenue of $2.6 million which did not recur in 2020 since we sold this line of business in August 2019. Excluding these sales dollars from Q1 2019 revenues and the contributions of Diversigen, which we acquired in the fourth quarter of 2019, would result in an aggregate product and service revenue increase of 13% in the first quarter of 2020.

As Steve mentioned, international HIV sales increased 74% to $6.9 million from $4.0 million in the first quarter of 2019 due to higher sales of our HIV Self-Test into Africa. Domestic HIV sales

decreased 2% to $4.2 million from $4.3 million in 2019 due to COVID-19 stay-at-home orders and the resulting deferral or shut-down of public health testing activities. This was offset by the launch of our In-Home HIV test into a new retail chain and the increased use of this OTC product in public health settings in reaction to COVID-19.

Domestic HCV sales decreased 18% in the first quarter of 2020 to $1.5 million from $1.8 million in the prior-year period, also largely due to the cessation of testing programs as a result of COVID-19, as well as the redirection of funding away from HCV testing to COVID testing.

International HCV sales in the first quarter of 2020 decreased 25% to $1.1 million from $1.5 million in the same period of 2019, primarily due to lower sales into Asia.

Our total molecular revenues including other revenues increased 16% to $13.8 million in the first quarter compared to $11.9 million in 2019. Royalty income declined 59% to $446,000 in the first quarter of 2020, from $1.1 million in the same period of 2019. This reflects the continuing challenges faced in the consumer genomics ancestry market. Genomics product revenues increased 14% to $9.1 million in 2020 compared to $8.1 million in 2019 due to organic growth of existing customers and a shift from blood to saliva collection by customers using both sample types due to the inability to collect blood samples as a result of restrictions related to COVID-19. Microbiome product sales remained largely flat at $1.6 million in both the first quarters of 2020 and 2019. Lab service revenues generated by our subsidiaries, CoreBiome and Diversigen, increased 237% to $2.4 million in the first quarter of 2020 from $717,000 in the same period of 2019, largely due to the inclusion of revenues generated by Diversigen which was acquired in the fourth quarter of 2019.

Gross profit percentage for the first quarter of 2020 was 51% compared to 60% reported for the first quarter of 2019. The decline is related to a revenue mix higher in sales of lower gross profit percentage products and services - including the addition of microbiome services acquisitions -and the absence of higher margin cryosurgical product sales, increased international freight costs, higher scrap and spoilage expense, and a decline in other revenues which contribute 100% to the gross profit percentage.

Our operating expenses for the first quarter of 2020 were $24.2 million compared to $21.9 million in the comparable period of 2019. The increase in operating expense in the first quarter of 2020 was largely due to increased staffing costs, higher lab supply and consulting costs in support of bioinformatics and new product initiatives, increased legal fees and the inclusion of operating expenses incurred by Diversigen.

We reported a net loss of $7.3 million, or $0.12 per share on a fully-diluted basis, for the first quarter of 2020, compared to a net loss of $3.3 million, or $0.05 per share, for Q1 2019. Results in these periods included acquisition-related charges of $1.1 million and $1.3 million respectively. Results in Q1 2019 also included $597,000 of transaction expenses. These charges amounted to approximately $0.02 and $0.03 in the first quarters of 2020 and 2019, respectively.

As Steve mentioned, we continue to maintain a solid cash and liquidity position. Our cash and investments balance at March 31, 2020 was $176.2 million compared to $189.8 million at December 31, 2019. Cash generated by operating activities during the three months ended March 31, 2020 was $2.5 million compared to $528,000 million in the same period of 2019.

As Steve will describe in a bit more detail, the COVID-19 pandemic will likely not just exert downward pressure on certain existing lines of business, but will also present new opportunities for both existing products and services and for development efforts we are undertaking to address COVID-19 testing needs specifically. The net effect of these future opportunities and challenges is difficult to predict reliably, and for this reason we are withdrawing financial guidance for 2020. However, I do want to reiterate that this is because of the difficult-to-predict potential upside as well as downside presented by the pandemic.

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

Infectious Disease Testing – Steve Tang

Thank you, Roberto. Turning now to Infectious Disease –

HIV and HCV Businesses

Our global HIV business continued to deliver a strong performance with revenues increasing 34% in the first quarter compared to Q1 2019. The major driver was a 74% increase in international HIV revenues. We shipped 2.0 million HIV Self-Tests to international markets in Q1, and this business rose 98% compared to the year-ago quarter as established countries continue to scale up testing and new countries begin to come on line. Our domestic business was down 2% for the first quarter.

The COVID-19 pandemic is having its greatest impact on our domestic HIV business and global HCV business. During the first quarter, most domestic HIV testing programs were either reduced or put on hold, which lowered demand for our professional products. Because this started later in the quarter, our Q1 results were not significantly affected. In contrast, international HIV testing remained strong and we experienced only relatively minor issues resulting from COVID-19 related to shipping product overseas, which we were able to manage effectively. If the COVID-19 pandemic begins to subside by the middle of the year, we believe there is a good chance that it will have little impact on our HIV Self-Test sales in future periods. However, we expect the downward revenue pressure from COVID-19 to continue in the domestic HIV business. How long this will last and the exact impact on revenues will depend on when the COVID-19 pandemic is resolved and the stay-at-home and social distancing restrictions are lifted.

Apart from COVID-19, we remain optimistic about HIV self-testing. Population Services International has indicated it will extend the Self Testing Africa, or “STAR” initiative, to seven new countries (India, Indonesia, Uganda, Nigeria, Tanzania, Cameroon and Mozambique) under Phase III of that initiative. We expect to receive orders under this Phase to begin in the second quarter with shipments occurring in the third and fourth quarters. The size of the program is expected to be similar to the 750,000 tests purchased under Phase I. Not only will Phase III drive additional volume, it will also provide assistance for additional countries to start HIV self-testing programs on a national scale. In this regard, the President’s Emergency Plan for AIDS Relief, or PEPFAR, which is a U.S. governmental initiative to address the global HIV/AIDS epidemic, has communicated guidance to its funded countries to consider increasing HIV self-testing during the COVID-19 pandemic as a way of continuing testing while maintaining social distancing.

The value of HIV self-testing in the face of COVID-19 is also being recognized domestically. Although sales of our professional HIV test are being negatively impacted, many public health departments are increasing purchases of our FDA approved in-home HIV test in order to enable their clients to continue HIV testing without having to come to a clinic. In fact, the Centers for Disease Control and Prevention just last week issued a letter to all of their funded sites, encouraging them to use in-home self-testing for HIV in order to continue testing while complying with COVID-19 safety restrictions. Since we have the only FDA approved in-home HIV test, we expect our revenues will be positively impacted, although it will likely not fully offset the downward pressure on our professional HIV franchise. Of course, the ultimate impact will depend on when the COVID-19 situation begins to mitigate.

Turning briefly to HCV, revenues from this part of the business declined in Q1 compared to the prior year. Many testing programs in the U.S. have been put on hold as both money and personnel are being shifted to COVID-related response activity. Depending on when the COVID-19 situation is resolved, we would anticipate this business to eventually return to more normal levels of revenue. Our international business was not materially affected by COVID-19 in Q1, although it declined due to lower sales in Asia.

As previously mentioned, despite the challenges related to COVID-19, we see a number of upside opportunities, which could be substantial.

- In April, we announced a contract with the Biomedical Advanced Research and Development Authority, or "BARDA," to develop a pan-SARS-coronavirus rapid antigen in-home self-test that uses oral fluid samples. This funding will help pay the costs for development and receipt of an Emergency Use Authorization ("EUA") from the FDA. If everything goes as planned, we hope to have this test on the market by the early fall of 2020. The value of an oral fluid antigen self-test is that it will allow detection of current infection by individuals at home by using an oral fluid sample that is easier and less painful to collect than a nasopharyngeal or oropharyngeal sample. We believe, as BARDA has said publicly, a test like this could be a "game changer" that will reduce the pressure on overburdened healthcare systems and reference laboratories, while protecting healthcare

providers. Testing millions of people in their homes, identifying those who are infected with COVID-19, and isolating them will help safeguard our communities and restart our economy.

- We are also developing an oral fluid microplate test for coronavirus antibodies to be run on high-volume laboratory equipment. Samples would be self-collected using our OraSure® oral specimen collection device. We contemplate that this test will allow patients to more easily collect their sample at home and mail it to a laboratory for testing. Antibody tests will be used to show past infection, helping to determine if people have acquired immunity to COVID-19 and can safely return to work and other normal activities. Completion of this test and receipt of EUA approval is targeted for early summer.
- Finally, we are pursuing collaborations with multiple organizations, both domestic and international. Some of these are intended to help fund an expansion of production capacity as we model various assumptions and demand scenarios to meet potential high demand for our products. We are also exploring third party collaborations for development and commercialization of coronavirus testing products different than the ones we are currently developing internally. We will provide appropriate updates on these collaborations as they develop.

Molecular Solutions – Steve Tang

Turning to the Molecular Solutions Segment –

Revenues from our molecular business were up 25% compared to Q1 2019. Our commercial genomics business delivered a strong performance with some organic growth and increased purchases from a number of customers who historically used a combination of saliva and blood collection but are now shifting to a greater reliance on saliva, given the difficulties of obtaining blood samples in the COVID-19 environment. We added 31 new commercial customers in Q1 and reported a 44% increase in the number of customers that are using both our genomics and microbiome products and in some cases services as well. During Q1, we received a general use 510(k) clearance for our Oragene®•Dx family of products. This clearance strengthens our

regulatory and competitive position in the market and reduces the burden for test providers to adopt Oragene® • Dx as an approved collector for their molecular assays.

Despite the strong first quarter results, as mentioned previously, sales to our academic customers were negatively impacted by COVID-19 as many of these customers delayed research activities not associated with COVID-19 testing. This affected sales of our genomics, microbiome and urine collection kits to this market. We remain confident that both our genomics business in the disease risk management submarket and the microbiome market will return to double-digit annual growth after the pandemic.

As with the Infectious Disease Segment, we are also seeing a number of opportunities for increased business related to COVID-19. These could be significant and may more than offset any negative revenue impact on our Molecular Segment. With the current issues with sample collection and overall testing capacity, the medical community is seeking alternatives to the accepted standard of collecting oropharyngeal and nasopharyngeal samples for COVID-19 testing. Several publications have indicated that saliva, in addition to being quicker and more comfortable to collect for both patient and healthcare workers, is a technically superior sample type for the detection of COVID-19. Our product lines, specifically Oragene® • Dx, ORAcollect® • RNA and OMNIgene® • Oral, are well suited for this purpose. Our proprietary stabilization chemistries are proven to be effective at stabilizing viral DNA and RNA. Our Oragene®•Dx line of products has been used by millions of consumers in both home and professional settings and is the only device of this type granted 510(k) clearance. It is safe, non-toxic and easy to use, making it an ideal device for self-collection of samples for COVID-19 testing either at home or under supervision in a clinic.

We are working with several laboratories and diagnostic companies to validate our sample collection products for use with COVID-19 assays and feel confident that our devices will be compatible with at least some of the leading extraction techniques and testing platforms. To date, we have engaged with over 150 customers from all over the world who all share the same goal – to broaden the scope of COVID-19 tests offered and provide an easy-to-use collection solution. These customers span all types of test providers, including manufacturers of genetic tests, commercial labs and teaching hospitals. To date, we have shipped kits for COVID validations to

over 60 customers and now have 10 purchase orders of significance in house expected to result in approximately $3.6 million in 2Q revenue, with more expected shortly.

As we announced on Monday, the first COVID-19 related Emergency Use Authorization, or "EUA," incorporating one of our devices was issued last week by the FDA to Biocerna, LLC. This EUA authorizes the use of our ORAcollect®•RNA kit for the collection of anterior nasal samples for testing with the Biocerna COVID-19 assay. We expect this to be the first of several EUAs incorporating our devices for COVID-19 testing using either nasal or saliva samples in professional and at-home settings.

In addition to the data we are generating with our customers, we have several ongoing studies of our own to confirm the safety and usability of our collection devices for COVID-19 testing. These include studies to support at-home sample collection. Preliminary data is encouraging and we look forward to using results from these studies to expand our regulatory clearances.

To meet the increased demand we are seeing for our products, we have been increasing capacity at our multiple suppliers. We expect to be able to leverage multiple shifts to help increase our production capabilities.

Finally, in the lab services area, we have seen a consistent demand for lab services from our existing commercial customers with dedicated microbiome projects. However, we anticipate a short-term weakening in the overall microbiome services market as major pharmaceutical companies re-focus efforts due to COVID-19. As I noted previously, there have also been some delays in the academic market due to COVID-19 restrictions because of limited access to microbiome samples.

We are also continuing to integrate our microbiome laboratory businesses. On May 8th, the CoreBiome service operation will relocate to a new, state-of-the-art, 17,000 square foot facility in St. Paul, MN. This facility has been designed to absorb the integration of both the legacy CoreBiome and Diversigen laboratory operations as well as part of our bioinformatics and software teams. The lab is expected to be 100% operational for our CoreBiome customers on May 18th. The relocation of the Diversigen laboratory operations will begin in mid-May with a target date for completion near the end of Q3 2020. Along with the physical integration, we will be

consolidating the branding for our microbiome services organizations under the Diversigen name. We are in the final stretch for this rebranding work and within the next few weeks, all microbiome services will be operating under the Diversigen name with a new logo.

Organizational Changes – Steve Tang

A final topic I want to cover is the recent organizational changes we have announced.

Tony Zezzo, who is the Business Unit Leader in charge of our Infectious Disease business, will be retiring this summer. Tony has been with the Company for almost 10 years and has made significant contributions, including the global commercialization of our rapid HCV test and the substantial growth of our HIV franchise. His dedication and steady leadership will certainly be missed and we wish him well in his retirement. Tony's successor will be Lisa Nibauer, who will join OraSure after serving for the past eight years with Becton Dickinson, most recently as the Vice President and General Manager of BD's Medication Delivery Solutions business. Lisa has had extensive general management, sales and marketing responsibility, both at BD and at other large companies, and has exactly the skill set needed for this role. I'm confident that she will be a strong leader for this important segment of our business.

We have also recently announced several Board changes. Dr. David Shulkin, who was formerly Secretary of the U.S. Department of Veteran Affairs, joined our Board last month and is now serving on the Audit Committee and the Nominating and Corporate Governance Committee. David has had a long and distinguished career in the medical and public health fields and has served at the highest levels within our Federal government. His track record of strong executive leadership will enable him to be a significant contributor to our Board.

We also announced the upcoming departure of two Board members. Aradhana Sarin, who joined the Board in 2018 and currently serves as Chair of the Audit Committee and a member of the Nominating and Corporate Governance Committee, will be leaving the Board prior to our Annual Meeting so that she can devote more time to her duties as Chief Financial Officer of Alexion Pharmaceuticals. In addition, Chuck Patrick, who has been with the Board almost 14 years and serves as a member of the Audit Committee and member of the Nominating and Corporate

Governance Committee, will be retiring from the Board effective May 16th. Both Aradhana and Chuck have been strong contributors to the Board and their advice and counsel will be missed. We wish both of them much success for their future endeavors.

Conclusion – Steve Tang

In closing, 2020 is off to a good start with a solid Q1 performance, in spite of the pandemic. Our HIV self-testing business is expected to continue to grow strongly and we are proud to leverage our expertise to help fight the COVID-19 pandemic. We believe the opportunities for a new rapid oral fluid in-home coronavirus antigen test and a laboratory-based oral fluid antibody test, along with the expanded use of our molecular saliva collection products, are promising and could generate revenues well in excess of any revenues lost as a result of the COVID-19 pandemic. Despite the uncertain current environment, our future is bright. We are strong financially and we have the technical and management capabilities on board to enable us to successfully capture the opportunities before us. At the same time, we continue to execute against our innovation growth strategy with the continued evaluation and pursuit of external acquisitions. We look forward to reporting back on any significant new developments as they become available.

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

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[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. Stay safe and be well.

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; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collector products and commercialize such products for COVID-19 tests; 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.