

**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): November 6, 2019**

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

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-16537**  
(Commission  
File Number)

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

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

**18015-1360**  
(Zip Code)

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

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

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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 November 6, 2019, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended September 30, 2019 and updated financial guidance. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

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

## Item 7.01 – Regulation FD Disclosure.

On November 6, 2019, the Company held a webcast conference call with analysts and investors, during which Stephen S. Tang, Ph.D., the Company’s President and Chief Executive Officer, and Roberto Cuca, the Company’s Chief Financial Officer, discussed the Company’s consolidated financial results for the quarter ended September 30, 2019, provided updated financial guidance and described certain business developments. A copy of the prepared remarks of Dr. Tang and Mr. Cuca is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

On November 6, 2019, the Company issued a press release in which it announced the execution of a definitive agreement to acquire Diversigen, Inc. A copy of the press release is attached as Exhibit 99.3 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	<a href="#">Press Release, dated November 6, 2019, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2019 and updated financial guidance.</a>
99.2	<a href="#">Prepared Remarks of Stephen S. Tang, Ph.D. and Roberto Cuca for OraSure Technologies, Inc. Third Quarter 2019 Analyst/ Investor Conference Call Held November 6, 2019.</a>
99.3	<a href="#">Press Release, dated November 6, 2019 announcing the acquisition of Diversigen, Inc.</a>
Exhibit 104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**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: November 6, 2019

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary



**OraSure Technologies, Inc.**

**Company Contact:**

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**OraSure Announces 2019 Third Quarter Financial Results**

**BETHLEHEM, PA** – November 6, 2019 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its financial results for the three and nine months ended September 30, 2019.

**Financial and Business Highlights**

- In November 2019, the Company entered into an agreement to acquire Diversigen Inc., a Texas-based microbiome industry pioneer, for a cash purchase price of \$12.0 million and the potential for an additional earn-out payment tied to revenue performance.
  - In October 2019, The Substance Abuse and Mental Health Services Administration (SAMHSA) published new guidelines permitting oral fluid drug testing in federal-regulated workplace settings and in other markets that follow the federal guidelines. None of these markets are currently being served by OraSure.
  - During August 2019, the Company sold its cryosurgical systems line of business to CryoConcepts LP. The Company recorded a pre-tax gain on the sale of business of \$10.2 million which is reflective of the \$12.0 million purchase price less the fair value of the assets sold and related transaction costs.
  - Net revenues for the third quarter of 2019 were \$36.0 million, a 22% decrease from the third quarter of 2018. Net product revenues were \$35.3 million, a 19% decrease from the third quarter of 2018.
  - Total molecular collection systems revenues including royalty income and other revenues were \$18.3 million during the third quarter of 2019, a decline of 31% from the third quarter of 2018. Molecular collection systems product and service revenues were \$17.4 million during the third quarter of 2019 which represents a 32% decrease from the third quarter of 2018.
  - International sales of the Company's OraQuick® HIV products of \$5.9 million in the third quarter of 2019 increased 36% compared to the third quarter of 2018. Domestic sales of the Company's OraQuick® HIV products of \$4.3 million in the third quarter of 2019 decreased 4% compared to the third quarter of 2018.
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- International sales of the Company's OraQuick® HCV product of \$1.1 million decreased 3% from the third quarter of 2018. Domestic sales of the Company's OraQuick® HCV product of \$2.0 million decreased 4% from the third quarter of 2018.
- Net income for the third quarter of 2019 was \$13.1 million, or \$0.21 per share on a fully-diluted basis, compared to net income of \$8.1 million, or \$0.13 per share on a fully-diluted basis, for the third quarter of 2018. This includes the pre-tax gain on the sale of the cryosurgical business of \$10.2 million and a non-cash benefit of \$2.4 million representing the change in fair value of contingent consideration associated with two acquisitions that closed at the beginning of the year. The third quarter of 2019 also includes \$443,000 of acquisition-related transaction costs. The net impact of the reduction in the fair value of contingent consideration and the additional transaction costs in the current quarter approximated \$0.03 per share on a fully-diluted basis.
- Cash and investments totaled \$201.2 million at September 30, 2019.

“Despite the headwinds during the third quarter, we remain optimistic about our future, as we continue to execute on our innovation-driven strategy, using our strong bottom line and healthy cash balances,” said OraSure President & CEO Stephen Tang, Ph.D. “We continue to realign our portfolio of businesses to focus on future growth, as outlined in our strategy. The acquisition of Diversigen will extend our leadership position as an end-to-end provider of microbiome products and services. At the same time, the divestiture of our cryosurgical unit enables us to focus our resources on growing our core Molecular Solutions and Infectious Disease businesses. During the quarter, we were pleased to see continued strength in our international HIV Self-Test business, strong growth in microbiome revenues, and some renewed growth in risk assessment testing, even as recent trends continue to affect our consumer genomics business.”

## Financial Results

Net product revenues for the third quarter of 2019 decreased 19% from the comparable period of 2018, primarily as a result of lower genomics product sales, lower domestic sales of the Company's OraQuick® HIV test, and the divestiture of the cryosurgical systems business in mid-August. The decreased sales were partially offset by higher international HIV product sales and higher sales of the Company's microbiome and risk assessment products.

International sales of the OraQuick® HIV Self-Test for the three months ended September 30, 2019 and 2018 included \$520,000 and \$840,000, respectively, of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation (“Gates Foundation”).

Royalty income from a litigation settlement associated with a molecular collection device was \$758,000 and \$1.1 million for the third quarters of 2019 and 2018, respectively. Other revenues, excluding royalty income, were \$(68,000) and \$1.3 million for the third quarters of 2019 and 2018, respectively. Other revenues in the current period decreased as a result of a rate true-up under the Company's contract with the U.S. Biomedical Advanced Research Development Authority (BARDA) and lower cost reimbursement from the Gates Foundation, which is separate from the support payments mentioned above.

Gross profit percentage was 60% and 62% for the third quarters of 2019 and 2018 respectively. Gross profit percentage in 2019 was negatively affected by the decline in other revenues and by the lower margins generated by the Company's newly acquired subsidiaries, CoreBiome and Novosanis, partially offset by lower royalty and freight costs.

For the three months ended September 30, 2019, operating expenses were \$8.6 million, a decrease of \$9.1 million from the \$17.7 million reported for the three months ended September 30, 2018. This decrease was

due primarily to the pre-tax gain on the sale of the cryosurgical business of \$10.2 million and a non-cash benefit of \$2.4 million in the current quarter for the change in fair value of contingent consideration associated with the recent acquisitions of CoreBiome and Novosanis, offset by the incremental operating expenses of CoreBiome and Novosanis and \$443,000 of acquisition-related transaction costs.

The Company generated operating income of \$13.1 million in the third quarter of 2019 compared to operating income of \$10.9 million in the third quarter of 2018.

During the third quarter of 2019, the Company recorded income tax expense of \$1.2 million compared to \$3.3 million recorded in the third quarter of 2018. This decrease reflects the lower pre-tax income generated by the Company's Canadian subsidiary, DNA Genotek, and includes an income tax benefit generated by Novosanis.

The Company's cash and investment balance totaled \$201.2 million at September 30, 2019, compared to \$201.3 million at December 31, 2018. For the nine months ended September 30 2019, the Company generated \$10.8 million in cash from operations compared with \$24.8 million in the same period of 2018.

### **Updated Full-Year 2019 Guidance**

The Company expects full-year 2019 net revenues to range from \$150 million to \$153 million and is projecting net income of \$0.28 to \$0.31 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.

## Financial Data

### Condensed Consolidated Financial Data

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
<b>Results of Operations</b>				
Net revenues	\$ 35,989	\$ 45,885	\$ 104,937	\$ 131,497
Cost of products sold	14,343	17,340	40,193	52,590
Gross profit	21,646	28,545	64,744	78,907
Operating expenses:				
Research and development	4,619	3,855	13,525	12,191
Sales and marketing	8,955	7,304	23,937	22,232
General and administrative	7,556	6,529	23,748	28,567
Change in fair value of acquisition-related contingent consideration	(2,387)	—	(843)	—
Gain on sale of business	(10,149)	—	(10,149)	—
Total operating expenses	8,594	17,688	50,218	62,990
Operating income	13,052	10,857	14,526	15,917
Other income	1,195	510	2,243	1,658
Income before income taxes	14,247	11,367	16,769	17,575
Income tax expense	1,169	3,271	2,551	7,477
Net income	\$ 13,078	\$ 8,096	\$ 14,218	\$ 10,098
Earnings per share:				
Basic	\$ 0.21	\$ 0.13	\$ 0.23	\$ 0.17
Diluted	\$ 0.21	\$ 0.13	\$ 0.23	\$ 0.16
Weighted average shares:				
Basic	61,726	61,208	61,656	61,059
Diluted	62,143	62,606	62,172	62,539

	Three Months Ended September 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2019	2018		2019	2018
<b>Market</b>					
Infectious disease testing	\$ 13,588	\$ 12,417	9 %	38 %	27 %
Risk assessment testing	3,312	2,842	17	9	6
Cryosurgical systems	961	2,696	(64)	3	6
Molecular collection systems	17,438	25,495	(32)	48	56
Net product and service revenues	35,299	43,450	(19)	98	95
Royalty income	758	1,132	(33)	2	2
Other	(68)	1,303	(105)	-	3
Net revenues	\$ 35,989	\$ 45,885	(22) %	100 %	100 %

	Nine Months Ended September 30,					
	Dollars			Percentage of Total Net Revenues		
	2019	2018	% Change	2019	2018	
<b>Market</b>						
Infectious disease testing	\$ 39,273	\$ 42,506	(8) %	37 %	32 %	
Risk assessment testing	9,246	9,159	1	9	7	
Cryosurgical systems	7,054	7,874	(10)	7	6	
Molecular collection systems	45,325	61,047	(26)	43	46	
Net product revenues	100,898	120,586	(16)	96	91	
Royalty income	2,956	4,827	(39)	3	4	
Other	1,083	6,084	(82)	1	5	
Net revenues	\$ 104,937	\$ 131,497	(20) %	100 %	100 %	

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	% Change	2019	2018	% Change
	<b>OraQuick® Revenues</b>					
Domestic HIV	\$ 4,259	\$ 4,455	(4) %	\$ 13,024	\$ 14,689	(11) %
International HIV	5,891	4,328	36	15,313	17,395	(12)
Net HIV revenues	10,150	8,783	16	28,337	32,084	(12)
Domestic HCV	1,977	2,066	(4)	5,907	5,424	9
International HCV	1,129	1,168	(3)	3,569	3,306	8
Net HCV revenues	3,106	3,234	(4)	9,476	8,730	9
Net product revenues	\$ 13,256	\$ 12,017	10 %	\$ 37,813	\$ 40,814	(7) %

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	% Change	2019	2018	% Change
	<b>Molecular Collection Systems Revenues</b>					
Genomics	\$ 14,080	\$ 23,804	(41) %	\$ 36,359	\$ 56,260	(35) %
Microbiome	3,063	1,691	81	8,362	4,787	75
Other	295	—	100	604	—	100
Net product and service revenues	17,438	\$ 25,495	(32)	45,325	\$ 61,047	(26)
Royalty income	758	1,132	(33)	2,956	4,827	(39)
Other	63	—	100	321	—	100
Total Molecular Collection Systems Revenues	\$ 18,259	\$ 26,627	(31) %	\$ 48,602	\$ 65,874	(26) %



**Condensed Consolidated Balance Sheets (Unaudited)**

	September 30, 2019	December 31, 2018
<u>Assets</u>		
Cash and cash equivalents	\$ 85,465	\$ 88,438
Short-term investments	78,215	68,134
Accounts receivable, net	27,764	34,842
Inventories	25,040	22,888
Other current assets	6,796	5,010
Property, plant and equipment, net	29,045	24,299
Right of use assets, net	4,850	—
Intangible assets, net	11,577	5,137
Goodwill	28,935	18,521
Long-term investments	37,563	44,752
Other non-current assets	3,971	3,550
<b>Total assets</b>	<b>\$ 339,221</b>	<b>\$ 315,571</b>
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 9,783	\$ 10,598
Deferred revenue	3,940	3,521
Contingent consideration obligation	3,039	—
Other current liabilities	12,174	13,861
Long-term lease liabilities	3,882	—
Long-term contingent consideration obligation	385	—
Other non-current liabilities	4,653	4,213
Stockholders' equity	301,365	283,378
<b>Total liabilities and stockholders' equity</b>	<b>\$ 339,221</b>	<b>\$ 315,571</b>

<b>Additional Financial Data (Unaudited)</b>	Nine Months Ended	
	September 30,	
	2019	2018
Capital expenditures	\$ 7,961	\$ 5,938
Depreciation and amortization	\$ 5,532	\$ 5,588
Stock-based compensation	\$ 3,283	\$ 12,526
Cash provided by operating activities	\$ 10,838	\$ 24,807

**Conference Call**

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2019 third 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 #8333048 or go to OraSure Technologies' web site, [www.orasure.com](http://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, November 16, 2019, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #8333048.

## **About OraSure Technologies**

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

For more information on OraSure Technologies, please visit [www.orasure.com](http://www.orasure.com).

## **Important Information**

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

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

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**OraSure Technologies, Inc.  
2019 Third Quarter  
Analyst/Investor Conference Call  
November 6, 2019**

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

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

**Introduction – Steve Tang**

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

During today’s call I would like to address two subjects that are most likely top of mind. The first is an update on the implementation of our innovation growth strategy, where I will outline our ongoing efforts to position OraSure to capitalize on some of the fastest growing segments within the molecular and diagnostics markets. Secondly, we will break down our financial performance for the third quarter and provide updated guidance. The information we share today will provide context and demonstrate that our business is largely on track with the exception of consumer genomics.

The announcement earlier today that we have signed an agreement to acquire Diversigen is yet another example of the progress we are making in executing our growth strategy. Diversigen is an exceptional company and a proven leader in the microbiome laboratory and analytics services industry. This acquisition will further strengthen our microbiome business and improve our ability to provide customers with industry-leading end-to-end microbiome product and service offerings. With over \$200 million in cash on the balance sheet as of the end of Q3, we are well positioned to make further additions to the Company. We believe OraSure is at the forefront of several nascent, but large, growth opportunities.

Another recent strategic step was the sale of our cryosurgical systems business which we announced in August. The divestiture allowed us to shed a non-strategic business line, prioritize

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our product portfolio, and refocus our resources on growing our core Molecular Solutions and Infectious Disease businesses.

Turning to the quarter, as I said, the trends we have outlined on prior calls, particularly those affecting the consumer genomics market, continue to impact our business. Overall, however, our business continues to perform largely as expected.

- Revenues came in a bit below our guidance. However, this was primarily caused by a timing issue. Specifically, three HIV Self-Test orders valued at \$1.9 million could not be delivered until the first week of October because of unexpected logistical delays. Otherwise, the business performed as reflected in our guidance.
- As reported in prior calls, our genomic testing business remains healthy. Apart from the previously-discussed single large customer that changed its promotional strategy, this business grew by strong double digits in the third quarter.
- The microbiome market continues to shine with a very robust performance in Q3. We continue to expect revenue growth in the double-digit range for the remainder of this year.
- Our integration of Novosanis and CoreBiome, which we acquired in January, is nearing completion, and we are seeing increasing contributions from both companies. We are also far along in planning the integration of Diversigen into our microbiome services business.
- On the infectious disease front, our HIV Self-Test business performed very well during the third quarter. We generated revenue growth of 36% over the prior year quarter, despite the slippage of the orders I just mentioned. We continue to project double-digit revenue growth for our international HIV franchise through the remainder of this year, primarily due to sales of our Self-Test.
- And finally, although not usually a focus on our earnings calls, our Risk Assessment Testing business for drugs of abuse grew 17% in the third quarter compared to the prior year period. We are optimistic about the future prospects for this business. As you may have seen, new Federal drug testing guidelines were recently issued which authorize the use of oral fluid in drug testing for federally-regulated markets for the first time. We

believe these guidelines will open up a large potential market opportunity for us that we are currently not serving.

With that, I will now turn the call over to Roberto for his financial review. I will then provide some additional commentary on our business and then take your questions.

**Third Quarter 2019 Financial Results – Roberto Cuca**

Thanks Steve, and good evening everyone.

Our third quarter net revenues decreased 22% to \$36.0 million from \$45.9 million reported in the third quarter of 2018. Our net product and services revenues decreased 19% to \$35.3 million compared to the prior-year period.

Our molecular net revenues including other revenues decreased 31% to \$18.3 million in the third quarter compared to \$26.6 million in 2018. Royalty income declined 33% to \$758,000 in the third quarter of 2019, from \$1.1 million in the same period of 2018. This also represents a sequential decline from the second quarter of 2019 of 32% versus a 46% sequential decline from the second quarter to the third quarter of 2018. Molecular product revenues decreased 32% to \$17.4 million in the third quarter of 2019 compared to \$25.5 million in the third quarter of 2018. Sales of our genomic products declined 41% to \$14.1 million largely due to lower customer demand, primarily from a large consumer genomics customer that changed its promotional strategy which impacted its purchasing patterns. Notably, excluding this single customer, genomic product revenues grew 30% compared to the third quarter of 2018. Microbiome sales increased 81% to \$3.1 million from \$1.7 million in the third quarter of last year primarily due the inclusion of lab service revenues generated by our newly-acquired subsidiary CoreBiome, as well as healthy double-digit organic growth.

Domestic HIV sales decreased 4% to \$4.3 million in the third quarter of 2019 compared to \$4.5 million in the third quarter of 2018, largely due to lower sales of our over-the-counter product.

International HIV sales increased 36% to \$5.9 million from \$4.3 million in the third quarter of 2018 due to higher sales of our HIV Self-Test into Africa notwithstanding the shipping challenges with three international orders that Steve described. All three of these shipments were completed in the first week of October.

Domestic HCV sales decreased 4% in the third quarter of 2019 to \$2.0 million from \$2.1 million in the prior-year period largely due to the timing of customer orders.

International HCV sales in the third quarter of 2019 decreased 3% to \$1.1 million from \$1.2 million in the same period of 2018 primarily due to lower sales into the Middle East partially offset by sales growth in Asia.

Other revenues were \$4.0 million in the current quarter compared to \$10.9 million in the prior year. The decrease is largely due to the lower royalty income I mentioned earlier and decreases in BARDA funding and cost reimbursement under our charitable support agreement with the Gates Foundation. The reduced BARDA funding reflects the conclusion of our projects under this program and our rotation of R&D resources to projects that are aligned with our long-term growth strategy.

Gross profit percentage for the third quarter of 2019 was 60% compared to 62% reported for the third quarter of 2018. The decline in gross profit is directly related to the decline in other revenues which contribute 100% to the gross profit percentage and the lower margins generated by CoreBiome and Novosanis, partially offset by lower royalty and freight costs during the quarter.

Our operating expenses for the third quarter of 2019 were \$8.6 million compared to \$17.7 million in the comparable period of 2018. Operating expense in the third quarter of 2019 included a pre-tax gain on the sale of the cryosurgical systems business of \$10.2 million and \$2.4 million of non-cash acquisition-related contingent consideration benefits offset by the incremental operating expenses generated by CoreBiome and Novosanis and \$443,000 of acquisition-related transaction costs. As a reminder, we provide EPS guidance that does not include the impact of changes in the fair value of acquisition-related contingent consideration and acquisition-related transition costs

since these items cannot be estimated. There were no similar acquisition-related costs in the third quarter of 2018.

In the third quarter of 2019 we recorded income tax expense of \$1.2 million compared to \$3.3 million in the same period last year. The decline in tax expense reflects the lower pre-tax earnings generated by our Canadian subsidiary and the results generated by Novosanis.

We reported net income of \$13.1 million, or \$0.21 per share, for the third quarter of 2019 compared to net income of \$8.1 million, or \$0.13 per share, for Q3 2018.

We continue to maintain a solid cash and liquidity position. Our cash and investments balance at September 30, 2019 was \$201.2 million compared to \$201.3 million at December 31, 2018. During the first quarter of 2019, we used \$13.2 million of cash to acquire CoreBiome and Novosanis and in the third quarter of 2019 we received \$12.0 million in proceeds from the sale of our cryosurgical systems business. Cash generated by operating activities during the first nine months of 2019 was \$10.8 million compared to \$20.8 million in the same period of 2018.

Turning to guidance: For the full year of 2019, we are projecting revenues of \$150 million to \$153 million and net income of \$0.28 to \$0.31 per share. These projections do not account for the impact of changes in the fair value of acquisition-related contingent consideration or potential business development transaction costs since the full extent of those items cannot be determined at this time.

The decrease in projected revenues and EPS from our prior guidance is driven primarily by revised expectations for our genomics collection device sales with a smaller contribution from international sales of HIV testing devices. As many of you know, during the third quarter, the U.S. Justice Department indicted 35 individuals accused of offering fraudulent genetic testing primarily to seniors in order to collect insurance. This had little effect on any of our customers in the third quarter, but has created enough uncertainty in the market that customers have signaled the likelihood of lower orders in the fourth quarter. Additionally the media attention this has drawn can create mistrust and cynicism towards genetic testing and may be contributing to the



more general slowdown that we and others are seeing in the broader consumer genomics space. Based on discussions with our customers and the trends we saw persisting in the third quarter, we have lowered our forecast for genomics revenues in the fourth quarter.

The revision to our expectations for international HIV testing sales is the result of forecasted slippage of an order from the fourth quarter of this year into next year. Note that this is unconnected to the \$1.9M in orders that moved from the third to the fourth quarter of this year. The fourth quarter slippage is related to the increasing expansion of our sales outside the original STAR country markets. Under STAR, the ordering and shipping processes were consistent from country to country with long, predictable lead times. As we have expanded our sales outside of the original STAR countries, we have expanded the addressable market for our products considerably, yet we have also increased exposure to significant variability in ordering and shipping processes and timelines between markets. Once each new market is established, the process will stabilize and be more predictable but we are experiencing some delays in planned orders in the meantime.

We are of course disappointed that we have had to make this change. Nonetheless, to the extent that all of the infectious disease and some of the genomics reduction was due to timing of sales, we continue to be confident in the underlying health of our businesses. Moreover, in light of our ongoing success with regards to business development opportunities, the continued expansion of our self-test markets in Africa, the growth we continue to see in the disease risk management submarket of the genomics business, and the strength of the microbiome product and services markets, we remain very optimistic about our future prospects.

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

***Business Update – Steve Tang***

Thanks Roberto. I'll first focus on our Molecular Solutions business.

**Human Genomics**

As mentioned in my opening remarks, and Roberto’s report, both the positive and negative trends that impacted our genomics business are continuing. On the one hand, we see many signs of growth in our genomics business despite the impact of a single large consumer genomics customer. Product revenues excluding this customer were up 30% in the third quarter compared to 2018. We are also seeing consistent growth in the number of new commercial genomics customers being added to our business.

Importantly, we continue to see growth in the number of disease risk management companies adopting our FDA-cleared collection devices for clinical applications. Overall, there seems to be an uptick in the use of FDA-cleared devices and platforms in the genomics testing market. We believe this is being driven, at least in part, by the FDA’s efforts to enforce the need for using cleared devices in clinical genomic testing applications. As we have shared in the past, we have an active regulatory program to bolster our global growth. We are also actively working with several customers to obtain FDA clearances for their tests. This type of collaboration is important in that it strengthens our regulatory position and deepens our relationships with emerging clinical test providers.

Despite the underlying strength in much of genomics, the ancestry or genealogy testing segment within the consumer genomics market continues to decline and is impacting our product revenues and royalty income. As we have noted in previous calls, over time we expect that other sub-markets within genetic testing, most notably disease risk management, augmented by animal health and lifestyle genomics, will eventually offset these declines.

So, in summary, despite challenges in the consumer genomics market, we continue to believe that our overall genomics business is healthy and offers great opportunity. Excluding the large customer that has negatively impacted this business, we continue to believe that genomics will deliver double-digit growth for the remainder of this year.

## Microbiome

Another bright spot is the microbiome business, which delivered a strong third quarter. New customer acquisitions grew by double digits compared to the third quarter of 2018. Overall, the microbiome business, including both products and services, was up 81% over the same quarter of 2018, with the highest growth rates coming from the Asia Pacific and European markets. This growth was driven by a 53% increase in product revenue and a 152% increase in services revenue during the third quarter compared to 2018 as a result of our acquisition of CoreBiome. I would note that the third quarter 2019 services revenue was also sequentially up 29% compared to the prior quarter.

We are clearly starting to see the impact of our CoreBiome acquisition, both in terms of revenue generation and the expansion of our microbiome offerings. In fact, CoreBiome was recently chosen as the sequencing and custom bioinformatics provider for the development of a new microbiome diagnostic test. In addition, members of the CoreBiome scientific team recently published a peer-reviewed longitudinal multiomics study of the avian microbiome that integrated host gene expression with the microbiome to measure the effects of alternative treatments to antibiotics.

We believe the acquisition of Diversigen will provide significant benefits and further strengthen our presence in the microbiome arena. Diversigen is truly a pioneer, in providing solutions for sequencing, analysis and consulting, focused on the microbiome of living organisms and environments. They have developed state-of-the-art techniques to extract high-quality nucleic acids from a variety of sample types for metagenomics analysis using technology licensed from the Baylor College of Medicine. Their strength, expertise, regulatory status and focus on superior customer service have been key factors in establishing a leadership position in the industry, with an impressive customer list that includes many of the top 10 pharma companies in the world, along with a leading microbiome therapeutics provider.

Diversigen was the first company to establish microbiome protocols in accordance with College of American Pathologists (CAP) accreditation and Clinical Laboratory Improvements Amendments of 1988 (CLIA) guidelines. Approximately ninety percent of Diversigen's

business is from big pharma, and the leading microbiome therapeutic company is also a top customer. The powerful combination of Diversigen's strength, expertise and focus on customer service along with CoreBiome's technical innovation in microbiome analysis, and DNA Genotek's proven microbiome sample collection and stabilization devices will give us industry-leading product and service offerings, from sampling to rich analytics, that can provide actionable insights. Collectively, Diversigen and CoreBiome represent over 100 person-years of microbiome experience and 300 scientific publications on the microbiome. We are very excited about expanding our presence within the microbiome services market and look forward to aligning and growing these businesses in 2020 and beyond.

### Multiomics

In addition to our new products and services focused on the microbiome, we continue to see significant growth potential in the broader field of multiomics. As I've described in previous calls, this emerging area of life science and data analytics provides a multifactorial examination of an individual's health, by examining the different "omes" including the microbiome and the genome. Our initial entry into multiomics materialized when a number of our existing human genomics customers added a microbiome component to their studies and offerings. Year to date, we have seen a 35% increase in the number of customers who are using both genomics and microbiome kits. We expect this trend to continue.

### Urine Collection

Finally, there have been continued positive developments in Novosanis' urine collection business. As I noted in our last call, Novosanis entered into a non-exclusive agreement with Fujirebio for the distribution of the Colli-Pee® collection device for use with Fujirebio's INNO-LiPA HPV genotyping EXTRA II assay. The assay has now been CE-IVD marked for use with Colli-Pee®-collected first void urine samples.

During the third quarter, Novosanis completed development and launched two new versions of its Colli-Pee® collection device that allow the collection of either a smaller or larger volume of first-void urine, as compared to the original 20 ml device. These new versions will enable Novosanis

to expand the use of the Colli-Pee® device, with additional applications in the areas of infectious disease and oncology. The smaller version captures up to 10 ml of urine and is compatible with many high throughput instruments, thereby offering improved lab workflow and collection of a bio-marker rich urine sample. The larger version captures the first 45 ml of first-void urine, supports multiomic testing, and can be used to solve issues related to lower analyte concentrations. This larger volume version has applications in the detection and monitoring of some cancers where a large volume of urine may be required.

In our last call, we mentioned that the Colli-Pee® device is being used with a lab developed test offered by Bio-Techne called ExDx® Prostate Intelliscore, or EPI, which allows a physician to predict if a patient presenting for internal biopsy does not have high-grade prostate cancer. Bio-Techne recently announced the issuance of a local insurance coverage decision for the EPI test for men who are being considered for an initial prostate biopsy. This decision enables Medicare reimbursement for the test and is effective for tests administered on or after December 1. Bio-Techne also noted that its EPI test has received FDA breakthrough designation and is included on the National Comprehensive Cancer Network guidelines for early detection in men, for both initial and repeat biopsy. This is obviously good news and is evidence of how the Colli-Pee® device can be used with this and other LDT applications in the future.

***Infected Disease Testing – Steve Tang***

Turning now to Infectious Disease:

The third quarter was a good one for our HIV franchise. Global revenues were up 16% when compared to 2018, driven primarily by a 36% increase in international HIV Self-Test sales. We sold approximately 1.5 million HIV Self-Tests in Q3. Importantly, these strong results were achieved despite the fact that \$1.9 million in Self-Test orders had to be moved to early in the fourth quarter as a result of unexpected logistical issues.

As you know, we previously participated in the STAR, or Self Testing Africa program, which has largely been completed. We continue to see new country registrations for our Self-Test in

countries outside of the STAR program. To date, we have received 19 registrations - two since our last earnings call - and there are 13 additional submissions pending. One recent important registration for our Self-Test is in Nigeria. We expect to receive their initial scale up order in the fourth quarter and we believe the Nigerian program will eventually be one of the larger programs deploying our test. We also are participating in the formal launch of HIV self testing in Uganda, with the full support of the Ministry of Health's Permanent Secretary and USAID. Plans for deployment of our Self-Test are underway and we expect our initial shipment to go out this quarter.

We recently received a change notification from the World Health Organization (WHO) to add a pediatric testing claim to both our pre-qualified professional HIV test and our HIV Self-Test. These new claims will allow us to participate with PEPFAR in the Rome Action Plan For Pediatric HIV, a program intended to enhance and expand pediatric diagnostic testing for HIV around the world. They should also give us a competitive advantage for these products in an increasingly competitive marketplace. While good news, these new claims alone will not drive further adoption of our products. We still need evidence of the utility of pediatric testing for HIV, in order to drive investment by international funding sources. Those impact studies are now under way with money provided by the Centers for Disease Control and Protection (CDC). We expect these changes to eventually allow doctors with our professional test and parents and guardians with our Self-Test to test children as young as age two.

On the domestic front, the U.S. Department of Health and Human Services has proposed a new initiative called "Ending the HIV Epidemic: A Plan for America," with the goal of ending HIV in the U.S. within 10 years. The Plan for America will leverage highly successful programs, resources and infrastructure for HIV prevention, diagnosis, treatment and outbreak response to coordinate action across several Federal agencies. The initial focus of this initiative will be in communities that are now hardest hit by the HIV epidemic. Since much of the initial work will occur outside of clinics and hospitals, we believe our OraQuick® In-Home HIV test, which is the only FDA approved test of its kind for home use, can play an important role in outreach programs to achieve the goals of this initiative. Funding in the amount of \$291 million is currently in the Administration's 2020 budget and is working its way through the Congressional approval process. The CDC is beginning to put plans in place to begin execution in 2020.

So in short, we remain optimistic about the overall long-term potential for our HIV franchise and we are projecting double-digit growth in international HIV revenues for the full year.

Turning briefly to HCV, revenues from this part of the business were down for both international and domestic markets due to a mix of reasons. However, we expect to see ongoing funding and demand for our HCV product in future quarters, and we continue to expect our HCV franchise to contribute growth to our infectious disease business going forward.

### Risk Assessment Testing

Another area I want to touch on is risk assessment testing, which includes our oral fluid drug testing product line. Under long-awaited oral fluid drug testing guidelines recently announced by The Substance Abuse and Mental Health Services Administration (SAMHSA), oral fluid drug testing is now permitted in federally-regulated markets. Oral fluid drug testing allows for better differentiation between recent drug use and historic use to effectively determine potential impairment on the job. The guidelines stipulate test parameters and oral fluid collection device requirements that manufacturers have to meet to be able to sell their products into the regulated markets. We have finalized the design of an oral fluid collection device that we believe will meet these requirements and are working with Thermo Fisher to develop automated drug testing assays that meet these new requirements. In addition, laboratories interested in being an accredited oral fluid testing facility under the guidelines can begin making their applications beginning on January 1, 2020. It is estimated that the implementation of the new guidelines will take approximately 18 months. SAMHSA expects that approximately 25% - 30% of federally regulated drug testing will eventually be oral fluid, which translates into roughly 12 million tests per year at the low end of this range. This obviously is a positive development and we believe it could have a significant positive impact on our Risk Assessment Testing business.

## Ebola

A last point I want to mention is the FDA's recent decision to grant 510(k) clearance for our OraQuick® Rapid Ebola test. This test can be used with blood samples from living individuals and oral fluid samples taken from recently deceased individuals. The clearance came through the FDA's Breakthrough Devices Program that allows for expedited clearance for the treatment or diagnosis of life-threatening or irreversibly debilitating diseases. The claims for our test are limited to individuals who meet certain criteria indicating they may be infected, so the test will not be available for general screening of individuals who do not meet these criteria. This is the first and only rapid Ebola test to be cleared for sale in the U.S. and should be commercially available in the first quarter of 2020. We continue to believe that the largest opportunity for this product will be outside the U.S. and that the CDC and WHO will be the primary purchasers for this product. We are currently in discussions with these organizations to understand their potential short and long-term needs for the test.

### ***Conclusion - Steve Tang***

In closing, despite the slowdown in the consumer genomics market overshadowing many positive developments at the Company, we continue to make demonstrable progress in executing against our innovation-driven growth strategy. We have improved our competitive profile and expanded our addressable market by adding new capabilities – and those efforts will continue. So far, we have completed three acquisitions this year and divested a non-strategic business line. We are confident that our strategy will allow us to capitalize on multiple large opportunities, which are still in their early days. Our strong balance sheet affords us the ability to continue acquiring additional products and services to augment our current capabilities. Our pipeline of acquisition candidates remains robust.

We expect continued growth from both our global HIV and HCV franchises and believe our molecular solutions business is healthy and well-positioned to leverage a number of growth opportunities. We expect the growth from these burgeoning areas will be more evident, as the impact of consumer genomics rolls out of our quarter-to-quarter comparisons beginning in 2020.



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

\* \* \*

**[Q&A session]**

***Final Conclusion – Steve Tang***

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

**Important Information**

This document contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration

(“FDA”) or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company’s products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention (“CDC”) or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; impact of increased reliance on U.S. government contracts; impact of negative economic conditions; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company’s stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could affect our results are discussed more fully in the our

Securities and Exchange Commission (“SEC”) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2018, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this call, and we undertake no duty to update these statements.



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**OraSure Technologies, Inc. Announces Purchase of Diversigen**  
*Acquisition extends OraSure's leadership position in the microbiome services industry*

**Bethlehem, PA** – November 6, 2019 – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point of care diagnostic tests and specimen collection and stabilization devices, today announced that it has entered into a definitive agreement to acquire the outstanding equity of Diversigen in an all-cash transaction.

Diversigen is a privately held microbiome industry pioneer based in Houston, Texas. Diversigen provides science-driven, customized solutions for metagenomics sequencing, bioinformatics, and statistical analysis for the study of the microbiome. The company was founded in 2013 by Dr. Joseph Petrosino, director of the Alkek Center for Metagenomics and Microbiome Research at the Baylor College of Medicine (BCM), where Diversigen is a BCM portfolio company.

As the first company to establish microbiome protocols in accordance with College of American Pathologists (CAP) accreditation and Clinical Laboratory Improvements Amendments of 1988 (CLIA) guidelines, Diversigen has a strong track record of supporting microbiome-focused clinical trials for big pharma customers, as well as thought-leading microbiome-focused biotech companies.

“Diversigen is a trailblazer in the microbiome arena. Their addition to the OraSure family of companies, which includes CoreBiome and DNA Genotek, positions us to be an industry leader and accelerates our innovation-driven growth trajectory,” said Stephen S. Tang, Ph.D., OraSure President & CEO.

“Ninety percent of Diversigen’s business is from big pharma and a leading microbiome therapeutic company is also a top customer,” Dr. Tang continued. “The powerful combination of Diversigen’s strength, expertise, and focus on customer service along with CoreBiome’s technical innovation in microbiome analysis and DNA Genotek’s innovative sampling kits gives us industry-leading product and service offerings from sampling to rich analytics to drive actionable insights. We are excited to unite these microbiome innovators whose unparalleled scientific bench and informatics strength is defining the evolving microbiome arena.”

“Since 2013 Diversigen has united the pioneering research efforts of the Alkek Center for Metagenomics and Microbiome Research at Baylor and the microbiome discovery community to enable translation of microbiome science,” said Diversigen founder Dr. Joseph Petrosino. “We’re very excited to combine the CLIA and CAP-accredited microbiome work-flows we’ve developed at Baylor with the portfolio at OraSure. This union creates an organization that is unrivaled in its ability to support microbiome discovery and evolution.”

“Baylor College of Medicine is pleased to partner with OraSure in bringing innovative microbiome related services to the forefront of this evolving market,” said Dr. Paul Klotman, president, CEO and executive dean of Baylor. “The College’s innovative culture and commitment to translational discovery allows us to engage in strong relationships like this with OraSure to bring scientific discoveries to market at an accelerated pace.”

### **Financial Considerations**

The transaction is structured to include an upfront cash payment of \$12 million and the potential for an additional earn-out payment tied to revenue performance during 2019. The transaction is expected to close in the next several days.

### **About OraSure Technologies**

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

For more information on OraSure Technologies, please visit [www.orasure.com](http://www.orasure.com).

### **Important Information**

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