



OraSure Technologies, Inc.

## OraSure Announces 2019 Third Quarter Financial Results

November 6, 2019

BETHLEHEM, Pa., Nov. 06, 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<sup>®</sup> 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<sup>®</sup> HIV products of \$4.3 million in the third quarter of 2019 decreased 4% compared to the third quarter of 2018.
- International sales of the Company's OraQuick<sup>®</sup> HCV product of \$1.1 million decreased 3% from the third quarter of 2018. Domestic sales of the Company's OraQuick<sup>®</sup> 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<sup>®</sup> 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			Percentage of Total Net Revenues		
	2019	2018	% Change	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	%

	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

<b>Assets</b>		
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>
<b>Liabilities and Stockholders' Equity</b>		
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>

**Nine Months Ended  
September 30,**

<b>Additional Financial Data (Unaudited)</b>	<b>2019</b>	<b>2018</b>
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<sup>®</sup> 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.

Company Contact:

Roberto Cuca  
Chief Financial Officer  
610-882-1820  
[Investorinfo@orasure.com](mailto:Investorinfo@orasure.com)  
[www.orasure.com](http://www.orasure.com)

Jeanne Mell  
VP Corporate Communications  
484-353-1575  
[media@orasure.com](mailto:media@orasure.com)  
[www.orasure.com](http://www.orasure.com)



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