



## OraSure Announces 2018 Third Quarter Financial Results

November 7, 2018

BETHLEHEM, PA., Nov. 07, 2018 (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, 2018.

### Financial Highlights

- Net revenues for the third quarter of 2018 were \$45.9 million, an 8% increase from the third quarter of 2017. Net product revenues were \$43.5 million, representing a 6% increase from the third quarter of 2017.
- Net revenues for the nine months ended September 30, 2018 were \$131.5 million, a 14% increase from the comparable period of 2017. Net product revenues for the first nine months of 2018 were \$120.6 million, representing an 8% increase over the first nine months of 2017.
- Net molecular collection systems revenues were \$25.5 million during the third quarter of 2018, which represents a 37% increase over the third quarter of 2017. Net molecular collection systems revenues during the nine months ended September 30, 2018 were \$61.0 million, a 35% increase from the comparable period of 2017.
- International sales of the Company's OraQuick<sup>®</sup> HIV products of \$4.3 million increased 41% compared to the third quarter of 2017. For the first nine months of 2018, international sales of the Company's OraQuick<sup>®</sup> HIV products of \$17.4 million increased 125% compared to the first nine months of 2017. The increases in both periods were primarily the result of higher sales of the Company's OraQuick<sup>®</sup> HIV Self-Test.
- International sales of the Company's OraQuick<sup>®</sup> HCV product of \$1.2 million decreased 81% for the third quarter of 2018 compared to the third quarter of 2017. International sales of the Company's OraQuick<sup>®</sup> HCV product of \$3.3 million for the first nine months of 2018 decreased 79% from the comparable period of 2017. These declines were primarily the result of the non-renewal of a foreign government supply contract in support of a countrywide HCV eradication program at the end of 2017. This program contributed \$4.7 million of sales during the third quarter of 2017 and \$11.6 million during the first nine months of 2017.
- Net income for the third quarter of 2018 was \$8.1 million, or \$0.13 per share on a fully diluted basis, which compares to net income of \$5.8 million, or \$0.09 per share on a fully diluted basis, for the third quarter of 2017. Net income for the nine months ended September 30, 2018 was \$10.1 million, or \$0.16 per share on a fully diluted basis, which compares to net income of \$23.6 million, or \$0.39 per share on a fully diluted basis, for the comparable period of 2017. Net income for the year-to-date period included \$8.6 million of transition costs associated with the retirement of the Company's former Chief Executive Officer and Chief Financial Officer and the hiring of their successors. These transition costs approximated \$0.14 per share for the nine month period ended September 30, 2018 and primarily consisted of non-cash stock compensation charges. Net income for the nine months ended September 30, 2017 included a \$12.5 million gain related to the settlement of litigation against Ancestry.com DNA and its contract manufacturer. This gain was accounted for as a reduction of operating expenses and approximated \$0.15 per share on a fully diluted after-tax basis in that period.
- Cash and investments totaled \$192.1 million at September 30, 2018.

"Our solid third quarter performance was driven by strong growth in our molecular collections and international HIV Self-Test businesses," said Dr. Stephen S. Tang, President and Chief Executive Officer of OraSure Technologies. "An abundance of opportunity remains in the growth drivers for our business and capitalizing on these opportunities will remain a priority for our management team. In addition, as we execute against our strategic goals, we continue to actively explore ways to leverage our strong balance sheet to further enhance our growth. We are very well positioned to compete in our key markets and expect to deliver a strong end to the year."

### Financial Results

Net product revenues for the third quarter of 2018 increased 6% from the comparable period of 2017, primarily as a result of higher sales of the Company's molecular collections products and higher international sales of the OraQuick<sup>®</sup> HIV Self-Test, partially offset by lower international sales of the Company's OraQuick<sup>®</sup> HCV test and lower domestic sales of the professional OraQuick<sup>®</sup> HIV test.

Net product revenues for the first nine months of 2018 increased 8% over the comparable period of 2017, primarily as a result of higher sales of the

Company's molecular collection systems products and higher international sales of the OraQuick<sup>®</sup> HIV Self-Test, partially offset by lower sales of the Company's HCV product, lower domestic sales of the professional OraQuick<sup>®</sup> HIV test and lower sales of the Company's cryosurgical systems products.

Sales of the OraQuick<sup>®</sup> HIV Self-Test for the three and nine months ended September 30, 2018 included \$840,000 and \$3.6 million, respectively, of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation").

Other revenues were \$2.4 million and \$1.2 million for the third quarter of 2018 and 2017, respectively. Other revenues were \$10.9 million and \$3.3 million for the first nine months of 2018 and 2017, respectively. Other revenues in the third quarter of 2018 included royalty income of \$1.1 million associated with a litigation settlement agreement, Ebola and Zika-related funding received from the U.S. Biomedical Advanced Research Development Authority ("BARDA") of \$1.1 million and cost reimbursement under the Company's charitable support agreement with the Gates Foundation of \$220,000, which is separate from the support payments mentioned above. Other revenues in the first nine months of 2018 included royalty income associated with the litigation settlement of \$4.8 million, BARDA funding of \$4.5 million, and cost reimbursement from the Gates Foundation of \$1.5 million. Other revenues in the third quarter of 2017 included \$939,000 of BARDA funding and \$218,000 of cost reimbursement. Revenues in the first nine months of 2017 consisted of \$3.0 million of BARDA funding and \$218,000 of cost reimbursement.

Gross profit percentage was 62% and 60% for the three and nine months ended September 30, 2018, respectively, and 58% and 61% for the three and nine months ended September 30, 2017, respectively. Gross profit percentage in the current quarter benefited from lower manufacturing costs associated with the Company's Oragene<sup>®</sup> product, lower royalty expense, and the increase in other revenues. The decline in gross profit percentage for the first nine months of 2018 was primarily due to an increase in lower profit percentage product sales partially offset by the increase in other revenues.

Operating expenses increased modestly to \$17.7 million during the third quarter of 2018 compared to \$17.3 million in the third quarter of 2017. For the nine months ended September 30, 2018, operating expenses were \$63.0 million, an increase of \$22.6 million from the \$40.4 million reported for the nine months ended September 30, 2017. The third quarter increase was largely due to higher research and development spending and higher commissions and consulting costs, partially offset by lower staffing expenses. The increase for the nine-month period was largely due to the inclusion of \$8.6 million of management transition costs and higher spending on research and development and sales and marketing during the period and by the absence of the \$12.5 million litigation gain associated with the settlement of litigation against Ancestry.com DNA and its contract manufacturer that was included in the first nine months of 2017. There was no similar gain recorded during the first nine months of 2018.

The Company reported operating income of \$10.9 million in the third quarter of 2018, compared to operating income of \$7.3 million in the third quarter of 2017. Operating income for the nine months ended September 30, 2018 was \$15.9 million compared \$30.1 million for the nine months ended September 30, 2017.

Income tax expense was \$3.3 million during the third quarter of 2018 compared to \$1.7 million recorded in the third quarter of 2017. Income tax expense was \$7.5 million during the first nine months of 2018 compared to \$7.1 million during the first nine months of 2017. Income tax expense in 2018 reflects the higher pre-tax income generated by the Company's Canadian subsidiary. Income tax expense in the first nine months of 2017 included the additional taxes due as a result of the \$12.5 million litigation settlement gain.

The Company's cash and investment balance totaled \$192.1 million at September 30, 2018, compared to \$176.6 million at December 31, 2017. For the nine months ended September 30, 2018, the Company generated \$24.8 million in cash from operations.

#### Fourth Quarter 2018 Outlook

The Company expects net revenues to range from \$46.5 million to \$48.0 million - which implies full year 2018 revenue growth of 7% over 2017 - and is projecting net income of \$0.09 to \$0.11 per share for the fourth quarter of 2018.

#### Financial Data

##### Condensed Consolidated Financial Data

(In thousands, except per-share data)

##### Unaudited

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<b>Results of Operations</b>				
Net revenues	\$ 45,885	\$ 42,314	\$ 131,497	\$ 115,036
Cost of products sold	17,340	17,670	52,590	44,605
Gross profit	28,545	24,644	78,907	70,431
Operating expenses:				
Research and development	3,855	3,228	12,191	9,536
Sales and marketing	7,304	7,162	22,232	21,541
General and administrative	6,529	6,935	28,567	21,777
Gain on litigation settlement	—	—	—	(12,500)
Total operating expenses	17,688	17,325	62,990	40,354
Operating income	10,857	7,319	15,917	30,077
Other income	510	113	1,658	676
Income before income taxes	11,367	7,432	17,575	30,753

Income tax expense	3,271	1,669	7,477	7,121
Net income	\$ 8,096	\$ 5,763	\$ 10,098	\$ 23,632
Earnings per share:				
Basic	\$ 0.13	\$ 0.10	\$ 0.17	\$ 0.40
Diluted	\$ 0.13	\$ 0.09	\$ 0.16	\$ 0.39
Weighted average shares:				
Basic	61,208	60,090	61,059	58,511
Diluted	62,606	62,172	62,539	60,569

#### Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended September 30,			Percentage of Total Net Revenues			
	Dollars						
	2018	2017	% Change	2018	2017		
<b>Market</b>							
Infectious disease testing	\$ 12,417	\$ 16,577	(25 ) %	27	39	%	
Risk assessment testing	2,842	3,149	(10 )	6	7		
Cryosurgical systems	2,696	2,879	(6 )	6	7		
Molecular collection systems	25,495	18,552	37	56	44		
Net product revenues	43,450	41,157	6	95	97		
Other	2,435	1,157	110	5	3		
Net revenues	\$ 45,885	\$ 42,314	8 %	100	100	%	

	Nine Months Ended September 30,			Percentage of Total Net Revenues			
	Dollars						
	2018	2017	% Change	2018	2017		
<b>Market</b>							
Infectious disease testing	\$ 42,506	\$ 47,822	(11 ) %	33	42	%	
Risk assessment testing	9,159	9,517	(4 )	7	8		
Cryosurgical systems	7,874	9,116	(14 )	6	8		
Molecular collection systems	61,047	45,316	35	46	39		
Net product revenues	120,586	111,771	8	92	97		
Other	10,911	3,265	234	8	3		
Net revenues	\$ 131,497	\$ 115,036	14 %	100	100	%	

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
<b>OraQuick® Revenues</b>						
Domestic HIV	\$ 2,749	\$ 3,622	(24 ) %	\$ 10,043	\$ 12,401	(19 ) %
International HIV	4,328	3,069	41	17,395	7,738	125
Domestic OTC HIV	1,706	1,515	13	4,646	4,951	(6 )
Net HIV revenues	8,783	8,206	7	32,084	25,090	28
Domestic HCV	2,066	1,889	9	5,424	5,980	(9 )
International HCV	1,168	6,154	(81 )	3,306	15,817	(79 )
Net HCV revenues	3,234	8,043	(60 )	8,730	21,797	(60 )
Net product revenues	\$ 12,017	\$ 16,249	(26 ) %	\$ 40,814	\$ 46,887	(13 ) %

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
<b>Cryosurgical Systems Revenues</b>						
Domestic professional	\$ 1,349	\$ 1,426	(5 ) %	\$ 3,292	\$ 4,368	(25 ) %
International professional	220	179	23	633	552	15
Domestic OTC	333	325	2	917	957	(4 )
International OTC	794	949	(16 )	3,032	3,239	(6 )
Net product revenues	\$ 2,696	\$ 2,879	(6 ) %	\$ 7,874	\$ 9,116	(14 ) %

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
<b>Molecular Collection Systems Revenues</b>						
Commercial Genomics	\$ 21,505	\$ 14,544	48 %	\$ 48,024	\$ 34,615	39 %
Academic Genomics	2,299	3,232	(29 )	8,236	8,316	(1 )
Microbiome	1,691	776	118	4,787	2,385	101
Net product revenues	\$ 25,495	\$ 18,552	37 %	\$ 61,047	\$ 45,316	35 %

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
<b>Other Revenues</b>						
Royalty income	\$ 1,132	\$ —	N/A	\$ 4,827	\$ —	N/A
BARDA funding	1,083	939	15 %	4,540	3,047	49 %
Charitable support reimbursement	220	218	1	1,544	218	608
Other revenues	\$ 2,435	\$ 1,157	110 %	\$ 10,911	\$ 3,265	234 %

#### Condensed Consolidated Balance Sheets (Unaudited)

	September 30, 2018	December 31, 2017
<b>Assets</b>		
Cash and cash equivalents	\$ 78,146	\$ 72,869
Short-term investments	72,192	83,028
Accounts receivable, net	33,284	42,521
Inventories	19,899	19,343
Other current assets	4,376	4,144
Property and equipment, net	24,395	21,372
Intangible assets, net	6,053	8,223
Goodwill	19,568	20,083
Long-term investments	41,788	20,690
Other non-current assets	4,606	3,928
Total assets	\$ 304,307	\$ 296,201
<b>Liabilities and Stockholders' Equity</b>		
Accounts payable	\$ 8,064	\$ 10,228
Deferred revenue	3,106	1,314
Other current liabilities	10,250	20,695
Other non-current liabilities	4,649	3,932
Deferred income taxes	1,484	1,951
Stockholders' equity	276,754	258,081

Total liabilities and stockholders' equity

\$ 304,307

\$ 296,201

<b>Additional Financial Data (Unaudited)</b>	<b>Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
Capital expenditures	\$ 5,938	\$ 3,462
Depreciation and amortization	\$ 5,588	\$ 4,589
Stock-based compensation	\$ 12,526	\$ 5,213
Cash provided by operating activities	\$ 24,807	\$ 30,361

### Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2018 third quarter financial results, certain business developments and financial guidance for the fourth quarter of 2018, 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 either dial 844-831-3030 (Domestic) or 315-625-6887 (International) and reference Conference ID #8850417 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 14, 2018, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #8850417.

### About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of point-of-care diagnostic and 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 HCV on the OraQuick® platform, oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications, and oral fluid laboratory tests for detecting various drugs of abuse. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, commercial and industrial entities and consumers. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health.

### 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 market and sell products, whether through our internal, direct sales force or third parties; 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 significant customer concentration in the genomics business; impact of increased reliance on U.S. government contracts; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our 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; impact of negative economic conditions; reduction or deferral of public or other 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 testing, collection or other products; 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; 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 meet financial covenants in credit agreements; 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, 2017, 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.