



OraSure Announces 2018 Second Quarter Financial Results

August 8, 2018

BETHLEHEM, Pa., Aug. 08, 2018 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its consolidated financial results for the three and six months ended June 30, 2018.

Financial Highlights

- Consolidated net revenues for the second quarter of 2018 were \$43.6 million, a 9% increase from the second quarter of 2017. Consolidated net product revenues were \$38.8 million, representing a 1% decrease from the second quarter of 2017.
- Consolidated net revenues for the six months ended June 30, 2018 were \$85.6 million, an 18% increase from the comparable period of 2017. Consolidated net product revenues for the first six months of 2018 were \$77.1 million, representing a 9% increase over the first half of 2017.
- Net molecular collection systems revenues were \$17.2 million during the second quarter of 2018, which represents a 7% increase over the second quarter of 2017. Net molecular collection systems revenues during the six months ended June 30, 2018 were \$35.6 million, a 33% increase from the comparable period of 2017.
- International sales of the Company's OraQuick[®] HIV products of \$7.4 million increased 265% compared to the second quarter of 2017. International sales of the Company's OraQuick[®] HIV products of \$13.1 million increased 180% compared to the first six months of 2017. The increases in both periods were primarily the result of higher sales of the Company's OraQuick[®] HIV Self-Test.
- International sales of the Company's OraQuick[®] HCV product of \$1.5 million decreased 72% for the second quarter of 2018 compared to the second quarter of 2017. International sales of the Company's OraQuick[®] HCV product of \$2.1 million for the first six months of 2018 decreased 78% from the comparable period of 2017. These declines were a 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 \$4.1 million of sales during the second quarter of 2017 and \$6.9 million during the first six months of 2017.
- Consolidated net income for the second quarter of 2018 was \$4.1 million, or \$0.07 per share on a fully diluted basis, which compares to consolidated net income of \$5.4 million, or \$0.09 per share on a fully diluted basis, for the second quarter of 2017. Consolidated net income for the six months ended June 30, 2018 was \$2.0 million, or \$0.03 per share on a fully diluted basis, which compares to consolidated net income of \$17.9 million, or \$0.30 per share on a fully diluted basis, for the comparable period of 2017. Consolidated net income for the current quarter and year to date period included \$2.2 million and \$8.6 million, respectively, of transition costs associated with the retirement of the Company's Chief Executive Officer and Chief Financial Officer and the hiring of their successors. These transition costs approximated \$0.04 and \$0.14 per share, respectively, for the three and six month periods ended June 30, 2018, and primarily consisted of non-cash stock compensation charges. Consolidated net income for the six months ended June 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 \$0.16 per share on a fully diluted after-tax basis in that period.
- Cash and investments totaled \$181.2 million at June 30, 2018.

"Our financial results for the second quarter of 2018 exceeded expectations and continued the solid performance started in Q1," said Dr. Stephen S. Tang, President and CEO of OraSure Technologies. "Continued strong international sales of our HIV Self-Test and another strong quarter by our molecular collections business were the primary drivers of this performance. We expect that our HIV Self-Test and molecular businesses will continue to be key growth contributors for the rest of 2018."

Financial Results

Consolidated net product revenues for the second quarter of 2018 decreased 1% from the comparable period of 2017, primarily as a result of lower sales of the Company's OraQuick[®] HCV and cryosurgical systems products and lower domestic sales of the professional OraQuick[®] HIV test, partially offset by higher international sales of the OraQuick[®] HIV Self-Test and higher sales of the Company's molecular collections products.

Consolidated net product revenues for the first six months of 2018 increased 9% 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[®] HIV Self-Test, partially offset by lower sales of the Company's HCV product, lower domestic sales of the professional OraQuick[®] HIV test and lower sales of the Company's cryosurgical systems products.

Sales of the OraQuick® HIV Self-Test for the three and six months ended June 30, 2018 included \$1.7 million and \$2.7 million, respectively, of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation").

Consolidated other revenues were \$4.8 million and \$1.0 million for the second quarter of 2018 and 2017, respectively. Consolidated other revenues were \$8.5 million and \$2.1 million for the first six months of 2018 and 2017, respectively. Other revenues in the second quarter of 2018 included royalty income of \$2.1 million associated with a litigation settlement agreement, Ebola and Zika-related funding received from the U.S. Biomedical Advanced Research Development Authority ("BARDA") of \$1.9 million and cost reimbursement under the Company's charitable support agreement with the Gates Foundation of \$795,000, which is separate from the support payments mentioned above. Other revenues in the first six months of 2018 included royalty income from the litigation settlement of \$3.7 million, BARDA funding of \$3.5 million, and cost reimbursement from the Gates Foundation of \$1.3 million. Other revenues in the second quarter and first six months of 2017 consisted only of BARDA funding.

Consolidated gross profit percentage was 59% for the three and six months ended June 30, 2018 and 63% for the three and six months ended June 30, 2017. Gross profit percentage declined in both periods primarily due to an increase in lower profit percentage product sales partially offset by an increase in other revenues.

Consolidated operating expenses increased to \$20.3 million during the second quarter of 2018 compared to \$18.6 million in the second quarter of 2017. For the six months ended June 30, 2018, consolidated operating expenses were \$45.3 million, an increase of \$22.3 million from the \$23.0 million reported for the six months ended June 30, 2017. The quarter increase was largely due to the inclusion of \$2.2 million of retirement-related transition costs as discussed above and increased spending in research and development, partially offset by lower staffing costs. The increase for the year to date period was largely due to the inclusion of \$8.6 million of transition costs and higher spending on research and development and sales and marketing, partially offset 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 half of 2017. There was no similar gain recorded during the first half of 2018.

The Company reported operating income of \$5.6 million in the second quarter of 2018, compared to operating income of \$6.9 million in the second quarter of 2017. Operating income for the six months ended June 30, 2018 was \$5.1 million compared \$22.8 million for the six months ended June 30, 2017.

Income tax expense was \$2.2 million during the second quarter of 2018 compared to \$1.6 million recorded in the second quarter of 2017. Income tax expense was \$4.2 million during the first six months of 2018 compared to \$5.5 million during the first six 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 six 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 \$181.2 million at June 30, 2018, compared to \$176.6 million at December 31, 2017. For the six months ended June 30, 2018, the Company generated \$13.9 million in cash from operations.

Third Quarter 2018 Outlook

The Company expects consolidated net revenues to range from \$44.0 million to \$45.5 million and is projecting consolidated net income of \$0.10 to \$0.12 per share for the third quarter of 2018.

Financial Data

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

	Unaudited			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Results of Operations				
Net revenues	\$ 43,625	\$ 40,176	\$ 85,612	\$ 72,722
Cost of products sold	17,730	14,699	35,250	26,935
Gross profit	25,895	25,477	50,362	45,787
Operating expenses:				
Research and development	4,261	3,338	8,336	6,308
Sales and marketing	7,429	7,502	14,928	14,379
General and administrative	8,647	7,750	22,038	14,842
Gain on litigation settlement	—	—	—	(12,500)
Total operating expenses	20,337	18,590	45,302	23,029
Operating income	5,558	6,887	5,060	22,758
Other income	736	96	1,148	563
Income before income taxes	6,294	6,983	6,208	23,321
Income tax expense	2,173	1,555	4,206	5,452
Net income	\$ 4,121	\$ 5,428	\$ 2,002	\$ 17,869
Earnings per share:				
Basic	\$ 0.07	\$ 0.09	\$ 0.03	\$ 0.31
Diluted	\$ 0.07	\$ 0.09	\$ 0.03	\$ 0.30
Weighted average shares:				
Basic	61,100	58,478	60,983	57,708
Diluted	62,244	60,728	62,379	59,755

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended June 30,			Percentage of Total Net Revenues			
	Dollars						
	2018	2017	% Change	2018		2017	
Market							
Infectious disease testing	\$ 15,919	\$ 16,663	(4) %	36 %		41 %	
Risk assessment testing	3,315	3,238	2	8		8	
Cryosurgical systems	2,392	3,174	(25)	6		8	
Molecular collection systems	17,192	16,057	7	39		40	
Net product revenues	38,818	39,132	(1)	89		97	
Other	4,807	1,044	360	11		3	
Net revenues	\$ 43,625	\$ 40,176	9 %	100 %		100 %	

	Six Months Ended June 30,			Percentage of Total Net Revenues			
	Dollars						
	2018	2017	% Change	2018		2017	
Market							
Infectious disease testing	\$ 30,090	\$ 31,245	(4) %	35 %		43 %	
Risk assessment testing	6,316	6,368	(1)	7		9	
Cryosurgical systems	5,177	6,237	(17)	6		8	
Molecular collection systems	35,553	26,764	33	42		37	
Net product revenues	77,136	70,614	9	90		97	
Other	8,476	2,108	302	10		3	
Net revenues	\$ 85,612	\$ 72,722	18 %	100 %		100 %	

	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	% Change	2018	2017	% Change
OraQuick® Revenues						
Domestic HIV	\$ 3,881	\$ 4,965	(22) %	\$ 7,293	\$ 8,779	(17) %
International HIV	7,397	2,025	265	13,067	4,669	180
Domestic OTC HIV	1,308	1,894	(31)	2,941	3,436	(14)
Net HIV revenues	12,586	8,884	42	23,301	16,884	38
Domestic HCV	1,730	2,382	(27)	3,358	4,091	(18)
International HCV	1,473	5,261	(72)	2,138	9,664	(78)
Net HCV revenues	3,203	7,643	(58)	5,496	13,755	(60)
Net product revenues	\$ 15,789	\$ 16,527	(4) %	\$ 28,797	\$ 30,639	(6) %

	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	% Change	2018	2017	% Change
Cryosurgical Systems Revenues						
Domestic professional	\$ 1,068	\$ 1,445	(26) %	\$ 1,943	\$ 2,941	(34) %
International professional	264	243	9	413	373	11
Domestic OTC	295	347	(15)	584	632	(8)
International OTC	765	1,139	(33)	2,237	2,291	(2)
Net product revenues	\$ 2,392	\$ 3,174	(25) %	\$ 5,177	\$ 6,237	(17) %

	Three Months Ended June 30,				Six Months Ended June 30,			
	2018	2017	% Change		2018	2017	% Change	
Molecular Collection Systems Revenues								
Commercial Genomics	\$ 12,263	\$ 12,815	(4) %	\$ 26,519	\$ 20,072	32	%
Academic Genomics	3,105	2,399	29		5,937	5,083	17	
Microbiome	1,824	843	116		3,097	1,609	92	
Net product revenues	\$ 17,192	\$ 16,057	7	%	\$ 35,553	\$ 26,764	33	%

	Three Months Ended June 30,				Six Months Ended June 30,			
	2018	2017	% Change		2018	2017	% Change	
Other Revenues								
Royalty income	\$ 2,092	\$ —	N/A		\$ 3,694	\$ —	N/A	
BARDA funding	1,920	1,044	84	%	3,458	2,108	64	%
Charitable support reimbursement	795	—	N/A		1,324	—	N/A	
Other revenues	\$ 4,807	\$ 1,044	360	%	\$ 8,476	\$ 2,108	302	%

Condensed Consolidated Balance Sheets (Unaudited)

	June 30, 2018	December 31, 2017
Assets		
Cash and cash equivalents	\$ 71,069	\$ 72,869
Short-term investments	74,269	83,028
Accounts receivable, net	31,648	42,521
Inventories	20,599	19,343
Other current assets	4,637	4,144
Property and equipment, net	23,946	21,372
Intangible assets, net	6,622	8,223
Goodwill	19,231	20,083
Long-term investments	35,828	20,690
Other non-current assets	4,513	3,928
Total assets	\$ 292,362	\$ 296,201
Liabilities and Stockholders' Equity		
Accounts payable	\$ 9,659	\$ 10,228
Deferred revenue	1,621	1,314
Other current liabilities	9,837	20,695
Other non-current liabilities	4,474	3,932
Deferred income taxes	1,600	1,951
Stockholders' equity	265,171	258,081
Total liabilities and stockholders' equity	\$ 292,362	\$ 296,201

	Six Months Ended June 30,	
	2018	2017
Additional Financial Data (Unaudited)		
Capital expenditures	\$ 4,484	\$ 1,567
Depreciation and amortization	\$ 3,746	\$ 2,891
Stock-based compensation	\$ 11,262	\$ 3,631
Cash provided by operating activities	\$ 13,928	\$ 21,704

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2018 second quarter financial

results, certain business developments and financial guidance for the third 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 #4795505 or go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Relations page. Please click on the webcast link and follow the prompts for registration and access 10 minutes prior to the call. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until midnight, August 15, 2018, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #4795505.

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 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.