



OraSure Announces 2018 First Quarter Financial Results

May 2, 2018

BETHLEHEM, Pa., May 02, 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 quarter ended March 31, 2018.

Financial Highlights

- Consolidated net revenues for the first quarter of 2018 were \$42.0 million, a 29% increase from the first quarter of 2017. Consolidated net product revenues were \$38.3 million, representing a 22% increase over the first quarter of 2017.
- Net molecular collection systems revenues were \$18.4 million during the first quarter of 2018, which represents a 72% increase over the first quarter of 2017.
- International sales of the Company's OraQuick[®] HIV products of \$5.7 million increased 117% compared to the first quarter of 2017. This increase was primarily the result of higher sales of the Company's HIV self-test.
- International sales of the Company's OraQuick[®] HCV product of \$665,000 for the first quarter of 2018 decreased 85% compared to the first quarter of 2017 as 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 \$2.8 million of sales during the first quarter of 2017.
- Consolidated net loss for the first quarter of 2018 was \$2.1 million, or \$0.03 per share, which compares to consolidated net income of \$12.4 million, or \$0.21 per share on a fully diluted basis, for the first quarter of 2017. Consolidated net loss for the current quarter included \$6.4 million of transition costs associated the retirement of the Company's Chief Executive Officer and Chief Financial Officer and the hiring of their successors. These transition costs approximated \$0.10 per share and primarily consist of non-cash stock compensation charges. Consolidated net income for the three months ended March 31, 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 an after-tax and fully diluted basis in that period.
- Cash and investments totaled \$178.4 million and working capital amounted to \$175.6 million at March 31, 2018.

"We are pleased to see that our growth strategy is delivering the expected results and 2018 is off to a strong start," said Stephen S. Tang, Ph.D., President and Chief Executive Officer of OraSure Technologies. "Our first quarter benefitted from robust growth in sales of our molecular collections and international HIV products. Importantly, we expect to see continued growth from those businesses for the remainder of the year. Our years of planning and investment are paying off and OraSure has never been financially stronger than it is now. We see significant opportunity in our existing markets and we will look to expand our addressable markets where possible."

Financial Results

Consolidated net product revenues for the first quarter of 2018 increased 22% over 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[®] HIV self-test, partially offset by lower international sales of the OraQuick[®] HCV test. First quarter 2018 sales of the OraQuick[®] HIV self-test included \$985,000 of support payments under the Company's charitable support agreement with the Bill & Melinda Gates Foundation ("Gates Foundation").

Consolidated other revenues were \$3.7 million and \$1.1 million for the first quarter of 2018 and 2017, respectively. Other revenues in the first quarter of 2018 included royalty income of \$1.6 million associated with a litigation settlement agreement, Ebola and Zika-related funding received from the U.S. Biomedical Advanced Research Development Authority ("BARDA") of \$1.5 million and cost reimbursement under the Company's charitable support agreement with the Gates Foundation of \$529,000, which is separate from the support payments mentioned above. Other revenues in the first quarter of 2017 consisted only of BARDA funding.

Consolidated gross margin was 58% and 62% for the three months ended March 31, 2018 and 2017, respectively. Gross margin was lower for the current quarter primarily due to an increase in lower margin product sales and a decrease in the absorption of fixed costs as a result of lower production levels in the first quarter of 2018, partially offset by an increase in other revenues and lower scrap and spoilage costs as compared to the first quarter of 2017.

Consolidated operating expenses increased to \$25.0 million during the first quarter of 2018 compared to \$4.4 million in the first quarter of 2017. This increase was largely due to the inclusion in the current quarter of \$6.4 million of transition costs as discussed above and the absence of the \$12.5 million litigation gain associated with the settlement of litigation against Ancestry.com DNA that was included in the first quarter of 2017. There was no similar gain recorded during the first quarter of 2018. The first quarter of 2018 also included higher spending on the Company's Ebola and Zika products and higher staffing and consulting costs, partially offset by a reduction in legal expenses.

The Company reported an operating loss of \$498,000 in the first quarter of 2018, compared to operating income of \$15.9 million in the first quarter of 2017.

Income tax expense was \$2.0 million during the first quarter of 2018 compared to \$3.9 million recorded in the first quarter of 2017. Income tax expense in the first quarter of 2017 included the additional taxes due as a result of the \$12.5 million litigation settlement gain. Income tax expense in the first quarter of 2018 reflects the higher pre-tax income generated by the Company's Canadian subsidiary.

The Company's cash and investment balance totaled \$178.4 million at March 31, 2018, compared to \$176.6 million at December 31, 2017. Working capital was \$175.6 million at March 31, 2018, compared to \$189.7 million at December 31, 2017. For the three months ended March 31, 2018, the Company generated \$7.6 million in cash from operations.

Second Quarter 2018 Outlook

The Company expects consolidated net revenues to range from \$42.0 million to \$42.5 million and is projecting consolidated net income of approximately \$0.03 per share for the second quarter of 2018. These results include approximately \$1.7 million in final management transition costs projected for the quarter.

Financial Data

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

Unaudited

	Three months ended March 31, 2018		2017	
Results of Operations				
Net revenues	\$	41,987	\$	32,546
Cost of products sold		17,520		12,236
Gross profit		24,467		20,310
Operating expenses:				
Research and development		4,075		2,970
Sales and marketing		7,499		6,877
General and administrative		13,391		7,092
Gain on litigation settlement		—		(12,500)
Total operating expenses		24,965		4,439
Operating income (loss)		(498)		15,871
Other income		412		467
Income (loss) before income taxes		(86)		16,338
Income tax expense		2,033		3,897
Net income (loss)	\$	(2,119)	\$	12,441
Earnings (loss) per share:				
Basic	\$	(0.03)	\$	0.22
Diluted	\$	(0.03)	\$	0.21
Weighted average shares:				
Basic		60,865		56,929
Diluted		60,865		58,772

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended March 31,			Percentage of Total Net Revenues			
	Dollars						
	2018	2017	% Change	2018	2017		
Market							
Infectious disease testing	\$ 14,170	\$ 14,583	(3)%	34%	45%		
Risk assessment testing	3,002	3,130	(4)%	7%	10%		
Cryosurgical systems	2,785	3,063	(9)%	6%	9%		
Molecular collection systems	18,361	10,706	72%	44%	33%		
Net product revenues	38,318	31,482	22%	91%	97%		
Other	3,669	1,064	245%	9%	3%		
Net revenues	\$ 41,987	\$ 32,546	29%	100%	100%		

	Three Months Ended March 31,			
	2018	2017	% Change	
OraQuick® Revenues				
Domestic HIV	\$ 3,344	\$ 3,812	(12)%
International HIV	5,737	2,644	117	
Domestic OTC HIV	1,632	1,542	6	
Net HIV revenues	10,713	7,998	34	
Domestic HCV	1,627	1,709	(5)
International HCV	665	4,402	(85)
Net HCV revenues	2,292	6,111	(62)
Net product revenues	\$ 13,005	\$ 14,109	(8)%

	Three Months Ended March 31,			
	2018	2017	% Change	
Cryosurgical Systems Revenues				
Domestic professional	\$ 875	\$ 1,496	(42)%
International professional	150	130	15	
Domestic OTC	289	285	1	
International OTC	1,471	1,152	28	
Net product revenues	\$ 2,785	\$ 3,063	(9)%

	Three Months Ended March 31,			
	2018	2017	% Change	
Molecular Collection Systems Revenues				
Commercial Genomics	\$ 14,256	\$ 7,254	97	%
Academic Genomics	2,832	2,685	5	
Microbiome	1,273	767	66	
Net product revenues	\$ 18,361	\$ 10,706	72	%

	Three Months Ended March 31,			
	2018	2017	% Change	
Other Revenues				
Royalty income	\$ 1,602	\$ -	N/A	
BARDA funding	1,538	1,064	45	%
Charitable support reimbursement	529	-	N/A	
Other revenues	\$ 3,669	\$ 1,064	245	%

Condensed Consolidated Balance Sheets (Unaudited)

	March 31, 2018	December 31, 2017
Assets		
Cash and cash equivalents	\$ 64,065	\$ 72,869
Short-term investments	79,446	83,028

Accounts receivable, net	28,197	42,521
Inventories	20,907	19,343
Other current assets	4,139	4,144
Property and equipment, net	22,975	21,372
Intangible assets, net	7,390	8,223
Goodwill	19,584	20,083
Long-term investments	34,880	20,690
Other non-current assets	4,340	3,928
Total assets	\$ 285,923	\$ 296,201

Liabilities and Stockholders' Equity

Accounts payable	\$ 9,622	\$ 10,228
Deferred revenue	1,799	1,314
Other current liabilities	9,765	20,695
Other non-current liabilities	4,258	3,932
Deferred income taxes	1,761	1,951
Stockholders' equity	258,718	258,081
Total liabilities and stockholders' equity	\$ 285,923	\$ 296,201

Three Months Ended March 31,

Additional Financial Data (Unaudited)

	2018	2017
Capital expenditures	\$ 1,897	\$ 878
Depreciation and amortization	\$ 1,868	\$ 1,419
Stock-based compensation	\$ 7,483	\$ 1,518
Cash provided by operating activities	\$ 7,636	\$ 12,619

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2018 first quarter financial results, certain business developments and financial guidance for the second quarter of 2018, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Stephen S. Tang, Ph.D., President and Chief Executive Officer, and Ronald H. Spair, Chief Financial Officer and Chief Operating 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 #4298046 or go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Relations page. Please click on the webcast link and follow the prompts for registration and access 10 minutes prior to the call. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until midnight, May 9, 2018, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #4298046.

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.