



OraSure Announces 2019 First Quarter Financial Results

May 8, 2019

BETHLEHEM, Pa., May 08, 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 quarter ended March 31, 2019.

"Our first quarter 2019 performance was in line with our expectations for both the top and bottom lines," said Stephen S. Tang, Ph.D., President and CEO of OraSure Technologies. "We are optimistic about the second quarter and full-year performance of our underlying businesses, despite the impact of a previously announced change in market approach by a large consumer genetics customer. The foundations of our business are strong, and we believe we are on the right path with our innovation-driven growth strategy."

"We continue to diversify our molecular collections business and are seeing opportunity in key segments of the genomics market. Our microbiome business has continued to grow year-over-year in every quarter since we first began breaking out its revenues in 2016. Our HCV business grew both domestically and internationally, and we expect our OraQuick® HIV sales to show solid growth for the full year. Our recent acquisitions are just the first examples of implementation of our growth strategy and we remain committed to making additional strategic growth investments."

Financial and Business Highlights

- In January 2019, the Company acquired innovation growth companies Novosanis NV and CoreBiome, Inc. for an aggregate purchase price of approximately \$13.3 million. Novosanis is a leader in urine sample collection devices targeted primarily at the liquid biopsy, sexually transmitted infection screening, and urological cancer markets, and CoreBiome is an early-stage microbiome services provider that accelerates discovery for customers in the pharmaceutical, agricultural and research communities. The sales generated by these new subsidiaries are included in the revenues of the Company's molecular collection systems segment.
- The Company's financial performance during the first quarter of 2019 was in line with expectations. Net revenues for the first quarter of 2019 were \$30.1 million, a 28% decrease from the first quarter of 2018. Net product revenues were \$28.3 million, representing a 26% decrease from the first quarter of 2018. These decreases were primarily the result of a previously-disclosed change in marketing strategy by a large consumer genetics customer.
- International sales of the Company's OraQuick® HCV product of \$1.5 million increased 119% for the first quarter of 2019 compared to the first quarter of 2018. Domestic sales of the Company's OraQuick® HCV product of \$1.8 million increased 12% over the comparable period of the prior year.
- International sales of the Company's OraQuick® HIV products of \$4.0 million in the first quarter of 2019 decreased 30% compared to the first quarter of 2018. Domestic sales of the Company's OraQuick® HIV products of \$4.3 million decreased 14% compared to the comparable period of the prior year.
- Molecular collection systems revenues including royalty income and other revenues were \$11.9 million during the first quarter of 2019, a decline of 40% from the first quarter of 2018. Molecular collection systems product and service revenues were \$10.6 million during the first quarter of 2019, which represents a 42% decrease from the first quarter of 2018.
- Net loss for the first quarter of 2019 was \$3.3 million, or \$0.05 per share, which compares to a net loss of \$2.1 million, or \$0.03 per share, for the first quarter of 2018. Net loss for the first quarter of 2019 included acquisition-related charges of \$1.3 million for the change in fair value of contingent consideration and \$597,000 of transaction costs. These charges had a combined impact of approximately \$0.03 per share. The net loss for the first quarter of 2018 included \$6.4 million of pre-tax transition costs, or \$0.10 per share, associated with executive management changes which occurred in 2018. These transition costs primarily consisted of non-cash stock compensation charges.
- Cash and investments totaled \$183.6 million at March 31, 2019.

Financial Results

Net product revenues for the first quarter of 2019 decreased 26% from the comparable period of 2018, primarily as a result of lower sales of the Company's molecular collections products and OraQuick® HIV tests, partially offset by higher OraQuick® HCV test sales.

International sales of the OraQuick® HIV Self-Test for the three months ended March 31, 2019 and 2018 included \$709,000 and \$985,000 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 \$1.1 million and \$1.6 million for the first quarters of 2019 and 2018, respectively. Other revenues, excluding royalty income, were \$706,000 and \$2.1 million for the first quarters of 2019 and 2018, respectively. Other revenues decreased due to lower funding received from the U.S. Biomedical Advanced Research Development Authority and lower cost reimbursement from the Gates Foundation.

Gross profit percentage was 60% and 58% for the three months ended March 31, 2019 and 2018, respectively. Gross profit percentage in 2019 benefited from improved product mix associated with an increase in sales of higher gross profit products and lower royalty expense, partially offset by lower royalty income.

For the three months ended March 31, 2019, operating expenses were \$21.9 million, a decrease of \$3.1 million from the \$25.0 million reported for the three months ended March 31, 2018. This decrease was largely due to the absence of \$6.4 million of transition costs associated with executive management changes that occurred in the first quarter of 2018, partially offset by a non-cash charge of \$1.3 million for the change in fair value of contingent consideration associated with the recent acquisition of CoreBiome and Novosanis, the incremental operating expenses of CoreBiome and Novosanis, and \$597,000 of transaction costs associated with the recent acquisitions. There were no similar acquisition costs in the first quarter of 2018.

The Company reported an operating loss of \$3.8 million in the first quarter of 2019, compared to an operating loss of \$498,000 in the first quarter of 2018.

During the first quarter of 2019, the Company recorded an income tax benefit of \$29,000 compared to income tax expense of \$2.0 million recorded in the first quarter of 2018. The decrease in income tax expense reflects the lower pre-tax income generated by the Company's Canadian subsidiary in the current period and includes an income tax benefit generated by Novosanis.

The Company's cash and investment balance totaled \$183.6 million at March 31, 2019, compared to \$201.3 million at December 31, 2018. For the three months ended March 31, 2019, the Company generated \$528,000 in cash from operations.

Second Quarter and Full Year 2019 Outlook

The Company expects second quarter 2019 net revenues to range from \$40.0 million to \$42.0 million and is projecting net income of approximately \$0.02 per share. For the full year of 2019, the Company is expecting net revenues to range from \$170.0 million to \$175.0 million and is projecting net income of \$0.22 to \$0.24 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.

"As in prior years, we expect the Company's financial performance will progress and grow from our solid first quarter driven by both our core infectious disease and molecular collection businesses. Our results also reflect performance by CoreBiome and Novosanis and the seasonality of certain parts of our business," Dr. Tang said. "It should be clear from our second quarter and full-year guidance that we anticipate a very strong second half of the year, reflecting full-year growth in all of our core strategic product lines, when the effect of the large consumer genetics customer's change in market strategy is excluded."

Financial Data

Condensed Consolidated Financial Data

(In thousands, except per-share data)	Three Months Ended	
	March 31,	
	2019	2018
Results of Operations		
Net revenues	\$ 30,122	\$ 41,987
Cost of products sold	12,042	17,520
Gross profit	18,080	24,467
Operating expenses:		
Research and development	4,371	4,075
Sales and marketing	7,295	7,499
General and administrative	8,930	13,391
Change in fair value of acquisition-related contingent consideration	1,295	—
Total operating expenses	21,891	24,965
Operating loss	(3,811)	(498)
Other income	524	412
Loss before income taxes	(3,287)	(86)
Income tax expense (benefit)	(29)	2,033
Net loss	\$ (3,258)	\$ (2,119)
Loss per share:		
Basic	\$ (0.05)	\$ (0.03)
Diluted	\$ (0.05)	\$ (0.03)
Weighted average shares:		
Basic	61,531	60,865
Diluted	61,531	60,865

	Three Months Ended March 31,			Percentage of Total Net Revenues			
	Dollars						
				%			
	2019	2018	Change	2019	2018		
Market							
Infectious disease testing	\$ 12,338	\$ 14,170	(13)%	41	34	%	%
Risk assessment testing	2,836	3,002	(6)	9	7		
Cryosurgical systems	2,575	2,785	(8)	9	6		
Molecular collection systems	10,583	18,361	(42)	35	44		
Net product and service revenues	28,332	38,318	(26)	94	91		
Royalty income	1,084	1,602	(32)	4	4		
Other	706	2,067	(66)	2	5		
Net revenues	\$ 30,122	\$ 41,987	(28)%	100	100	%	%

	Three Months Ended March 31,						
				%			
	2019	2018	Change				
OraQuick® Revenues							
Domestic HIV	\$ 4,304	\$ 4,976	(14)%				
International HIV	4,001	5,737	(30)				
Net HIV revenues	8,305	10,713	(22)				
Domestic HCV	1,828	1,627	12				
International HCV	1,457	665	119				
Net HCV revenues	3,285	2,292	43				
Net product revenues	\$ 11,590	\$ 13,005	(11)%				

	Three Months Ended March 31,						
				%			
	2019	2018	Change				
Molecular Collection Systems Revenues							
Genomics	\$ 8,047	\$ 17,088	(53)%				
Microbiome	2,326	1,273	83				
Other	210	-	100				
Net product and service revenues	10,583	\$ 18,361	(42)				
Royalty income	1,084	1,602	(32)				
Other	222	-	100				
Total Molecular Collection Systems Revenues	\$ 11,889	\$ 19,963	(40)%				

Condensed Consolidated Balance Sheets (Unaudited)

	March 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	\$ 69,516	\$ 88,438
Short-term investments	77,474	68,134
Accounts receivable, net	24,909	34,842
Inventories	26,213	22,888
Other current assets	7,226	5,010

Property, plant and equipment, net	25,970	24,299
Right of use assets, net	5,265	-
Intangible assets, net	12,929	5,137
Goodwill	28,903	18,521
Long-term investments	36,585	44,752
Other non-current assets	3,935	3,550
Total assets	\$ 318,925	\$ 315,571
Liabilities and Stockholders' Equity		
Accounts payable	\$ 10,638	\$ 10,598
Deferred revenue	4,234	3,521
Contingent consideration obligation	3,638	-
Other current liabilities	8,798	13,861
Long-term lease liabilities	4,375	-
Long-term contingent consideration obligation	1,987	-
Other non-current liabilities	4,748	4,213
Stockholders' equity	280,507	283,378
Total liabilities and stockholders' equity	\$ 318,925	\$ 315,571

	Three Months Ended	
	March 31,	
Additional Financial Data (Unaudited)	2019	2018
Capital expenditures	\$ 2,628	\$ 1,897
Depreciation and amortization	\$ 1,726	\$ 1,868
Stock-based compensation	\$ 1,231	\$ 7,483
Cash provided by operating activities	\$ 528	\$ 7,636

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2019 first 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 either dial 844-831-3030 (Domestic) or 315-625-6887 (International) and reference Conference ID #5270658 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 15, 2019, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #5270658.

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.

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: successfully managing and integrating 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; 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 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; 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.

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