OraSure Announces 2020 First Quarter Financial Results and Provides COVID-19 Update

May 6, 2020

BETHLEHEM, Pa., May 06, 2020 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests, specimen collection devices and microbiome laboratory and analytical services, today announced its financial results for the three months ended March 31, 2020 and provided an update on COVID-19 activities.

Financial and Business Highlights

- Net revenues for the first quarter of 2020 were $31.6 million, a 5% increase from the first quarter of 2019. Net product and services revenues were $30.9 million, a 9% increase from the first quarter of 2019. Excluding cryosurgical revenues, the line of business the Company sold in August 2019, and Diversigen revenues, which the Company acquired in November 2019, net revenues and product and services revenues grew 8% and 13%, respectively, from the first quarter of 2019.

- Other revenue highlights include:

  - International sales of the Company's OraQuick ® HIV products increased 74% compared to the first quarter of 2019. This increase was primarily the result of higher sales of the Company's OraQuick ® HIV Self-Test.

  - Total genomics revenues were $9.1 million during the first quarter of 2020, an increase of 14% from the first quarter of 2019.

  - Total laboratory service revenues in the first quarter of 2020 were $2.4 million compared to $717,000 in the first quarter of 2019. Laboratory services in 2020 include the service revenues generated by the Company's subsidiaries, CoreBiome, Inc. and Diversigen, Inc.

- Net loss for the first quarter of 2020 was $7.3 million, or $0.12 per share on a fully-diluted basis, compared to a net loss of $3.3 million, or $0.05 per share on a fully-diluted basis, for the first quarter of 2019. Net loss for the first quarter of 2020 included a $1.1 million non-cash pre-tax charge associated with the change in fair value of acquisition-related contingent consideration. The net impact of the change in the fair value of contingent consideration in the current quarter was approximately $0.02 per share on a fully-diluted basis. Net loss in the first quarter of 2019 included a $1.3 million non-cash pre-tax charge associated with the change in the fair value of acquisition-related contingent consideration and $597,000 of acquisition-related transaction costs. The combined impact of these charges reduced fully diluted earnings per share by approximately $0.03.

- Cash and investments totaled $176.2 million at March 31, 2020.

COVID-19 Update

OraSure is working in several ways to improve and increase testing for the novel coronavirus ("COVID-19"):

- The Company was awarded a $710,310 contract from the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services (HHS), to develop a pan-SARS-coronavirus rapid antigen in-home self-test that uses oral fluid samples. This support from BARDA will enable OraSure to file for U.S. food and Drug Administration (FDA) Emergency Use Authorization (EUA), potentially allowing for an in-home self-test to debut into the U.S. market. The Company anticipates having the test on the market by Fall 2020, if its development efforts are successful.

- The Company is also developing an Enzyme-Linked Immunosorbent Assay (ELISA) for the detection of human anti-SARS-CoV-2 antibodies in oral fluid specimens. The oral fluid ELISA could dramatically increase the throughput of COVID-19 antibody testing. The Company expects to file for FDA EUA for the ELISA test in June 2020.

- The Company believes that oral samples collected using its currently marketed liquid saliva collection kits or oral swab collectors could be a suitable alternative to nasopharyngeal or oropharyngeal swabs for COVID-19 testing. The Company's molecular business unit is working with several labs and researchers to determine if its sample collection technologies can be used to safely collect and transport COVID-19 samples. In addition, several customers are currently validating various

OraSure/DNA Genotek products for COVID-19 testing. If the data supports it, the Company will explore these avenues for COVID-19 sample collection and testing.

- The Company is also seeing increased demand for its molecular collection products from customers who conduct both saliva and blood-based testing. As it becomes increasingly difficult to collect blood in clinics or healthcare settings, these customers are increasingly relying on the saliva collection alternative, presenting another opportunity for OraSure's product lines.

"Our underlying business was strong in the first quarter as evidenced by year over year double-digit growth in both Infectious Disease Testing and Molecular Collection Systems. We are encouraged by the continued strength of our International HIV Self-test franchise as well as our genomics business," said Stephen S. Tang, Ph.D., President and Chief Executive Officer.

"Nevertheless, we do expect downward revenue pressure in certain parts of the business as customers repurpose funding and testing and research projects are deferred as a result of the pandemic. The good news is that we also see potentially significant opportunity from COVID-19 across our business which may more than offset any revenue declines. For example, public health customers in the U.S. are buying more of our In-Home HIV tests to allow continued HIV testing by individuals while adhering to social distancing requirements. A number of our molecular customers are already placing increased orders for our saliva collection and oral swab products as they move from blood collection to saliva collection as a result of the difficulties in collecting blood samples due to the stay-at-home and social distancing restrictions. In addition, with the massive amount of testing likely required to get the COVID-19 pandemic under control and restart our economy, we believe our pan-SARS coronavirus rapid antigen in-home self-test and ELISA antibody test, once developed and approved by the FDA, as well as expanded use of our saliva collection products once validated, could play significant roles in helping end the pandemic," Dr. Tang continued.

Financial Results

Net product and service revenues for the first quarter of 2020 increased 9% from the comparable period of 2019, primarily as a result of higher international HIV Self-Test sales, higher sales of the Company's genomics products, and increased laboratory services revenues. The increased sales were partially offset by the absence of cryosurgical sales in the quarter, as the cryosurgical systems business was sold in August 2019 and by lower world-wide HCV product sales.

Royalty income from a litigation settlement associated with a molecular collection device was $446,000 and $1.1 million for the first quarter of 2020 and 2019, respectively. Other revenues were $264,000 and $706,000 for the first quarter of 2020 and 2019 respectively.

Gross profit percentage was 51% and 60% for the three months ended March 31, 2020 and 2019, respectively. Gross profit percentage in the first quarter of 2020 was negatively affected by a less favorable product mix as a result of higher sales of lower gross profit products and services, increased international freight costs, higher scrap and spoilage expense, and the decline in other revenues which contribute 100% to our gross profit percentage.

For the three months ended March 31, 2020, operating expenses were $24.2 million, an increase of $2.3 million from the $21.9 million reported for the three months ended March 31, 2019. This increase was due primarily to increased staffing costs, higher lab supply and consulting costs in support of bioinformatics and new product initiatives, higher legal fees, and the inclusion of operating expenses incurred by Diversigen.

The Company generated an operating loss of $8.0 million in the first quarter of 2020 compared to an operating loss of $3.8 million in the first quarter of 2019.

During the first quarter of 2020, the Company recorded income tax expense of $712,000 compared to an income tax benefit of $29,000 recorded in the first quarter of 2019. This tax increase largely reflects the higher pre-tax income generated by the Company's Canadian subsidiary.

The Company's cash and investment balance totaled $176.2 million at March 31, 2020, compared to $189.8 million at December 31, 2019. For the year ended March 31, 2020, the Company generated $2.5 million in cash from operations compared with $528,000 in the same period of 2019.

Full- Year 2020 Guidance

The Company is withdrawing its previously announced full-year 2020 financial guidance because of the unpredictable impact of the COVID-19 global pandemic on its results of operations. Although the Company may be able to capture new revenue opportunities from the initiatives described above, the pandemic is also likely to affect certain business lines negatively, and the extent of either effect is impossible to estimate reliably at this time.

Financial Data

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

(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Results of Operations		
Net revenues	$ 31,596	$ 30,122
Cost of products sold	15,465	12,042

Gross profit	16,131	18,080
Operating expenses:		
Research and development	5,644	4,371
Sales and marketing	7,369	7,295
General and administrative	10,054	8,930
Change in fair value of acquisition-related contingent consideration	1,110	1,295
Total operating expenses	24,177	21,891
Operating loss	(8,046)	(3,811)
Other income	1,430	524
Loss before income taxes	(6,616)	(3,287)
Income tax expense (benefit)	712	(29)
Net loss	$ (7,328)	$ (3,258)
Loss per share:		
Basic	$ (0.12)	$ (0.05)
Diluted	$ (0.12)	$ (0.05)
Weighted average shares:		
Basic	61,937	61,531
Diluted	61,927	61,531

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended March 31,				
	Dollars			Percentage of Total Net Revenues	
	2020	2019	% Change	2020	2019
Market					
Infectious disease testing	$ 14,664	$ 12,338	19%	46%	41%
Risk assessment testing	3,000	2,836	6	9	9
Cryosurgical systems	—	2,575	(100)	—	9
Molecular collection systems	13,222	10,583	25	43	35
Net product and service revenues	30,886	28,332	9	98	94
Royalty income	446	1,084	(59)	1	4
Other	264	706	(63)	1	2
Net revenues	$ 31,596	$ 30,122	5%	100%	100%

* Note cryosurgical systems business divested in August 2019.

	Three Months Ended March 31,		
	2020	2019	% Change
OraQuick® Revenues			
Domestic HIV	$ 4,216	$ 4,304	(2)%
International HIV	6,949	4,001	74
Net HIV revenues	11,165	8,305	34
Domestic HCV	1,494	1,828	(18)
International HCV	1,097	1,457	(25)
Net HCV revenues	2,591	3,285	(21)

Net product revenues	$ 13,756	$ 11,590	19 %

	Three Months Ended March 31,		
	2020	2019	% Change
Molecular Collection Systems Revenues			
Genomics	$ 9,135	$ 8,047	14 %
Microbiome	1,645	1,609	2
Other product revenues	27	210	(87)
Laboratory services	2,415	717	237
Net product and service revenues	13,222	10,583	25
Other	582	1,306	(55)
Net revenues	$ 13,804	$ 11,889	16 %

Condensed Consolidated Balance Sheets (Unaudited)

	March 31, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 83,365	$ 75,715
Short-term investments	82,735	80,623
Accounts receivable, net	27,861	36,948
Inventories	22,694	23,155
Other current assets	6,790	8,109
Property, plant and equipment, net	31,829	30,339
Intangible assets, net	15,746	14,674
Goodwill	34,544	36,201
Long-term investments	10,070	33,420
Other non-current assets	9,438	10,111
Total assets	$ 325,072	$ 349,295
Liabilities and Stockholders' Equity		
Accounts payable	$ 6,881	$ 9,567
Deferred revenue	4,312	3,713
Contingent consideration obligation	1,220	3,500
Other current liabilities	13,926	15,933
Other non-current liabilities	8,581	9,437
Stockholders' equity	290,152	307,145
Total liabilities and stockholders' equity	$ 325,072	$ 349,295

Additional Financial Data (Unaudited)

	Three Months Ended March 31,	
	2020	2019
Capital expenditures	$ 2,595	$ 2,628
Depreciation and amortization	$ 2,197	$ 1,726
Stock-based compensation	$ 1,376	$ 1,231
Cash provided by operating activities	$ 2,499	$ 528

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2020 first quarter results, updated

financial guidance, and certain business developments, 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 #5498040 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 13, 2020, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #5498040.

About OraSure Technologies

OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate essential information. Together with its wholly-owned subsidiaries (DNA Genotek, CoreBiome, Diversigen and Novosanis), OraSure provides its customers with end-to-end solutions that encompass tools, services and diagnostics. The OraSure family of companies is a leader in the development, manufacture and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular product and services solutions designed to discover and detect critical medical conditions. OraSure's portfolio of products is sold globally to clinical laboratories, hospitals, physician's offices, clinics, public health and community-based organizations, research institutions, distributors, government agencies, pharma, commercial entities and direct to 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: 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; impact of increased or different risks arising from the acquisition of companies located in foreign countries; 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; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collector products and commercialize such products for COVID-19 tests; 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 contracting with the U.S. government; 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, 2019, 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. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this press release and we undertake no duty to update these statements.

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