# OraSure Technologies, Inc. Announces Third Quarter 2020 Financial Results and Provides Update on COVID-19 Developments

November 4, 2020

*Net Third Quarter Revenues of $48.0 Million Increased 33% Year-Over-Year, Driven by $18.4 Million in Sales of Oral Fluid Collection Devices for COVID-19 Molecular Testing*

*Company Has Submitted EUA Application For Its Lab-based Oral Fluid SARS-CoV-2 Antibody Test*

*Management to Host Conference Call and Webcast Today at 5:00 p.m. ET*

BETHLEHEM, Pa., Nov. 04, 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- and nine-month periods ended September 30, 2020.

"We achieved strong top-line results in the third quarter driven by the performance of our Molecular Solutions business unit, which marked its highest quarter ever, with $31.7 million in total revenue. The Company's ability to quickly respond to the need for increased COVID-19 testing resulted in $18.4 million in sales of sample collection devices for molecular testing in the third quarter, which is more than double the COVID-19 related revenue achieved in the first half of the year," said Stephen S. Tang, Ph.D., President and Chief Executive Officer. "We are confident in our ability to meet the massive and persistent need for COVID-19 testing and sample collection. We recently submitted an application for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) for our laboratory-based oral fluid SARS-CoV-2 Antibody test. To date there are no oral fluid antibody tests for COVID-19 authorized for sale in the U.S. We continue to make progress on our rapid antigen self-test and have completed studies to confirm the assay's proprietary chemistry. Additionally, we were pleased to see growth in the quarter from our international HIV business."

**Third Quarter Financial Highlights**

- Net revenues for the third quarter of 2020 were $48.0 million, a 33% increase from the third quarter of 2019. Net product and services revenues were $46.7 million, a 32% increase from the third quarter of 2019.
- Total product and service revenues for the Company's Molecular Solutions business unit were $31.2 million during the third quarter of 2020, an increase of 79% from the third quarter of 2019. This increase included $18.4 million in sales of oral fluid sample collection devices for COVID-19 molecular testing, which was partially offset by a decrease in genomics sales.
- International sales of the Company's OraQuick ® HIV Self-Test increased 17% compared to the third quarter of 2019.
- Net income for the third quarter of 2020 was $1.0 million, or $0.01 per share on a fully-diluted basis, compared to net income of $13.1 million, or $0.21 per share on a fully-diluted basis, for the third quarter of 2019.
- Cash and investments totaled $263.7 million at September 30, 2020.

**COVID-19 Update**

*Molecular/PCR:*

- **In the third quarter, sales of oral fluid collection devices for molecular/PCR COVID-19 testing grew substantially, two of the Company's collection devices received Emergency Use Authorization (EUA), and the Company's collection devices are expected to be part of future customer EUAs.**
  - COVID-19 testing revenue grew to $18.4 million in the third quarter, up 118% from the second quarter of 2020. About half of these sales were to customers not currently holding EUAs.
  - The OMNIgene®·ORAL (OM-505, OME-505) and the ORAcollect®·RNA (OR-100, ORE-100) collection devices were granted EUAs by the FDA for the collection, stabilization and transport of saliva specimens suspected of containing SARS-CoV-2 RNA. The authorizations also allow the products to be used as a component of an authorized or cleared self-collection kit for unsupervised home-use. This means the devices can be part of a kit that is authorized under its own EUA for use by an individual to collect saliva specimens at home.[1] Both devices also have CE marking for in vitro diagnostic use in the European Union.
  - The Company's molecular collection kits have also been included in six EUAs granted by the FDA to DNA Genotek customers for COVID-19 testing.
  - Costco is selling COVID-19 saliva collection kits in conjunction with P23 Labs, which received an FDA EUA for the laboratory test workflow with its PCR test for COVID-19. The workflow includes OMNIgene·ORAL as the saliva collection device.

*Antibody:*

- **OraSure recently submitted an EUA application to the FDA for its laboratory-based oral fluid SARS-CoV-2**

**Antibody ELISA test. To date, there are no oral fluid antibody tests for COVID-19 authorized for sale in the U.S.**

- The Company plans to commercialize the laboratory-based test in the fourth quarter, subject to receipt of the EUA.
- The OraSure SARS-CoV-2 Antibody ELISA is intended for qualitative detection of total antibodies (including IgM/IgA/IgG) to SARS-CoV-2 in human oral fluid specimens collected with the OraSure Oral Antibody Collection Device.
- Oral sample collection is quick, painless, non-invasive and requires less human contact than a blood draw, minimizing the need for personal protective equipment and reducing exposure to potentially infected patients.
- With this test, individuals would use a collection pad to self-collect an oral fluid sample under the observation of a healthcare professional. The sample would then be placed into the OraSure Oral Antibody Collection Device buffer for storage and transport, and then later dispensed onto the OraSure ELISA microplate for testing in a laboratory.
- This lab-based antibody test can aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.
- Antibody tests are well suited for community surveillance and seroprevalence studies to identify people in a population or community who have antibodies against an infectious disease such as COVID-19.

*Antigen:*

- **The Company continues to make progress on its OraQuick® Coronavirus Rapid Antigen Self-Test and expects to apply for its first EUA in the first quarter of 2021. To date, there are no self-tests authorized in the U.S. to detect active COVID-19 infection that enable individuals to test themselves and read the results at the point of collection with no instrumentation needed**.
  - Between now and the filing of the EUA application OraSure will finalize the device design and complete the EUA studies necessary to demonstrate achievement of the high performance standards the FDA demands of a self-test.
  - Subject to receipt of an EUA, this product would test for active COVID-19 infection using nasal samples self-collected from the lower nostril. Results would be available at the point of collection, with no instrumentation or laboratory analysis needed to interpret results.
  - Subject to regulatory approvals, the Company intends to sequentially introduce its antigen test to the market for three different uses:
    - **Professional Test** for use at drive-through sites, physician offices, public health testing sites, and employer/university health centers. In this instance, a physician would prescribe the test and the patient would conduct a self-swab in the presence of a healthcare provider who would then interpret the results.
    - **Prescription Self-Test** for use by individual consumers (with prescription) at home or in any location, by employers/universities on or off-site, or by physicians or public health via remote testing. In this instance, a physician would prescribe the test and the patient would conduct a self-swab at home, or in any location, where they would then interpret their own results.
    - **OTC Self-Test** for use by consumers who would purchase online or at retail without prescription, and conduct the test and receive the results themselves anytime, anywhere.
  - OraSure expects to file for the Professional Test EUA in Q1 2021, with the Prescription Self-Test and OTC Self-Test EUAs to follow as soon as possible thereafter. Although the timing of the EUA receipt is subject to FDA review, the Company will be prepared to launch the test, subject to authorization, without delay.

*Manufacturing:*

- **OraSure's plans to increase manufacturing capacity to meet demand for COVID-19 sample collection kits and tests continue on schedule.**

**Financial Results for the Three Months Ended September 30, 2020**

Net revenues for the third quarter of 2020 of $48.0 million increased 33% from the comparable period of 2019, primarily as a result of strong sales of molecular sample collection kits for COVID-19 testing, an increase in international sales of the Company's HIV Self-Test and in laboratory service revenues. These increases were partially offset by lower sales of the Company's genomics, risk assessment, HCV, and domestic HIV products.

Gross profit percentage was 63% and 60% for the three months ended September 30, 2020 and 2019, respectively. Gross profit percentage in the third quarter of 2020 benefited from an improved product mix associated with higher gross profit percentage product sales.

For the three months ended September 30, 2020, operating expenses were $25.9 million, an increase of $17.3 million from the $8.6 million reported for the three months ended September 30, 2019. This increase was due primarily to increased spend associated with COVID-19 product development and the inclusion of expenses incurred by the Company's newly acquired subsidiaries, UrSure and Diversigen, whose results were not included in the third quarter of 2019. In addition, operating expenses in the third quarter of 2019 were reduced by a gain on the sale of the Company's cryosurgical business of $10.1 million and a $2.4 million decrease in the change in the fair value of contingent acquisition consideration.

The Company generated operating income of $4.4 million in the third quarter of 2020 compared to operating income of $13.1 million in the third quarter of 2019.

During the third quarters of 2020 and 2019, the Company recorded income tax expense of $3.7 million and $1.2 million, respectively. Income tax

expense in both periods largely consisted of foreign taxes due.

**Fourth Quarter 2020 Guidance**

The Company expects fourth quarter 2020 net revenues to range from $55 million to $60 million.

**Financial Data**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| **Results of Operations** | | | | |
| Net revenues | $ 48,011 | $ 35,989 | $ 108,866 | $ 104,937 |
| Cost of products and services sold | 17,722 | 14,343 | 45,182 | 40,193 |
| Gross profit | 30,289 | 21,646 | 63,684 | 64,744 |
| Operating expenses: | | | | |
| Research and development | 8,007 | 4,619 | 20,575 | 13,525 |
| Sales and marketing | 7,849 | 8,955 | 25,339 | 23,937 |
| General and administrative | 10,108 | 7,556 | 30,442 | 23,748 |
| Change in fair value of acquisition-related contingent consideration | (60) | (2,387) | 390 | (843) |
| Gain on sale of business | — | (10,149) | — | (10,149) |
| Total operating expenses | 25,904 | 8,594 | 76,746 | 50,218 |
| Operating income (loss) | 4,385 | 13,052 | (13,062) | 14,526 |
| Other income | 314 | 1,195 | 1,960 | 2,243 |
| Income (loss) before income taxes | 4,699 | 14,247 | (11,102) | 16,769 |
| Income tax expense | 3,659 | 1,169 | 5,680 | 2,551 |
| Net income (loss) | $ 1,040 | $ 13,078 | $ (16,782) | $ 14,218 |
| Income (loss) per share: | | | | |
| Basic | $ 0.01 | $ 0.21 | $ (0.25) | $ 0.23 |
| Diluted | $ 0.01 | $ 0.21 | $ (0.25) | $ 0.23 |
| Weighted average shares: | | | | |
| Basic | 71,537 | 61,726 | 66,088 | 61,656 |
| Diluted | 72,662 | 62,143 | 66,088 | 62,172 |

| | Three Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| | 2020 | 2019 | % Change | 2020 | 2019 |
| **Market** | | | | | |
| Infectious disease testing | $ 13,224 | $ 13,588 | (3) % | 28 % | 38 % |
| Risk assessment testing | 2,316 | 3,312 | (30) | 5 | 9 |
| Cryosurgical systems | — | 961 | (100) | — | 3 |
| Molecular collection systems | 31,209 | 17,438 | 79 | 65 | 48 |
| Net product and service revenues | 46,749 | 35,299 | 32 | 98 | 98 |
| Royalty income | 450 | 758 | (41) | 1 | 2 |
| Other | 812 | (68) | — | 1 | — |
| Net revenues | $ 48,011 | $ 35,989 | 33 % | 100 % | 100 % |

| | Nine Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| | 2020 | 2019 | % Change | 2020 | 2019 |
| **Market** | | | | | |
| Infectious disease testing | $ 36,625 | $ 39,273 | (7) % | 34 % | 37 % |
| Risk assessment testing | 6,848 | 9,246 | (26) | 6 | 9 |
| Cryosurgical systems | — | 7,054 | (100) | — | 7 |
| Molecular collection systems | 62,499 | 45,325 | 38 | 58 | 43 |
| Net product and service revenues | 105,972 | 100,898 | 5 | 98 | 96 |
| Royalty income | 1,623 | 2,956 | (45) | 1 | 3 |
| Other | 1,271 | 1,083 | 17 | 1 | 1 |
| Net revenues | $ 108,866 | $ 104,937 | 4 % | 100 % | 100 % |

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2020 | 2019 | % Change | 2020 | 2019 | % Change |
| **OraQuick® Revenues** | | | | | | |
| Domestic HIV | $ 3,909 | $ 4,259 | (8) % | $ 11,323 | $ 13,024 | (13) % |
| International HIV | 6,865 | 5,891 | 17 | 17,697 | 15,313 | 16 |
| Net HIV revenues | 10,774 | 10,150 | 6 | 29,020 | 28,337 | — |
| Domestic HCV | 1,186 | 1,977 | (40) | 3,437 | 5,907 | (42) |
| International HCV | 1,033 | 1,129 | (9) | 2,772 | 3,569 | (22) |
| Net HCV revenues | 2,219 | 3,106 | (29) | 6,209 | 9,476 | (34) |
| Net product revenues | $ 12,993 | $ 13,256 | (2) % | $ 35,229 | $ 37,813 | (7) % |

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2020 | 2019 | % Change | 2020 | 2019 | % Change |
| **Molecular Collection Systems Revenues** | | | | | | |
| Genomics | $ 8,519 | $ 13,647 | (38) % | $ 23,381 | $ 35,449 | (34) % |
| Microbiome | 1,828 | 1,878 | (3) | 4,259 | 5,325 | (20) |
| COVID-19 | 18,441 | — | N/A | 27,307 | — | N/A |
| Laboratory services | 2,418 | 1,618 | 49 | 7,472 | 3,947 | 89 |
| Other product revenues | 3 | 295 | (99) | 80 | 604 | (87) |
| Net product and service revenues | 31,209 | 17,438 | 79 | 62,499 | 45,325 | 38 |
| Other | 488 | 821 | (41) | 1,834 | 3,277 | (44) |
| Net product and service revenues | $ 31,697 | $ 18,259 | 74 % | $ 64,333 | $ 48,602 | 32 % |

**Condensed Consolidated Balance Sheets (Unaudited)**

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| Assets | | |
| Cash and cash equivalents | $ 162,859 | $ 75,715 |

| | | |
|---|---|---|
| Short-term investments | 72,961 | 80,623 |
| Accounts receivable, net | 30,638 | 36,948 |
| Inventories | 30,488 | 23,155 |
| Other current assets | 6,031 | 8,109 |
| Property, plant and equipment, net | 39,056 | 30,339 |
| Intangible assets, net | 18,111 | 14,674 |
| Goodwill | 39,480 | 36,201 |
| Long-term investments | 27,841 | 33,420 |
| Other non-current assets | 8,945 | 10,111 |
| Total assets | $ 436,410 | $ 349,295 |
| Liabilities and Stockholders' Equity | | |
| Accounts payable | $ 14,377 | $ 9,567 |
| Deferred revenue | 5,311 | 3,713 |
| Contingent consideration obligation | 764 | 3,500 |
| Other current liabilities | 16,775 | 15,933 |
| Non-current contingent consideration obligation | 3,176 | 112 |
| Other non-current liabilities | 8,115 | 9,325 |
| Stockholders' equity | 387,892 | 307,145 |
| Total liabilities and stockholders' equity | $ 436,410 | $ 349,295 |

| **Additional Financial Data (Unaudited)** | **Nine Months Ended September 30,** | |
|---|---|---|
| | **2020** | **2019** |
| Capital expenditures | $ 11,234 | $ 7,961 |
| Depreciation and amortization | $ 7,051 | $ 5,532 |
| Stock-based compensation | $ 5,913 | $ 3,283 |
| Cash provided by operating activities | $ 2,196 | $ 10,838 |

**Conference Call**

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2020 third quarter results 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 #9459222 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, November 18, 2020, by dialing 855-859-2056 (Domestic) or (404) 537-3406 (International) and entering the Conference ID #9459222.

It is recommended to dial-in at most 15 to 20 minutes prior to the call start to reduce waiting times. If a participant will be listen-only, they are encouraged to listen via the webcast on OraSure's Investor Relations page.

**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, Diversigen, CoreBiome (now operating under the Diversigen brand), UrSure 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 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, 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, products, product development activities, regulatory submissions and authorizations and other matters. 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, receive necessary regulatory approvals and authorizations and commercialize such products for COVID-19 testing; 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 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 OraSure Technologies undertakes no duty to update these statements.

[1] The ORAcollect·RNA and OMNIgene·ORAL sample collection devices have not been FDA cleared or approved; the devices have been authorized by FDA under an EUA. The ORAcollect·RNA and OMNIgene·ORAL sample collection devices have been authorized only to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA), not for any other viruses or pathogens; and the ORAcollect·RNA and OMNIgene·ORAL sample collection devices are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in medical devices during the COVID-19 outbreak under Section564(b)(1) of the Federal Food, Drug, and Cosmetic Act,21U.S.C. §360bbb-3(b)(1),unless the authorization is terminated or revoked sooner.


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