

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
Date of Report (Date of earliest event reported): August 3, 2021

OraSure Technologies, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-16537
(Commission File Number)

36-4370966
(I.R.S. Employer Identification No.)

220 East First Street
Bethlehem, Pennsylvania
(Address of Principal Executive Offices)

18015-1360
(Zip Code)

Registrant's telephone number, including area code: 610-882-1820

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|--|-------------------|---|
| Common Stock, \$0.000001 par value per share | OSUR | The NASDAQ Stock Market LLC |

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by a check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 – Results of Operations and Financial Condition.

On August 3, 2021, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended June 30, 2021 and certain other matters. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

The information in this Item and attached Exhibit shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

Item 7.01 – Regulation FD Disclosure.

On August 3, 2021, the Company held a webcast conference call with analysts and investors, during which Stephen S. Tang, Ph.D., the Company’s President and Chief Executive Officer, and Roberto Cuca, the Company’s Chief Financial Officer, discussed the Company’s consolidated financial results for the quarter ended June 30, 2021, and described certain business developments. A copy of the prepared remarks of Dr. Tang and Mr. Cuca is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference. A copy of a slide presentation used during the webcast conference call is attached as Exhibit 99.3 to this Form 8-K, is incorporated herein by reference and will be posted on the Company’s website at www.orasure.com.

The information in these Items and attached Exhibits shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

Item 9.01 – Financial Statements and Exhibits.**(d) Exhibits**

| Exhibit Number | Description |
|-----------------------|--|
| 99.1 | <u>Press Release, dated August 3, 2021, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2021 and certain other matters.</u> |
| 99.2 | <u>Prepared Remarks of Stephen S. Tang, Ph.D. and Roberto Cuca for OraSure Technologies, Inc. Second Quarter 2021 Analyst/ Investor Conference Call Held August 3, 2021.</u> |
| 99.3 | <u>Slide Presentation for OraSure Technologies, Inc. Second Quarter 2021 Analyst/Investor Conference Call Held August 3, 2021.</u> |
| Exhibit 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

Signatures

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ORASURE TECHNOLOGIES, INC.

Date: August 3, 2021

By: /s/ Jack E. Jerrett
Jack E. Jerrett
Senior Vice President, General Counsel and Chief Compliance Officer



OraSure Technologies, Inc.

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OraSure Technologies Reports 2Q21 Revenue of \$57.6 Million Driven by Strong Rebound in Core Business

- Excluding COVID-19 product revenues, revenues for the second quarter grew 122% YoY and 48% sequentially as the Company's core business began to return to pre-pandemic revenue levels
- Company received three Emergency Use Authorizations (EUAs) from the U.S. Food and Drug Administration (FDA) for its *InteliSwab*[™] COVID-19 Rapid Tests for Non-Prescription (OTC), Professional Point-of-Care and Prescription Home Use

Management to Host Analyst/Investor Call and Webcast Today at 5:00 p.m. ET

BETHLEHEM, PA, August 3, 2021 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care and home diagnostic tests, specimen collection devices, and microbiome laboratory and analytical services, today announced its financial results for the three months ended June 30, 2021.

"This quarter, OraSure once again demonstrated strong financial performance highlighted by a recovery in our core business as the Company began to return to pre-pandemic revenue levels. Importantly, we have now received three EUAs for our *InteliSwab*[™] COVID-19 Rapid Tests, signed up two major distributors, and established a significant pipeline of sales inquiries. This represents a significant achievement as we continue to demonstrate the ability of the Company to develop and launch new products," said Stephen Tang, Ph.D., President and CEO of OraSure Technologies.

Dr. Tang continued, "As we look to the second half of the year we believe the business is well positioned for year-over-year growth given the commercial launch of *InteliSwab*[™]. We are responding to strong global customer interest for *InteliSwab*[™] tests and anticipate exiting the year at a significant revenue run rate. Newer areas such as our microbiome kits and services business are becoming increasingly important to our growth story and achieved record revenue in the second quarter. Overall, we are highly focused on spurring innovation, strengthening our product pipeline, and deploying capital through strategically sound acquisitions that leverage our commercial infrastructure to drive long-term sustained growth and value for our stockholders."

Financial Highlights

- Net revenues for the second quarter of 2021 were \$57.6 million, a 97% increase from the second quarter of 2020. Excluding COVID-19 product revenues, revenues for the quarter increased 122% YoY and 48% sequentially as the company began to return to pre-pandemic revenue levels.

- Total revenues from the Company's Diagnostic business unit were \$19.3 million during the second quarter of 2021 and grew 85% relative to the same period last year. Revenue growth was driven predominantly by higher global OraQuick® HIV and OraQuick® HCV sales as clinics returned to testing for these critical diseases, along with higher risk assessment testing due to an increase in workplace testing.
- Total product and service revenues for the Company's Molecular Solutions business unit were \$38.3 million during the second quarter of 2021, an increase of 103% from the second quarter of 2020. The increase was driven by strengthening demand for genomic collection kits from commercial and academic customers, growth in microbiome collection kits and services, and modestly higher COVID-19 collection kit sales.
- Gross margin percentage in the second quarter was 53.2% compared to 59.0% in the prior year. Gross margins were negatively impacted by the build out of manufacturing capacity to support the *InteliSwab*™ COVID-19 Rapid Test launch as well as the higher mix of HIV testing revenue from international markets which carries a lower gross margin than the corporate average. We also saw an impact from increased labor and material costs.
- Operating income in the second quarter was \$1.8 million compared to a loss of (\$9.4) million in the second quarter of last year. Improved operating profit was driven by higher revenues and expense control with total operating expenses only increasing 8% year-over-year despite the 97% overall revenue growth.
- Net loss for the second quarter of 2021 was (\$1.4) million, or (\$0.02) per share on a fully-diluted basis, compared to a net loss of (\$10.5) million, or (\$0.16) per share on a fully-diluted basis, for the second quarter of 2020.
- Cash flow used in operations in the quarter was (\$3.5) million. Cash and investments totaled \$229.4 million at June 30, 2021.

Recent Business Highlights

COVID-19 Testing

- OraSure received three Emergency Use Authorizations (EUA) from the U.S. Food and Drug Administration (FDA) for its *InteliSwab*™ COVID-19 Rapid Tests. The FDA has authorized these tests for Over-the-Counter (OTC) use without a prescription. FDA has also authorized the *InteliSwab*™ COVID-19 Rapid Test Pro for professional use in point of care (POC) CLIA-waived settings, and the *InteliSwab*™ COVID-19 Rapid Test Rx for Prescription Home Use. The OTC and POC tests can be used for those with or without symptoms, when tested twice over two to three days, with 24-36 hours between tests.
- As anticipated, due to the timing of EUA for *InteliSwab*™ and the time required for product relabeling, OraSure did not recognize *InteliSwab*™ sales in the second quarter of 2021. OraSure signed distribution agreements for this product with two major U.S. distributors for US clinical and physician office channels. Additionally, the Company currently has received significant customer inquiries, including inquiries from 15 additional countries, all of which accept FDA EUA product to initiate local registration applications with labeling being modified for local language requirements.
- Following discussions with the FDA and their de-prioritization of antibody testing in the U.S., OraSure has decided to no longer pursue EUAs for its oral fluid COVID-19 antibody test. The Company will continue to offer the product for research use only and has several labs interested in COVID antibody surveillance and research applications.

Infectious Disease and Risk Assessment Testing

- Global OraQuick® HIV sales in the second quarter were \$10.9 million versus \$7.1 million in the prior year period. Sales increased due to improved domestic HIV sales along with continued strong double-digit international test volume growth.
- OraSure Technologies was selected by the Centers for Disease Control and Prevention (CDC) to distribute 100,000 HIV self-test kits to individuals who request them. The program sent out OraQuick® In-Home HIV Tests, which allow an individual to detect antibodies to both HIV-1 and HIV-2 with an oral test, and provide results in 20 minutes, at home.
- Global OraQuick® HCV sales grew 208% to \$4.3 million in the second quarter compared to \$1.4 million in the second quarter of 2020 as professional testing was reinstated in many countries.
- Risk assessment testing revenue grew 71% in the second quarter to \$2.6 million based primarily upon increased workplace drugs-of-abuse testing as economic conditions and hiring have improved.

Molecular Solutions

- Genomics collection kit revenue of \$19.6 million for the second quarter of 2021 grew 203% YoY. The growth was driven predominantly by growth in the key markets of consumer genomics, disease risk management, companion animal and research.
- Sales of OraSure's sample collection devices for molecular/PCR COVID-19 testing increased year-over-year to \$11.5 million in the second quarter of 2021 compared to \$8.5 million in the prior year period. However, on a sequential basis total sales declined by \$15.9 million as total U.S. PCR based test volumes for COVID-19 declined meaningfully from the March 2021 quarter to the June 2021 quarter.
- A new study was published in *Gynecologic Oncology* where the data indicated the ability of Colli-Pee®, OraSure's proprietary urine sample collection technology, to facilitate test results for human papilloma virus (HPV) using first-void urine samples from patients. In the study of approximately 500 women, the accuracy of testing utilizing Abbott's RealTime High Risk HPV assay was statistically equivalent using Colli-Pee® first-void urine-based samples as compared to clinician collected cervical tissue cell samples.
- Total microbiome revenue, including kits and services, was \$6.0 million in the quarter and grew 94% relative to the second quarter of last year. OraSure's Diversigen business now supports over 50 commercial customers including over 30 biopharmaceutical customers with 20 ongoing clinical trials.

Third Quarter 2021 Guidance

The Company expects third quarter 2021 net revenues to range from \$45 million to \$50 million.

The Company has also provided guidance for *InteliSwab*™ for the full year stating that it now anticipates total *InteliSwab*™ sales through December 2021 of approximately \$30 million with the preponderance of revenue coming in the fourth quarter of calendar year 2021.

The Company expects fiscal year 2021 total revenue of approximately \$230 million.

Financial Data (Unaudited)

| | Three Months Ended | | Six Months Ended | |
|--|--------------------|-------------|------------------|-------------|
| | June 30, | | June 30, | |
| | 2021 | 2020 | 2021 | 2020 |
| Results of Operations | | | | |
| Net revenues | \$ 57,607 | \$ 29,259 | \$ 116,189 | \$ 60,855 |
| Cost of products and services sold | 26,934 | 11,995 | 47,190 | 27,460 |
| Gross profit | 30,673 | 17,264 | 68,999 | 33,395 |
| Operating expenses: | | | | |
| Research and development | 7,682 | 6,924 | 16,674 | 12,568 |
| Sales and marketing | 10,420 | 10,121 | 19,950 | 17,490 |
| General and administrative | 10,993 | 10,280 | 21,181 | 20,334 |
| Change in fair value of acquisition-related contingent consideration | (220) | (660) | (1,026) | 450 |
| Total operating expenses | 28,875 | 26,665 | 56,779 | 50,842 |
| Operating income (loss) | 1,798 | (9,401) | 12,220 | (17,447) |
| Other income | 448 | 216 | 329 | 1,646 |
| Income (loss) before income taxes | 2,246 | (9,185) | 12,549 | (15,801) |
| Income tax expense | 3,610 | 1,309 | 10,139 | 2,021 |
| Net income (loss) | \$ (1,364) | \$ (10,494) | \$ 2,410 | \$ (17,822) |
| Earnings (loss) per share: | | | | |
| Basic | \$ (0.02) | \$ (0.16) | \$ 0.03 | \$ (0.28) |
| Diluted | \$ (0.02) | \$ (0.16) | \$ 0.03 | \$ (0.28) |
| Weighted average shares: | | | | |
| Basic | 71,983 | 64,745 | 71,931 | 63,335 |
| Diluted | 71,983 | 64,745 | 72,683 | 63,335 |

| | Three Months Ended | | | Six Months Ended | | |
|---|--------------------|------------------|-------------|-------------------|------------------|-------------|
| | June 30, | | | June 30, | | |
| | 2021 | 2020 | % Change | 2021 | 2020 | % Change |
| DIAGNOSTICS | | | | | | |
| Infectious Disease Testing Revenues | | | | | | |
| Domestic HIV | \$ 4,135 | \$ 3,197 | 29 % | \$ 9,050 | \$ 7,414 | 22 % |
| International HIV | 6,809 | 3,883 | 75 | 10,672 | 10,832 | (1) |
| Net HIV revenues | 10,944 | 7,080 | 55 | 19,722 | 18,246 | 8 |
| Domestic HCV | 2,571 | 757 | 240 | 3,754 | 2,251 | 67 |
| International HCV | 1,729 | 641 | 170 | 2,914 | 1,738 | 68 |
| Net HCV revenues | 4,300 | 1,398 | 208 | 6,668 | 3,989 | 67 |
| Net OraQuick® revenues | 15,244 | 8,478 | 80 | 26,390 | 22,235 | 19 |
| Other infectious disease revenues | 379 | 259 | 46 | 604 | 1,165 | (48) |
| Total Infectious Disease | 15,623 | 8,737 | 79 | 26,994 | 23,400 | 15 |
| Risk Assessment | 2,629 | 1,533 | 71 | 4,591 | 4,533 | 1 |
| Other non-product revenues | 1,059 | 157 | 575 | 2,272 | 286 | 694 |
| TOTAL DIAGNOSTIC NET REVENUE | 19,311 | 10,427 | 85 | 33,857 | 28,219 | 20 |
| MOLECULAR SOLUTIONS | | | | | | |
| Genomics | 19,582 | \$ 6,471 | 203 | \$ 30,646 | \$ 14,863 | 106 |
| Microbiome | 2,853 | 853 | 234 | 4,941 | 2,430 | 103 |
| COVID-19 | 11,491 | 8,472 | 36 | 38,880 | 8,866 | 339 |
| Laboratory services | 3,114 | 2,222 | 40 | 5,611 | 5,053 | 11 |
| Other product and services revenues | 449 | 49 | 816 | 657 | 78 | 742 |
| Net product and service revenues | 37,489 | 18,067 | 107 | 80,735 | 31,290 | 158 |
| Other non-product and service revenues | 807 | 765 | 5 | 1,597 | 1,346 | 19 |
| TOTAL MOLECULAR SOLUTIONS NET REVENUE | 38,296 | 18,832 | 103 | 82,332 | 32,636 | 152 |
| TOTAL NET REVENUES | \$ 57,607 | \$ 29,259 | 97 % | \$ 116,189 | \$ 60,855 | 91 % |

Condensed Consolidated Balance Sheets (Unaudited)

| | <u>June 30, 2021</u> | <u>December 31, 2020</u> |
|---|----------------------|--------------------------|
| <u>Assets</u> | | |
| Cash and cash equivalents | \$ 158,120 | \$ 160,802 |
| Short-term investments | 35,185 | 48,599 |
| Accounts receivable, net | 35,259 | 38,835 |
| Inventories | 48,170 | 31,863 |
| Other current assets | 8,316 | 8,794 |
| Property, plant and equipment, net | 72,034 | 51,860 |
| Intangible assets, net | 16,241 | 17,904 |
| Goodwill | 40,810 | 40,351 |
| Long-term investments | 36,131 | 47,718 |
| Other non-current assets | 14,783 | 7,746 |
| Total assets | \$ 465,049 | \$ 454,472 |
| <u>Liabilities and Stockholders' Equity</u> | | |
| Accounts payable | \$ 22,119 | \$ 17,407 |
| Deferred revenue | 4,240 | 4,811 |
| Contingent consideration obligation | 219 | 402 |
| Other current liabilities | 19,994 | 23,869 |
| Non-current contingent consideration obligation | 800 | 2,049 |
| Other non-current liabilities | 12,861 | 7,363 |
| Stockholders' equity | 404,816 | 398,571 |
| Total liabilities and stockholders' equity | \$ 465,049 | \$ 454,472 |

Additional Financial Data (Unaudited)

| | Six Months Ended | |
|-----------------------------------|-------------------------|-------------|
| | June 30, | |
| | <u>2021</u> | <u>2020</u> |
| Capital expenditures | \$ 22,929 | \$ 6,037 |
| Depreciation and amortization | \$ 5,524 | \$ 4,600 |
| Stock-based compensation | \$ 2,937 | \$ 4,048 |
| Cash used in operating activities | \$ 3,472 | \$ 2,184 |

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's second quarter 2021 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 (888) 771-4371 (Domestic) or (847) 585-4405 (International) and reference Conference ID # 50205303 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 14 days. A replay of the call can also be accessed until midnight, August 17, 2021, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID # 50205303.

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. OraSure, together with its wholly-owned subsidiaries, DNA Genotek, Diversigen, and Novosanis, 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, 2020, 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.

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OraSure Technologies, Inc.

Second Quarter 2021

Analyst-Investor Conference Call

August 3, 2021

Prepared Remarks of Dr. Stephen S. Tang and Roberto Cuca

Please see “Important Information” at the conclusion of the following prepared remarks

Operator Remarks

Good afternoon everyone and welcome to the OraSure Technologies second quarter 2021 financial results conference call and simultaneous webcast. As a reminder, today's conference is being recorded. All lines have been placed on mute to prevent any background noise. After the speaker's remarks, there will be a question and answer period. If you would like to ask a question during this time, simply press “star” then the number 1 on your telephone keypad. If you would like to withdraw your question, press the # key. To allow time for as many questions as possible, questioners are asked to limit themselves to only a single question with no more than one follow-up question related to the same topic. Once the follow-up is completed, a questioner can rejoin the queue for further questions.

I would now like to turn the call over to Scott Gleason, Senior Vice President of Investor Relations and Corporate Communications for OraSure. Scott?

Slide – 1

Scott Gleason – SVP of IR and Corp. Communications

Good afternoon and welcome to OraSure Technologies second-quarter 2021 earnings call. I am Scott Gleason, the SVP of Investor Relations and Communications. Presenting for OraSure today are Dr. Stephen Tang our President and Chief Executive Officer, and Roberto Cuca our Chief Financial Officer. As a reminder, today's webcast is being recorded and a slide presentation accompanying the webcast can be found on our investor relations website.

Slide – 2

Before we begin, you should know that this call may contain certain forward-looking statements, including statements with respect to revenues, expenses, profitability, earnings or loss per share and other financial performance, product development, performance, shipments and markets, business plans, regulatory filings and approvals, expectations and strategies. Actual results could be significantly different.

Factors that could affect results are discussed more fully in the Company's SEC filings, including its registration statements, its annual report on Form 10-K for the year ended December 31, 2020, its quarterly reports on Form 10-Q and its other SEC Filings. Although forward-looking statements help to provide complete information about future prospects, listeners should keep in mind that forward-looking statements are based solely on information available to management as of today. The Company

undertakes no obligation to update any forward-looking statements to reflect events or circumstances after this call.

With that, I am pleased to turn the call over to Dr. Stephen Tang.

Slide – 3

Dr. Stephen Tang, President and CEO of OraSure Technologies

Thanks Scott, and thank you to everyone for joining us on the call today. This quarter, OraSure saw an exceptionally strong recovery in our core business and excluding COVID-19 product revenue we grew 122% year-over-year and 48% sequentially. While we still have a ways to go, the beginning of a return to more normal activity for our customers is a welcome sign as we look to the second half of fiscal year 2021. This strengthening of the core allowed us to achieve strong financial results despite the anticipated slowdown in molecular solutions COVID revenue as PCR test volumes declined in the U.S. This quarter we also achieved a major milestone with the receipt of three emergency use authorizations (EUAs) for our IntelliSwab™ COVID-19 Rapid test in the U.S., which we continue to believe will be a very important driver of incremental revenue and a source of growth for the Company. The launch of our IntelliSwab™ test demonstrates the ability of the Company to develop, launch, and market new products, and in the coming year we will talk more about our renewed focus on innovation and our product pipeline as one of our strategic areas of focus. As we reflect on our strong quarterly results and our numerous COVID-19 launches, I would like to personally thank OraSure's dedicated employees around the world who have worked tirelessly to get us to this exciting point in our Company's journey.

Slide – 4

I would now like to discuss our strategic priorities which include capitalizing on the COVID-19 testing opportunity, expanding our sample collection and molecular services businesses into new sample types and testing modalities, expanding our global reach, and driving innovation with a focus on achieving higher growth through both internal R&D and M&A.

Slide – 5

First, as we look at the COVID-19 testing opportunity, this quarter we received three EUAs for our IntelliSwab™ COVID-19 Rapid Tests for over the counter (OTC), Professional Point-of-Care and Prescription Home Use. We believe IntelliSwab™ is competitively differentiated primarily because the test is remarkably simple to use. You just swab your nostrils with the gentle swab, swirl the swab in the tube, and see your test results in minutes. Unlike other rapid COVID-19 tests, there are no confusing steps, no batteries or electricity needed and no mailing samples to a lab. We like to say it's as simple as swab, swirl, and see. OraSure knows this simplicity is absolutely crucial to adoption and ongoing use by consumers and clinicians. It ensures confidence in the result, and enables testing absolutely anywhere, including outreach testing in underserved communities, exactly where our HIV and HCV tests are used today.

As is customary in medical devices and diagnostics, the conversion of customer leads to purchase orders takes time, and recall that we were limited in our ability to promote this new product prior to receipt of the EUAs in early June. So while we are in the initial phases of the customer acquisition process, we did

begin shipping orders in June, and continued to receive orders in July. We currently have customer inquiries representing over \$25 million including inquiries from over 15 different countries that will accept FDA EUA product with appropriate country specific documents and labeling. We believe the recent propagation of new variants has renewed the focus of global governments on a multipronged strategy to countering the pandemic consisting of vaccination, protection, and frequent testing. A study conducted by the National Institutes of Health, and recently published in the Journal of Infectious Diseases, indicated that antigen testing, when conducted every three days, has sensitivity equal to that of PCR lab-based testing. This supports the need for regular fast and frequent testing, which will be needed in remote locations and at home. One of the most critical requirements for this type of testing is ease of use and that is where IntelliSwab™ provides a real benefit.

Our country's response to the pandemic is well characterized by the CDC's program of protect, test, and vaccinate. We continue to believe that testing will be a critical component of the three-tiered response to counter the COVID-19 pandemic. As new variants such as delta and lambda propagate across the globe, there has been increased demand for testing in multiple global markets. Additionally, as students return to schools and employees return to work, we believe testing will be vital for ensuring safety and hygiene for all. We have already seen several announcements around programs incorporating both vaccinated and unvaccinated individuals. Additionally, large funding pools have become available from federal and state governments including the CDC's \$2.3 billion funding for underserved and rural communities for which our test is ideally suited, an additional \$1.6 billion from the Biden administration to address testing and mitigation in vulnerable communities, and \$10 billion from the Biden administration to fund back-to-school testing. That adds up to \$13.9 billion in federal funding to, in large part, address testing in congregate, underserved, and vulnerable communities, places where

vaccination rates are low and COVID-19 variants are now surging and our IntelliSwab™ test is ideally suited.

Lastly, as it pertains to COVID-19, I wanted to provide an update on our oral fluid antibody test. The FDA recently responded to us and declined to further review our submission as they focus on areas of higher priority. However, we will continue to offer this product as a research use only test with several laboratories interested in COVID-19 antibody surveillance and research applications.

Slide – 6

Next I would like to highlight one example of how we're trying to expand our sample collection business. As you know, we built the saliva sample collection portfolio by generating data to disrupt the standard of care for sample type, often blood, and by co-clearing our collection devices with relevant assays in the genomic space. We are pursuing a similar strategy with first void urine collection with our Novosanis subsidiary, as we look to bring the non-invasive benefits of urine sample collection to new markets. This quarter we had a significant new publication in *Gynecologic Oncology* demonstrating the ability of Colli-Pee®, OraSure's proprietary urine sample collection technology, to facilitate testing for human papilloma viruses (HPV) using first-void urine samples from patients. In the study of approximately 500 women, the sensitivity and specificity of Colli-Pee® collected first-void urine samples was shown to be similar to the sensitivity and specificity of clinician-collected cervical samples using the Abbott's RealTime High Risk HPV assay for the detection of neoplasia. . We have additional clinical studies in process with other major HPV test manufacturers that we expect to come out later this year. While there is still a significant pathway to full product validation and regulatory approval, we believe Colli-Pee® has the potential to transform cervical cancer screening to a better, less invasive, and more

cost effective modality where women can have the sample collected for cervical cancer and other sexually transmitted diseases in the privacy of their own homes. The market opportunity for HPV screening represents greater than 30 million tests per year in the U.S. alone making this a significant future opportunity.

In regard to Colli-Pee® for use in oncology, we also saw MDx Health, one of our top customers using Colli-Pee® for cancer screening, receive a draft local coverage determination from Palmetto GBA, a Medicare administrative contractor, for their SelectMDx urine test for prostate cancer risk assessment. Typically these types of reimbursement coverage decisions are catalysts for more significant commercial adoption of laboratory tests.

Slide – 7

This was also a record quarter for our microbiome business on both the service and kit side with over \$6 million in total revenue. We now have over 50 commercial customers in microbiome testing including over 30 biopharmaceutical companies conducting over 20 ongoing clinical studies. We are working with all of the top-5 companies in the microbiome space as well as five of the top ten pharmaceutical companies in the United States. Early data around microbiome based therapeutics has been positive and some of these studies are beginning to advance to the Phase 3 stage with the FDA which will lead to increasing revenue as the number of samples evaluated increases. We also believe eventual regulatory approvals of microbiome based therapeutics will lead to further research investment in this area which will benefit our business. Building on the growth in our microbiome business in the second half of this year we plan to offer a new gut metatranscriptome collection kit and a metatranscriptome service in

support of our customer's microbiome research. This is an important step toward our strategy of expanding samples types, analytes and services as we pursue our multi-omic strategy.

Slide – 8

Another important strategic component of our molecular solutions business is expanding our long-term competitive positioning in the market. Investors have asked us about recent low-tech COVID-19 collection devices launched by other companies and I believe it is important to highlight the unique features of our products. Our devices were designed for remote sample collection for genetic sequencing. In addition to the well proven easy to use and consumer friendly form factors, they feature proprietary patented designs and chemistries capable of stabilizing a variety of analytes, under a broad range of storage conditions, allowing shipment and storage at ambient temperatures. Because the DNA and RNA is preserved, samples collected in our devices are suitable for surveillance related sequencing, for variant detection, as an example. While there are lower cost devices on the market that can be used for COVID sample collection, they do not match our benefit profile. We continually innovate in both physical design and chemistry, and as a result, have significant intellectual property protecting our technology, many with expirations extending out many years. Additionally, we are increasingly pursuing regulatory approvals in conjunction with our strategic customer relationships, such as the clearance received for our oral fluid collection device in conjunction with Helix for their whole exome test this year. Finally, we have established long-term contracts with some of our key customers providing long-term visibility and we are increasingly adding a broader range of services to customer agreements such as fulfillment and customizations services.

Importantly, our customer base in these markets has become increasingly diverse and we have over 6,000 customers now with no single customer represented greater than seven percent of our revenue in fiscal year 2020. Consequently, we believe we are in an exceptionally strong competitive position as one of the global leaders in this market, with our ability to address diverse markets such as consumer genomics, clinical genomics, and home testing which are growing in the mid-teens, with our ability to expand our solution set into additional high growth areas and sample modalities.

Slide - 9

Moving on to our strategy to expand our global reach and presence, we continue to see strong adoption of our OraQuick® HIV tests internationally driven by the double-digit annual growth since 2016 of our HIV self-test, the only regulatory approved oral fluid self-test for HIV in the world. We are already using our established distribution channels for HIV for the new IntelliSwab™ COVID-19 rapid test where we have inquiries from several countries as COVID-19 continues to spread outside the United States. Across the OraSure portfolio, we continue to expand our global reach and now have over 400 product registrations in 95 countries. This not only applies to diagnostics but also to molecular solutions where we are also looking to increasingly expand outside the United States with our collection kits including our COVID-19 collection devices.

Slide – 10

Finally, I would like to discuss our strategic priority of driving innovation with a focus on higher growth spaces through internal R&D and M&A. I would like to provide some additional detail relating to our business development efforts where we have been very active in assessing a number of opportunities

and new technologies. From a prioritization standpoint, we are focused on companies and technologies which build upon the foundation of our existing business strategies in diagnostics and molecular solutions and would allow us to leverage our infrastructure and market expertise. In Diagnostics, we recognize that OraSure's strength, and what sets us apart, is our expertise in simpler, more effortless testing. With COVID-19, we saw in real time just how important this type of testing really is. So, as we think about the future of diagnostics, OraSure is ideally positioned to drive additional self-testing and more effortless testing at the point of care. We are actively investigating new technology platforms that can expand our menu of tests on a global basis and provide long-term competitive differentiation. With the molecular solutions business we are really looking at innovative solutions which expand our capabilities from a sample collection format, expand our reach into new high growth emerging areas of testing, further strengthen our competitive positioning, and expand the scope of data and services we can offer to our clients. We ended the quarter with \$229 million in cash and cash equivalents and we believe there is a significant opportunity to drive further growth and stockholder value through external M&A.

Overall, I am extremely excited about the outlook for the next 12 months at OraSure. We are currently conducting our annual strategic review which will incorporate both broad internal stakeholder input and outside expertise in order to ensure we are taking full advantage of the strategic opportunities in front of us. We will look to share the output of this review with investors when the review is completed, along with a broader look at the innovation occurring within the organization.

With that I am pleased to turn the call over to Roberto to discuss our financial results and outlook.

Roberto Cuca – Chief Financial Officer of OraSure Technologies

Thanks Steve, I am pleased to discuss our financial results for the second quarter.

First, from a top line perspective we delivered total revenue of \$57.6 million in the second quarter of 2021 compared to \$29.3 million in the prior year representing year-over-year growth of 97%. As a reminder, last year's second quarter was the most heavily impacted by the COVID-19 pandemic, however, as Steve previously noted our core business excluding COVID-19 product revenue grew 122% year-over-year and 48% sequentially this quarter representing a significant recovery and demonstrating meaningful progress in key areas such as domestic and international diagnostics, our consumer genomics sample kits, and microbiome kits and services.

Slide – 11

Total Diagnostic revenue in the quarter was \$19.3 million vs. \$10.4 million in the previous year reflecting 85% growth. Importantly, this quarter we saw an improvement in domestic HIV, HCV, and risk assessment testing revenue, as we start to return to pre-pandemic levels. Our International Diagnostics business saw 89% growth in the second quarter vs the prior year, and grew 8% in the first half of 2021 when compared to 2020. This strong growth was achieved despite two important headwinds. First, there were expected changes in the Bill and Melinda Gates Foundation subsidy for our HIV self-test which have impacted revenue growth year-to-date. This subsidy ended on June 30th of this year pursuant to the terms of our agreement with the Foundation, and has been tapering downward for some time. In addition, as COVID-19 is now spiking across Africa, with many major countries in

lock-down, our NGO customers have experienced challenging in-country logistics efforts, which then caused delays in Q2 orders.

Slide - 12

Looking at the molecular solutions business, total second quarter revenue was \$38.3 million and increased 103% vs. the prior year. We saw a strong rebound in customer activity in the consumer and clinical genomics areas. COVID-19 revenue in molecular solutions increased 36% year-over-year to \$11.5 million but declined by 58% sequentially as PCR testing rates in the US decreased and customers lowered inventory positions. The non-COVID-19 portion of the molecular solutions business grew 61% sequentially. Looking back to the pre-pandemic period in the second-quarter of 2019, our molecular solutions business grew 45% relative to this timeframe excluding COVID-19 revenue demonstrating strong growth in the base business.

Slide – 13

Now I would like to discuss our financial results beginning with our gross margin percentage. Gross margin percentage in the second quarter was 53.2% compared to 59.0% in the same period last year. The decline in overall gross margins reflects three factors. The first was product mix in the diagnostics segment with a higher proportion of revenue coming from the lower margin international business coupled with the decline in the Gates Foundation subsidy. The second factor was the significant hiring and equipment purchases to date for the IntelliSwab™ launch which do not yet have associated positive offsets from a revenue perspective. Finally we did see higher material and labor costs in the quarter.

From an expense standpoint, total operating expenses in the quarter were \$28.9 million compared to \$26.7 million in the second quarter of last year reflecting operating expense growth of eight percent. In the quarter, we generated operating income of \$1.8 million compared to an operating loss of \$9.4 million in the previous year. Moving to the bottom line, we generated a loss per share of (\$0.02) in the second quarter of this year compared to a net loss of (\$0.16) per share in the same quarter last year. Cash used in operations for the quarter was \$3.5 million.

Slide - 14

Moving on to our financial outlook, given the continued volatility and unpredictability around COVID-19 testing, we are providing top line guidance for the fiscal third quarter with some additional color on our full year outlook. For the third quarter, we expect revenue of \$45 million to \$50 million. Additionally, we anticipate full year IntelliSwab™ revenue of approximately \$30 million with the preponderance of that occurring in the fourth quarter. This would position us to deliver full year revenue of approximately \$230 million. I wanted to review a few factors underlying our assumptions with our third quarter guidance.

First, for IntelliSwab™, although we currently have an installed capacity of 55 million tests per year we have faced some manufacturing challenges with respect to tech transfer. Although we are confident in our ability to rapidly resolve these issues, they will impact the amount of product available for sale in the third quarter. As the COVID-19 pandemic continues to evolve in the US, we have noted a declining pricing environment and have also factored that into our projections. Despite these issues, as we previously discussed, we have been receiving significant inbound interest and expect our book of business to continue to expand throughout the quarter.

With our molecular collection kits for COVID-19 PCR based testing, we are assuming a significant sequential decline in revenue given current PCR based trends. However, given the proliferation of new viral variants, the upcoming fall cold and flu season, increasing international sales, and funding for back to school programs where PCR testing is predominantly used for younger children, we believe there will likely will be a rebound in our PCR kit sales for COVID-19 testing products this fall. So ultimately this assumption could prove conservative.

As we look to our fourth quarter we would anticipate a significant sequential uptick in revenue as IntelliSwab™ revenues become much more pronounced. Although our third quarter outlook is conservative, we are focused on establishing a revenue baseline that is achievable with the potential for upside if we outperform our current assumptions.

With that, I'll to turn the call back over to Steve.

Slide – 15

Dr. Stephen Tang, President and CEO of OraSure Technologies

Thanks Roberto, as a company we are at an exciting point in our history and the progress we have made from a fundamental perspective is beginning to become evident in our financial results. This quarter, we demonstrated the increasing strength of our core franchise with non-COVID revenue of \$46 million, representing almost a \$200 million annual run rate. That would be an historic high for our total revenue.

We have now entered the commercialization phase with IntelliSwab™. We remain confident that IntelliSwab™ will be a significant driver of revenue growth and free cash flow and also a long-term product for the Company as we ultimately enter the endemic phase of the disease. Our molecular solutions business is on increasingly strong footing as we build out new product and service capabilities, increase the number of sample types we can accommodate, and expand into new fields of testing with end markets growing in the mid-teens. Finally, we are reinvigorating the innovation engine of the Company, and look to introduce new technologies through internal R&D, external collaborations and M&A. Overall, we believe we will be poised to emerge from the pandemic a stronger, more innovative and faster growing company.

With that, I would like to turn the call back over to Scott for Q&A.

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Scott Gleason – SVP of IR and Corp. Communications

Thanks, Steve. Operator we are now ready to begin the Q&A portion of the call. We would ask that you limit your questions to one question and one follow up to ensure broad participation.

Final Conclusion

Thank you for participating in today's call and for your continued interest in OraSure. Have a good afternoon and evening. Stay safe and be well.

Important Information

This document 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 collection products 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 Securities and Exchange Commission (“SEC”) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2020, 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 call and we undertake no duty to update these statements.

OraSure 2Q21 Earnings

August 3, 2021



Forward-Looking Statements Disclaimer

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These and other factors that could affect the Company's 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, 2020, 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 presentation and OraSure Technologies undertakes no duty to update these statements.



2Q21 Financial Results



| FINANCIAL METRIC | 2Q21 RESULTS | 2Q20 RESULTS | GROWTH RATE |
|---|----------------|----------------|-------------|
| 2Q21 Total Revenue | \$57.6 million | \$29.3 million | 97% |
| 2Q21 Total Revenue Excluding COVID-19 Product Revenue | \$46.0 million | \$20.8 million | 122% |
| 2Q21 COVID-19 Product Revenue | \$11.6 million | \$8.5 million | 36% |



Key Focus Areas to Drive Shareholder Value



Capitalize on COVID-19 Testing Opportunity To Fund Future Growth



Expand Into New Sample Types and New Testing Modalities in Molecular Solutions



Expand Global Commercial Capabilities and Reach



Drive Higher Growth Through Expanded R&D and M&A



InteliSwab™: Designed to be the Simplest COVID-19 Test on the Market

- Authorized by FDA for OTC, Prescription Home Use and Professional Point-of-Care CLIA-Waived use
- Accuracy comparable to other point-of-care offerings (84% sensitivity / 98% specificity)
- Convenient sample collection with <1 min. of hands on time; results in 30 min. More than 98% of users find InteliSwab™ easy to use
- Visually read, lateral flow test; No instrumentation, internet access or laboratory analysis needed to interpret results
- Swab is fully integrated into the test stick eliminating dependence on nasal swabs



SWAB both nostrils



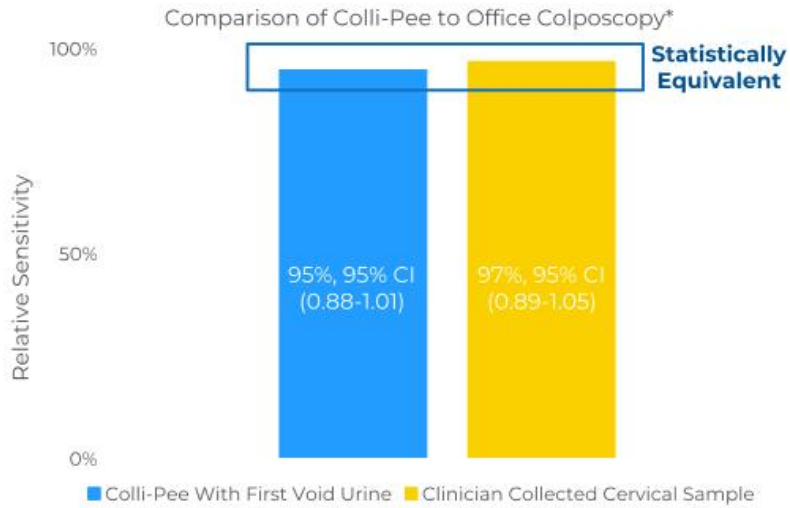
SWIRL in the tube



SEE your results



Colli-Pee® , New Innovation in Sample Collection; Addressing Global HPV Screening Market



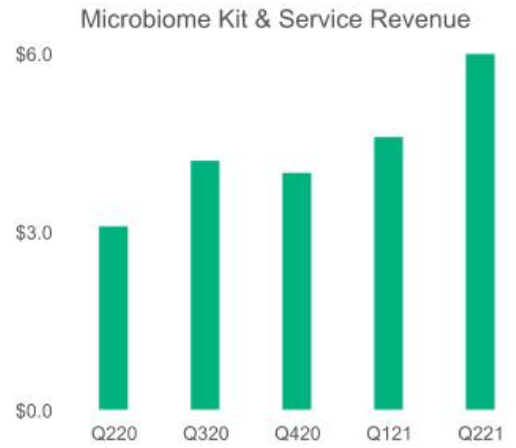
*Van Keer et al., <https://doi.org/10.1016/j.ygyno.2021.08.010>



Microbiome Becoming an Increasingly Important Growth Driver



- Partnered with top-5 companies in microbiome space
- Working with 5 of 10 of the top pharma companies globally
- Seeing growth from new market such as animal health



- Upcoming Catalysts:
- Maturity of clinical trials in progress
 - Meta-transcriptome launch
 - New gut collection kit



Expanding Molecular Collection Device Competitiveness Through Multiple Strategies



Expanding intellectual property portfolio through filed patents and technology acquisitions

(38 patents filed to date on collection devices)



Long-term contracts with major customers providing forward visibility



Increased regulatory approvals in conjunction with commercial partners



Customer kit specialization and increased service scope

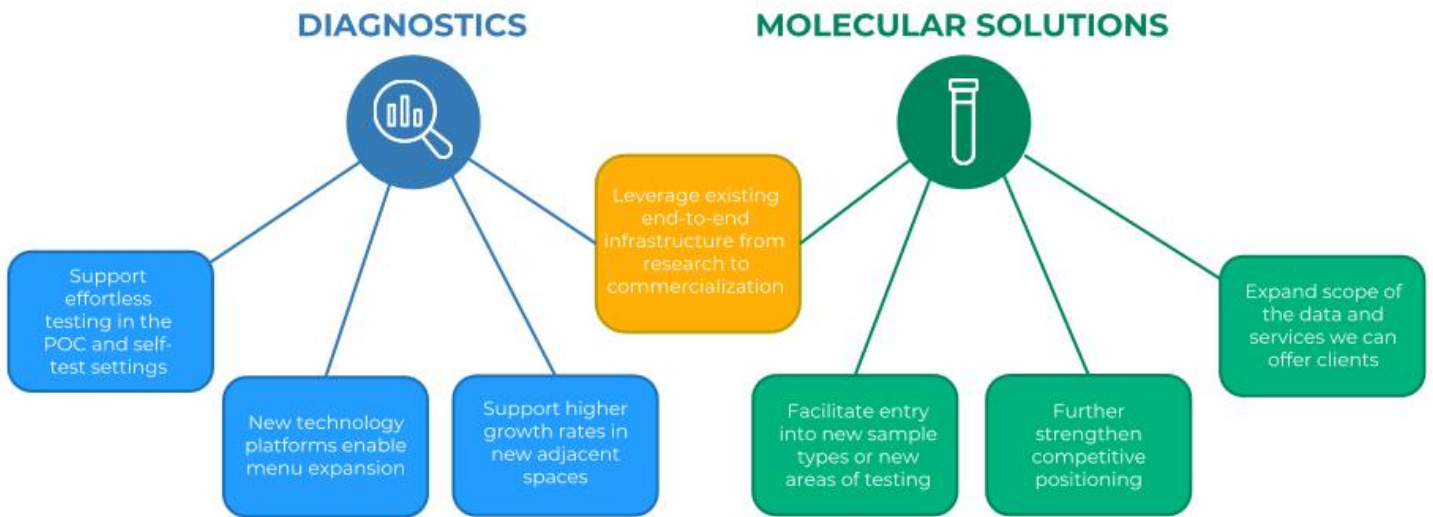


Expanding Global Reach To Broaden Market Access

We now have over **400**
product registrations in
95 countries globally



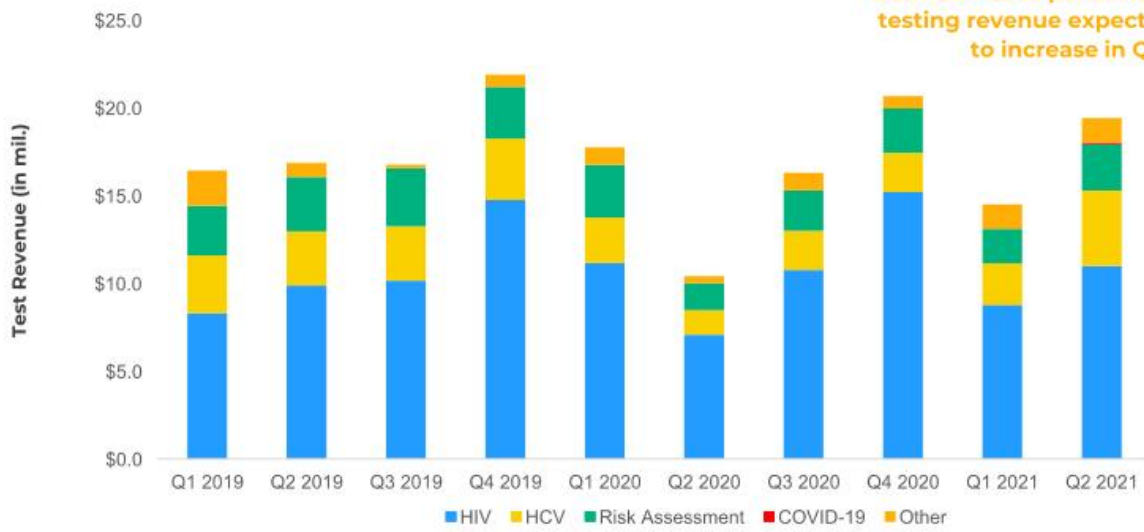
Actively Evaluating Strategically Sound M&A Opportunities



Revenue in Key Diagnostic Testing Categories

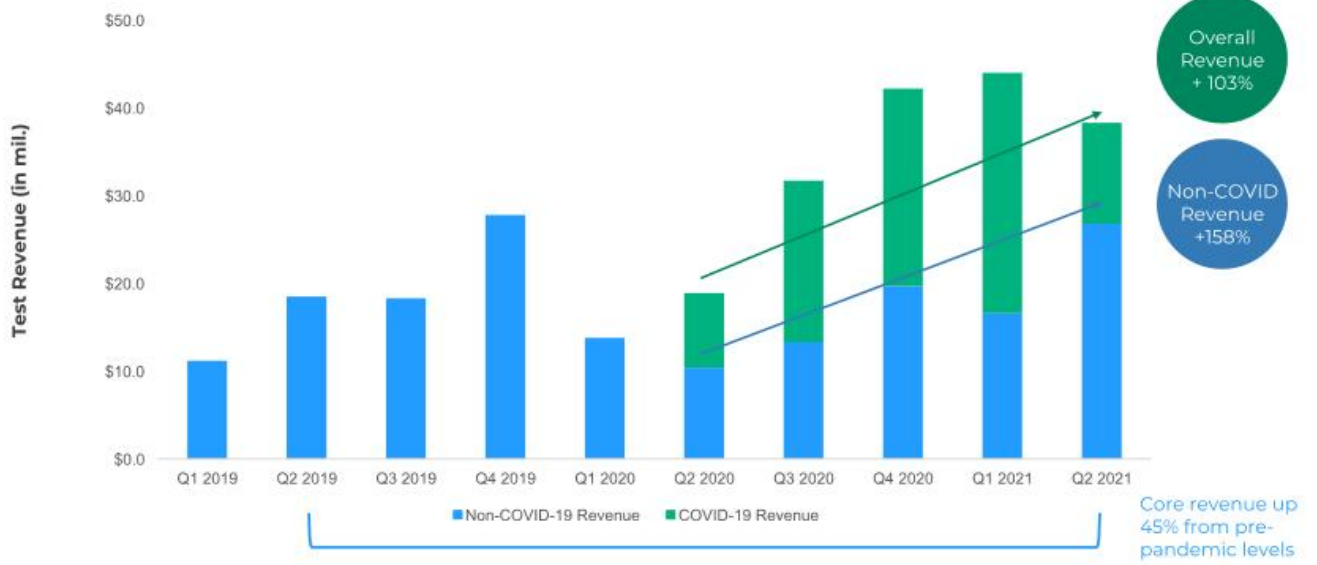
Recovering From Pandemic & Launching COVID-19 Antigen Test

Diagnostic business recovering from COVID-19 pandemic. COVID-19 testing revenue expected to begin to increase in Q321



Strong Core Growth in Molecular Solutions

One of Strongest Quarters Ever from Genomics & Microbiome Services



Financial Results

| | Three Months Ended | |
|--|--------------------|-------------|
| | June 30, | |
| | 2021 | 2020 |
| Results of Operations | | |
| Net revenues | \$ 57,607 | \$ 29,259 |
| Cost of products and services sold | 26,934 | 11,995 |
| Gross profit | 30,673 | 17,264 |
| Operating expenses: | | |
| Research and development | 7,682 | 6,924 |
| Sales and marketing | 10,420 | 10,121 |
| General and administrative | 10,993 | 10,280 |
| Change in fair value of acquisition-related contingent consideration | (220) | (660) |
| Total operating expenses | 28,875 | 26,665 |
| Operating income (loss) | 1,798 | (9,401) |
| Other income | 448 | 216 |
| Income (loss) before income taxes | 2,246 | (9,185) |
| Income tax expense | 3,610 | 1,309 |
| Net income (loss) | \$ (1,364) | \$ (10,494) |
| Earnings (loss) per share: | | |
| Basic | \$ (0.02) | \$ (0.16) |
| Diluted | \$ (0.02) | \$ (0.16) |
| Weighted average shares: | | |
| Basic | 71,983 | 64,745 |
| Diluted | 71,983 | 64,745 |



3Q21 Financial Guidance & FY21 IntelliSwab™ Guidance

| GUIDANCE METRIC | FINANCIAL GUIDANCE |
|---------------------------|---------------------|
| 3Q21 Total Revenue | \$45 - \$50 million |
| FY21 IntelliSwab™ Revenue | ≈\$30 million |
| FY21 Total Revenue | ≈\$230 million |



Summary

- Commercially tied to high growth areas of healthcare such as consumer/clinical genomics and shift to direct-to-patient/near patient testing
- Increased investment in internal R&D pipeline and reinvigorating innovation
- Significant opportunity with COVID-19 testing solutions to drive growth and fund additional investment
- Strong balance sheet with focus on deploying capital to drive growth and leverage infrastructure

Smart Science Made Simple



Q&A



OraSure Technologies

ONAGENOTEK™

 Diversigen

 novoSanis