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): May 10, 2022

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

220 East First Street	
Bethlehem, Pennsylvania	**18015-1360**
(Address of Principal Executive Offices)	**(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 May 10, 2022, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended March 31, 2022 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.

Item 7.01 – Regulation FD Disclosure.

On May 10, 2022, the Company held a webcast conference call with analysts and investors, during which members of the Company's management team, including Nancy J. Gagliano, M.D., M.B.A., the Company's interim Chief Executive Officer, and Scott Gleason, the Company's Interim Chief Financial Officer and Senior Vice President, Investor Relations and Corporate Communications, discussed the Company's consolidated financial results for the quarter ended March 31, 2022, and described certain business developments.

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 Exhibits 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 Exhibits.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated May 10, 2022, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2022 and certain other matters.
99.2	Slide Presentation for OraSure Technologies, Inc. First Quarter 2022 Analyst/Investor Conference Call Held May 10, 2022.
Exhibit 104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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

ORASURE TECHNOLOGIES, INC.

Date: May 10, 2022

By: */s/ Scott Gleason*

Scott Gleason

Interim Chief Financial Officer and Senior Vice President, Investor Relations and Corporate Communications

EXHIBIT 99.1

OraSure Technologies, Inc.

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OraSure Reports 1Q22 Record Revenue of $67.7 Million; +16% Year-Over-Year With 21% Growth in Non-COVID Revenue

InteliSwab® revenue of $22.1 million in Q1, up 50% sequentially with significant scaling in production

Non-COVID molecular kits increase 42% year-over-year demonstrating continued strong growth

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

BETHLEHEM, PA, May 10, 2022 (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 March 31, 2022.

“We made significant progress in the quarter scaling InteliSwab® production and improving the efficiency of our manufacturing process as we look to drive profitable growth,” said OraSure Interim President and CEO Nancy J. Gagliano, M.D., MBA. “Excluding COVID-19 products, both our Diagnostics and Molecular Solutions businesses grew at a double-digit rate year-over-year.”

She continued, “We once again saw exceptionally strong demand for our molecular kits business, with our non-COVID-19 core collection kit business growing 36% versus the same quarter a year ago. We also continue to launch innovative offerings such as our first-of-its-kind U.S. Food and Drug Administration (FDA) de novo authorized microbiome gut collection kit and our new metatranscriptome services offering, with new offerings to be launched this quarter. In addition, we continue to expand our market coverage with our base of active purchasing Molecular Solutions customers growing 6% in the quarter, positioning us for continued long-term growth.”

Financial Highlights

- Net revenues for the first quarter of 2022 were $67.7 million, a 16% increase from the first quarter of 2021 and a new record for the Company. Excluding COVID-19 product revenues, revenues for the quarter increased 21% year-over-year.
- Total revenues from the Company’s Diagnostic business unit were $38.3 million during the first quarter of 2022 and grew 163% relative to the same period last year. Revenue growth was driven primarily by InteliSwab®. Excluding InteliSwab® sales, total Diagnostic business unit revenue grew 11% year-over-year.

- Total product and service revenues for the Company's Molecular Solutions business unit were $29.4 million during the first quarter of 2022, a decline of 33% from the first quarter of 2021. The decline was driven entirely by lower sales of the Company's COVID-19 molecular collection kits given the expected transition to point of care solutions, as well as customers working through high inventory levels. Excluding these COVID-19 revenues, the molecular solutions business grew 28% year-over-year.
- Gross margin in the first quarter was 36% and was negatively impacted by one-time InteliSwab® manufacturing costs including high scrap rates during the quarter and under-absorption as the Company worked to scale InteliSwab® production. Additionally, average selling prices for InteliSwab® declined on a sequential basis as the mix of the first quarter revenue was primarily related to the Company's government procurement contract compared to fourth quarter 2021 revenue which consisted of predominantly commercial sales. Furthermore, product mix drove declining margins with more revenue coming from the Company's Diagnostic business unit, as well as lower revenues from higher margin COVD-19 collection kits. In addition, gross margin was negatively impacted by the expiration of subsidies for the international sale of our HIV Self-Test under the charitable support agreement with the Gates Foundation ,which expired in June 2021. The Company currently has a number of programs in place which are intended to improve gross margins including efficiency programs associated with production, changes in logistical processes, product packaging redesign, and supply chain consolidation.
- Operating loss in the first quarter was ($16.0) million compared to operating income of $10.4 million in the first quarter of last year. OraSure's operating loss in the quarter was driven by an increase in investments to support the InteliSwab® scale-up, one-time production inefficiencies, continued development, and approximately $4.9 million in one-time expenses tied to the company's strategic alternative process and CEO transition.
- Cash flow used in operations in the quarter was ($35.8) million which was impacted by working capital changes due to increases in accounts receivable and inventory levels associated with the InteliSwab® scale up. Cash and investments totaled $112.2 million at March 31, 2022. As of March 31, 2022, the Company also had approximately $16.9 million in funds committed to the capacity expansion build out associated with the Department of Defense contract which will be reimbursed in future periods.

Recent Business Highlights

InteliSwab® COVID-19 Testing

- InteliSwab® revenue in the quarter grew to $22.1 million representing over 50% sequential growth relative to the fourth quarter.
- Production volumes of InteliSwab® scaled dramatically during the first quarter. In early April, the company demonstrated the ability to produce tests at volume equivalent to the Company's installed capacity representing over a four-fold increase from production levels in early January. During the quarter, the company resolved major production issues and is now in full production phase.
- The Company has been highly focused on improving production efficiencies as well. Finished goods scrap rates for InteliSwab declined to less than 1% by late March from over 30% in early January.
- OraSure announced that the InteliSwab® COVID-19 rapid tests detect the Omicron variant with similar limits of detection to the original SARS-CoV-2 strain and other previous variants of concern, including Delta, Alpha, Beta and Gamma.

Diagnostics Business Results (excluding InteliSwab®)

- Excluding InteliSwab® revenue, the Diagnostics legacy revenue was $16.2M and grew 11% compared to the prior year quarter.
- International Diagnostics revenue was $5.6M in Q1, a20% increase compared to the prior year period. Excluding the impact of the Bill and Melinda Gates Foundation subsidy expiry in June 2021, the business grew 34% year-over-year.
- U.S. Diagnostics revenue, excluding InteliSwab®, was $10.5M and grew 7% year-over-year despite lapping the Q1 2021 Center for Disease Control's, "Let's Stop HIV Together," home testing program which was not repeated this quarter.
- The Company launched the OraQuick® HIV Self-Test, an oral swab in-home test for HIV-1 and HIV-2, into Europe. The test will be available in six European countries: United Kingdom, Germany, France, Italy, Spain and Portugal.

Molecular Solutions

- Genomics collection kit revenue of $15.1 million for the first quarter of 2022 grew 40% year-over-year.
- Sales of OraSure's sample collection devices for molecular/PCR COVID-19 testing decreased 68% year-over-year to $8.9 million in the first quarter of 2022 compared to $28.0 million in the prior year period. The decline in revenue is attributable to lower testing volumes with core customers as the market transitions to point-of-care solutions such as rapid antigen tests and customers work through current inventory levels of collection kits.
- Total microbiome revenue, including kits and services, was $3.7 million in the quarter and declined 12% relative to the first quarter of last year. During the quarter, services revenue was negatively impacted by the delayed timing of customer clinical trials. Microbiome collection kits grew 14% in Q1 compared to the prior year.
- Received U.S. Food and Drug Administration (FDA) de novo authorization for the OMNIgene®·GUT Dx (OMD-200) microbiome collection device and commercially launched the product. OMNIgene®·GUT Dx is the first FDA approved collection kit specifically targeted to the collection of stool-based microbiome samples.
- Launched a new service to provide metatranscriptomic sequencing and analysis of gut microbiome samples through the Company's Diversigen subsidiary. As part of the launch, the company created a comprehensive, curated database with more than 190,000 genomes, representing 31,000 species of microbes, to allow profiling of microbial gene expression, including functional modules and pathways. Metatranscriptomic sequencing provides powerful insights not possible with other sequencing technologies.

Strategic Alternatives Review and CEO Search

On January 5, 2022, the Company announced it is exploring strategic alternatives. The review is ongoing, and no decisions have been made.

Consistent with the first quarter, OraSure will not be providing guidance for the second quarter given the ongoing strategic alternative process.

Additionally, the company has hired an external search firm and is in the process of looking for a permanent chief executive officer. Dr. Nancy J. Gagliano has been appointed as interim President and CEO by the Board of Directors and is not a candidate for the full-time position.

Financial Data (Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Results of Operations		
Net revenues	$ 67,707	$ 58,582
Cost of products and services sold	43,435	20,256
Gross profit	24,272	38,326
Operating expenses:		
Research and development	8,413	8,992
Sales and marketing	12,717	9,530
General and administrative	19,156	10,188
Change in fair value of acquisition-related contingent consideration	(36)	(806)
Total operating expenses	40,250	27,904
Operating income (loss)	(15,978)	10,422
Other expense	(53)	(119)
Income (loss) before income taxes	(16,031)	10,303
Income tax expense	3,936	6,529
Net income (loss)	$ (19,967)	$ 3,774
Earnings (loss) per share:		
Basic	$ (0.28)	$ 0.05
Diluted	$ (0.28)	$ 0.05
Weighted average shares:		
Basic	72,194	71,878
Diluted	72,194	72,766

	Three Months Ended March 31,		
	2022	2021	% Change
DIAGNOSTICS			
Infectious Disease Testing Revenues			
Domestic HIV	$ 3,765	$ 5,293	(29) %
International HIV	4,401	3,486	26
Net HIV revenues	8,166	8,779	(7)
Domestic HCV	2,036	1,182	72
International HCV	1,221	1,184	3
Net HCV revenues	3,257	2,366	38
Net OraQuick® revenues	11,423	11,145	2
COVID-19	22,136	-	NM
Other infectious disease revenues	277	226	23
Total Infectious Disease	33,836	11,371	198
Risk Assessment	2,560	1,962	30
Other non-product revenues	1,914	1,213	58
TOTAL DIAGNOSTIC NET REVENUE	38,310	14,546	163
MOLECULAR SOLUTIONS			
Genomics	$ 15,093	$ 10,818	40
Microbiome	1,990	1,751	14
COVID-19	8,896	27,972	(68)
Laboratory services	1,733	2,497	(31)
Other product and services revenues	1,128	208	442
Net product and service revenues	28,840	43,246	(33)
Other non-product and service revenues	557	790	(29)
TOTAL MOLECULAR SOLUTIONS NET REVENUE	29,397	44,036	(33)
TOTAL NET REVENUES	$ 67,707	$ 58,582	16 %

Condensed Consolidated Balance Sheets (Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 70,721	$ 116,762
Short-term investments	41,503	36,279
Accounts receivable, net	59,671	45,323
Inventories	61,536	53,138
Other current assets	34,933	36,929
Property, plant and equipment, net	97,572	88,164
Intangible assets, net	13,692	14,343
Goodwill	40,389	40,279
Long-term investments	-	17,009
Other noncurrent assets	15,515	12,764
Total assets	$ 435,532	$ 460,990
Liabilities and Stockholders' Equity		
Accounts payable	$ 27,057	$ 28,024
Deferred revenue	2,906	2,936
Other current liabilities	25,624	37,104
Other non-current liabilities	15,059	12,393
Stockholders' equity	364,886	380,533
Total liabilities and stockholders' equity	$ 435,532	$ 460,990

Additional Financial Data (Unaudited)	Three months ended March 31,	
	2022	2021
Capital expenditures	$ 22,074	$ 11,061
Depreciation and amortization	$ 3,682	$ 2,489
Stock-based compensation	$ 3,524	$ 1,464
Cash used in operating activities	$ 35,821	$ 4,393

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's first quarter 2022 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. Nancy J. Gagliano, President and Chief Executive Officer, Lisa Nibauer, President Diagnostics, Kathleen Weber, President Molecular Solutions, and Scott Gleason, Interim 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 (877) 344-8082 (Domestic) or (213) 992-4618 (International) and reference Conference ID #4956626 with pin number 3180 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, May 24, 2022, by dialing 800-645-7964 and entering playback ID: 4132#.
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 InteliSwab®

OraSure has received Emergency Use Authorizations (EUA) from the FDA for its InteliSwab® COVID-19 rapid tests. The FDA has authorized the InteliSwab® COVID-19 Rapid Test for Over-the-Counter (OTC) use without a prescription. The 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. These remarkably simple COVID-19 lateral flow tests use samples self-collected from the lower nostrils. InteliSwab®'s unique design incorporates a built-in swab fully integrated into the test stick. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution, and the result appears right on the test stick within 30 minutes, with no instruments, batteries, smartphone or laboratory analysis needed to see the result. With less than one minute of "hands-on time," it is as simple as "Swab, Swirl, and See."

This product has not been FDA cleared or approved, but it has been authorized by the FDA under an EUA. The emergency use of this product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Multiple government agencies, including the U.S. Department of Defense (DoD) and Department of Health and Human Services (HHS) are working to address COVID-19 testing needs. Development of the InteliSwab® COVID-19 Rapid Test has been funded in whole or in part with federal funds from the HHS; the Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division

of Research, Innovation and Ventures under contract numbers 75A50120C00061 and 75A50121C00078, utilizing Health Care Enhancement Act (HCEA) funding. The DoD's Defense Assisted Acquisition (DA2) Cell led the manufacturing expansion effort for the InteliSwab® COVID-19 rapid test in coordination with the Department of the Air Force's Acquisition COVID-19 Task Force (DAF ACT). The manufacturing effort was funded through the American Rescue Plan Act (ARPA) to enable and support domestic industrial base expansion for critical medical resources.

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 products, product development activities, regulatory submissions and authorizations, revenue growth, increasing margins 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: risk that the Company's exploration of strategic alternatives may not result in any definitive transaction or enhance stockholder value and may create a distraction or uncertainty that may adversely affect operating results, business or investor perceptions; the diversion of management's attention from the Company's ongoing business and regular business responsibilities due to the Company's exploration of strategic alternatives; ability to resolve the Company's ongoing manufacturing challenges and satisfy customer demand; 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 the Company's business, supply chain, labor force, and 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; 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, civil unrest, hostilities and war ; 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, 2021, 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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EXHIBIT 99.2

OraSure 1Q22 Earnings

May 10, 2022

OraSure Technologies

DNAgenotek™ Diversigen® novosanis

Forward-Looking Statements Disclaimer

This presentation contains certain forward-looking statements, including with respect to 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: risk that the Company's exploration of strategic alternatives may not result in any definitive transaction or enhance stockholder value and may create a distraction or uncertainty that may adversely affect operating results, business or investor perceptions; the diversion of management's attention from the Company's ongoing business and regular business responsibilities due to the Company's exploration of strategic alternatives; ability to resolve the Company's ongoing manufacturing challenges and satisfy customer demand; 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 the Company's business and 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; 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.

1Q22 Financial Results

FINANCIAL METRIC	1Q22 RESULTS	1Q21 RESULTS	YEAR-OVER-YEAR GROWTH RATE
Quarterly Revenue	$67.7 million	$58.6 million	16%
Diagnostics Revenue	$38.3 million	$14.5 million	163%
Diagnostics Revenue W/O COVID-19 Products	$16.2 million	$14.5 million	11%
Molecular Solutions Revenue	$29.4 million	$44.0 million	(33%)
Mol. Solutions Revenue W/O COVID-19 Products	$20.5 million	$16.1 million	28%

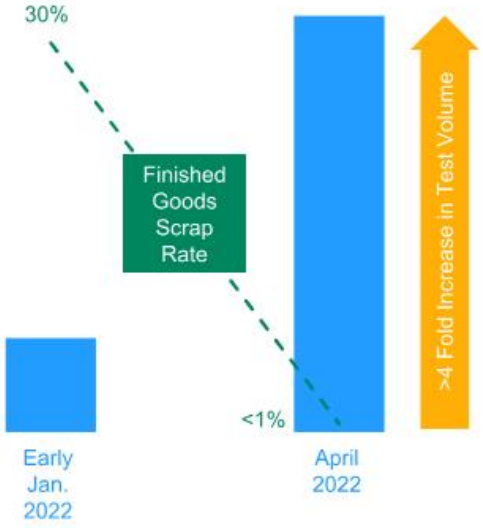
1Q22 Diagnostic Business Unit Results

	Q4 2021	% vs PY
Total DX BU	$38.3M	+163%
Core DX	$16.2M	11%
Core DX US	$10.5M	7%
Core DX OUS	$5.6M	20%
COVID-19	$22.1M	NM

Significant Improvements in Production Process

Major Process Changes

1. Eliminated manual handling steps
2. Changed settings on robotic assembly
3. Optimized settings on automated striping and assay card assembly machines
4. Significant ramp in hiring and training



US Government Continues Support for InteliSwab®

- **Continued Procurement as part of OraSure's Defense Logistics Agency/HHS contract**
  - Consistent ongoing testing needed in congregate settings
  - Evens out demand, enables shipments even during low points between surges

InteliSwab® Recent Expansions

InteliSwab® detects Omicron with same limit of detection as other variants of concern and original Wuhan strain

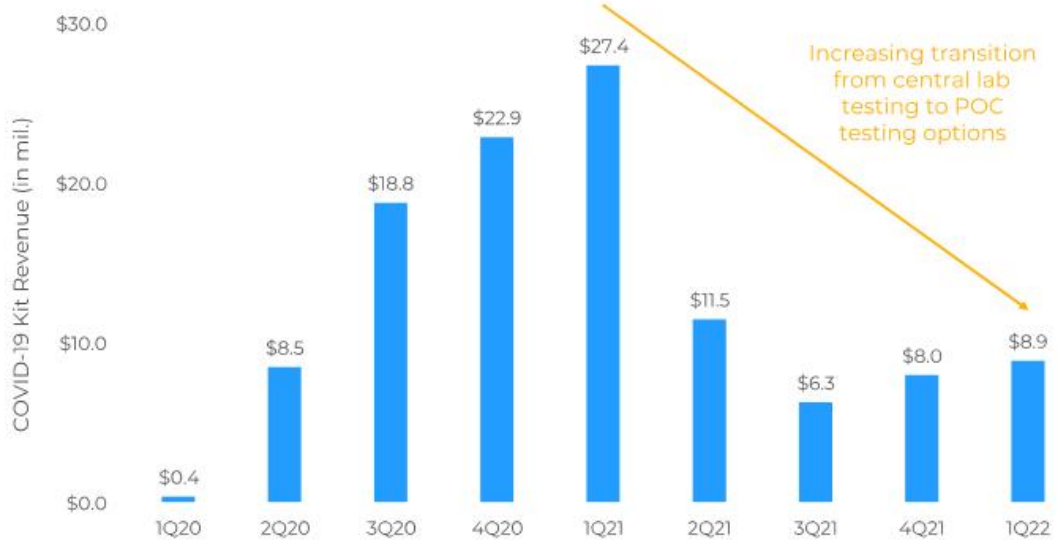
Pediatric indication for use in children ages 2-14 when performed by an adult

Launched the reporting app, InteliSwab® Connect

4Q21 and FY21 Molecular Solutions Business Unit Results

FINANCIAL METRIC	1Q22	1Q21	YEAR-OVER-YEAR GROWTH RATE
Quarterly Core Molecular Solutions	$20.5 million	$16.1 million	28%
Quarterly COVID-19 Kits	$8.9 million	$28.0 million	(68%)
Total Molecular Solutions	$29.4 million	$44.0 million	(33%)

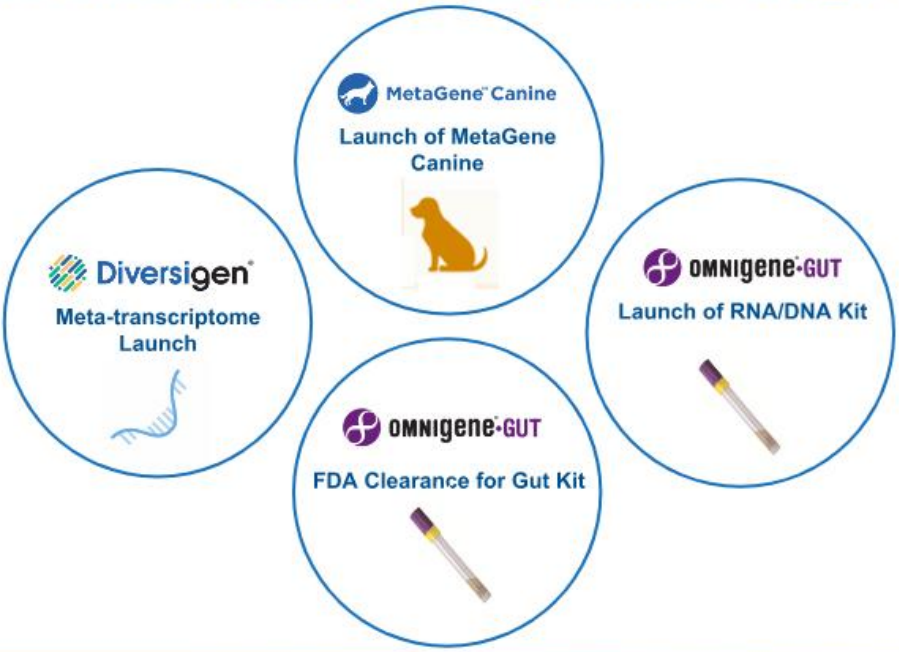
Molecular Solutions COVID-19 Kit Revenue



GOING FORWARD:

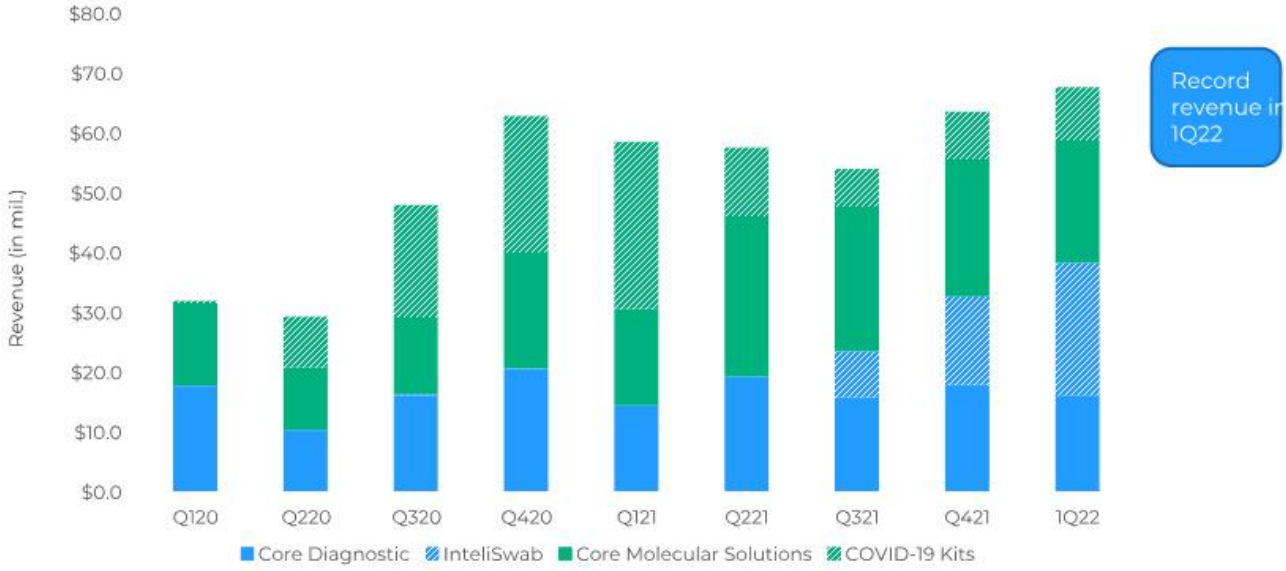
- International expansion
- Broader launch in viral surveillance

Enabling Multi-Omic Discovery and Diagnostics Through Innovation



Consolidated Revenue by Quarter

Record Revenue in 1Q22



Financial Results

Summary

- Significant improvements made in InteliSwab production and manufacturing efficiency
- Strong double-digit core growth in both business units
- 36% growth in molecular kits year-over-year
- Focused on continued efficiency and expense reduction

Smart Science Made Simple

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