

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): September 8, 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.

7.01 – Regulation FD Disclosure.

OraSure Technologies, Inc. (the “Company”) hereby furnishes the Investor Presentation that the Company will present to analysts and investors on or after the date hereof, which is attached as Exhibit 99.1 to this Current Report, is incorporated herein by reference and will be available on the Company’s website at www.orasure.com. The information contained in the Investor Presentation is summary information that is intended to be considered in the context of the Company’s Securities and Exchange Commission (“SEC”) filings and other public announcements that the Company may make, by press release or otherwise, from time to time.

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 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	OraSure Technologies, Inc. Investor Presentation dated August 2021.
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: September 8, 2021

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

Investor Presentation

August 2021



OraSure Technologies

DNAGENOTEK™



Diversigen®



novosanis

Forward-Looking Statements Disclaimer

This presentation contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; impact of increased or different risks arising from the acquisition of companies located in foreign countries; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration ("FDA") or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collector products and commercialize such products for COVID-19 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 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.



OraSure's Mission and Vision

OUR MISSION:

"Our mission to do good and help solve the world's greatest health challenges is what drives us. We are committed to making a difference in the world of individual and public health by enabling access to discovery and diagnostics."

OUR VISION:

"We envision a company that drives access to multiple layers of information and data to understand health, wellness, and disease states – and pioneers groundbreaking ways of understanding what's in us, on us and around us."

"Smart science made simple."



We Play Where Healthcare is Going



Move to point-of-care home testing



Growth of personalized medicine



Healthcare consumerism



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



Our Focused Business Units

DIAGNOSTICS

OraSure Technologies provides accurate, effortless, high-value point-of-care and self-test diagnostic solutions for:

- Infectious Disease Testing
 - HIV
 - HCV
 - COVID-19
 - EBOLA and FLU
- Oral fluid substance abuse testing



37% of FY20 product revenue

MOLECULAR SOLUTIONS

Sampling

Sample collection & stabilization by DNA Genotek and Novosanis devices, facilitate multi-omic testing and near-patient/home testing

- Best-in-class tools and chemistries
- Multiple samples/analytes

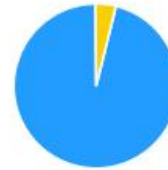


56% of FY20 product revenue

Services

Diversigen is the leader in the emerging, high-growth field of microbiome lab services

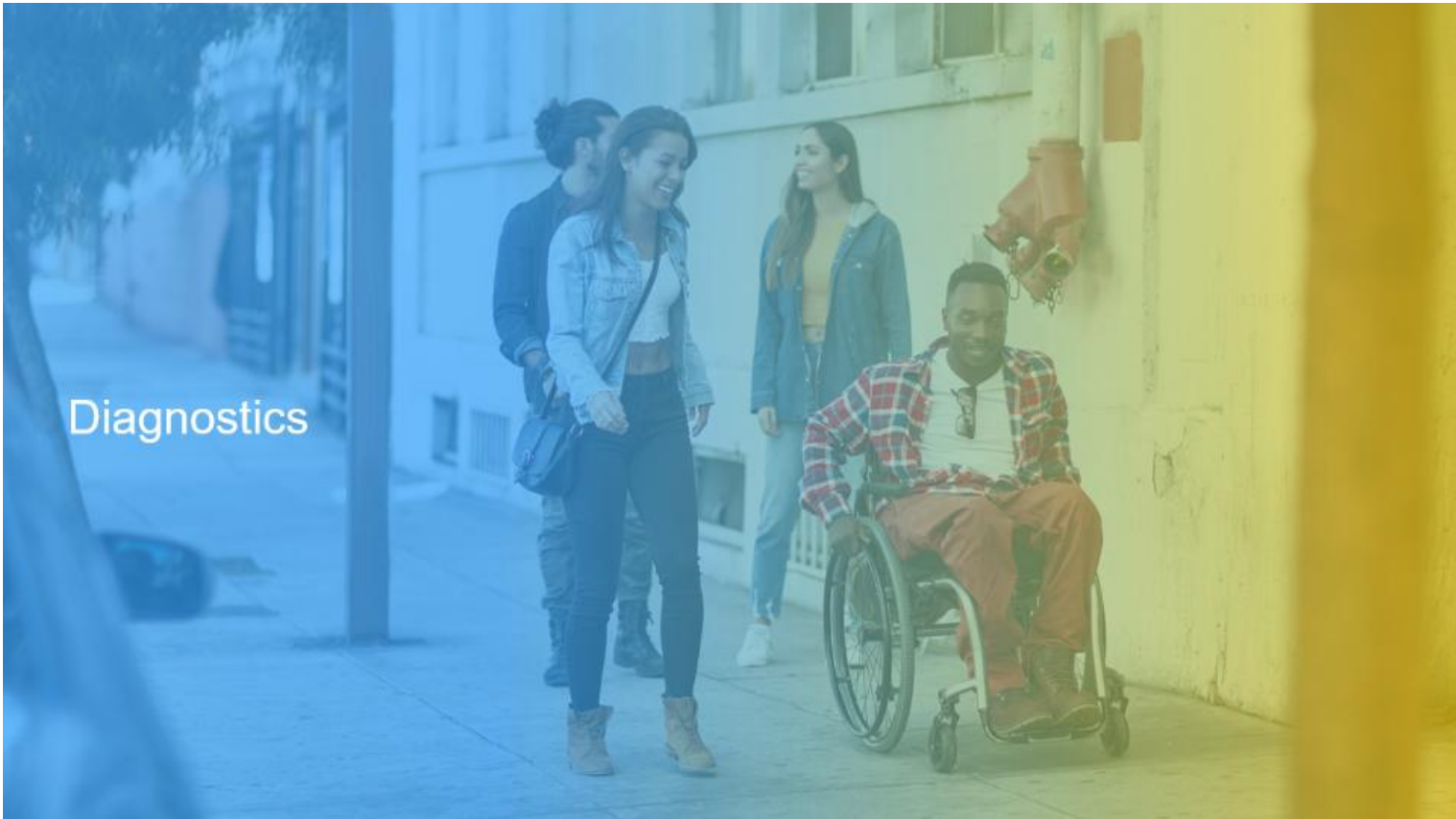
- Clinical trial support for pharma
- Consumer testing
- Customization, analysis, & consulting



4% of FY20 product revenue



Diagnostics



Expert in Effortless Near-Patient Testing for Public Health

Disease	OraSure Products	Product Differentiation	U.S./Global Disease Incidence	Testing Recommendations	Number of Tests in U.S. Each Year (All Methods)	Global Testing	% of Global Tests (POC)	Global Market Growth
COVID-19	<ul style="list-style-type: none"> IntelliSwab™ COVID-19 Rapid Test 	<ul style="list-style-type: none"> Designed to be one of the simplest tests on the market 	N/A	<ul style="list-style-type: none"> Testing has EUA in the professional, prescription self test, and over-the-counter settings 	≈ 250M (2020)	≈ 1.2B (2020)	> 60% antigen globally	Variable
HIV	<ul style="list-style-type: none"> OraQuick® HIV 	<ul style="list-style-type: none"> Only FDA approved test for over-the-counter home testing Saliva based test 	1.2M / 38M	<ul style="list-style-type: none"> 13-64 at least once in their life Those with risk factors tested annually or every 3-6 months 	30-40M	80-100M	20-25%	5-7%
HCV	<ul style="list-style-type: none"> OraQuick® HCV 	<ul style="list-style-type: none"> Simple highly accurate test using finger stick blood 	2.4M / 71M	<ul style="list-style-type: none"> Testing at least once in a lifetime All adults born between 1945-1965 Patients with high risk factors 	8-10M	75-90M	15-20%	5-7%
Substance Abuse	<ul style="list-style-type: none"> Intercept® Oral Fluid Drug Testing System 	<ul style="list-style-type: none"> Ability to use oral fluid as the sample collection and visually ensure compliance 	N/A	<ul style="list-style-type: none"> Employer screening Drug treatment and pain management Insurance screening 	15-20M	Less than 5% of products sold outside of North America	10% oral fluid	5-7%

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



Continued elevated need for simple point-of-care testing; Long-term market as COVID-19 becomes endemic

U.S. Testing Data



Pending Testing Catalysts

- Indication expansion for children 2-15
- COVID-19 public health reporting app launch
- Registrations in international markets accepting U.S. FDA EUA
- Back to school and back to work programs
- Upcoming cold and flu season
- Disease seasonality
- New variants of the virus
- CE Mark

Testing Capacity Expansion



Key Growth Drivers for the Diagnostic Business



OraQuick® HIV

- FY 2021 federal budget includes \$386 million for "Ending the HIV Epidemic," implementation, up from \$267 million in FY2020
- OUS testing grew at double digit rate (FY15-FY20)
- PrEP - need to verify HIV status routinely



OraQuick® HCV

- Advent of new effective treatments
- Declining cost of antiviral therapy
- OUS direct to patient opportunity



Intercept® Oral Fluid Drug Testing System

- Transition to oral fluid DOA testing (SAMHSA guidelines)
- Increase in hiring
- DTP testing laboratories



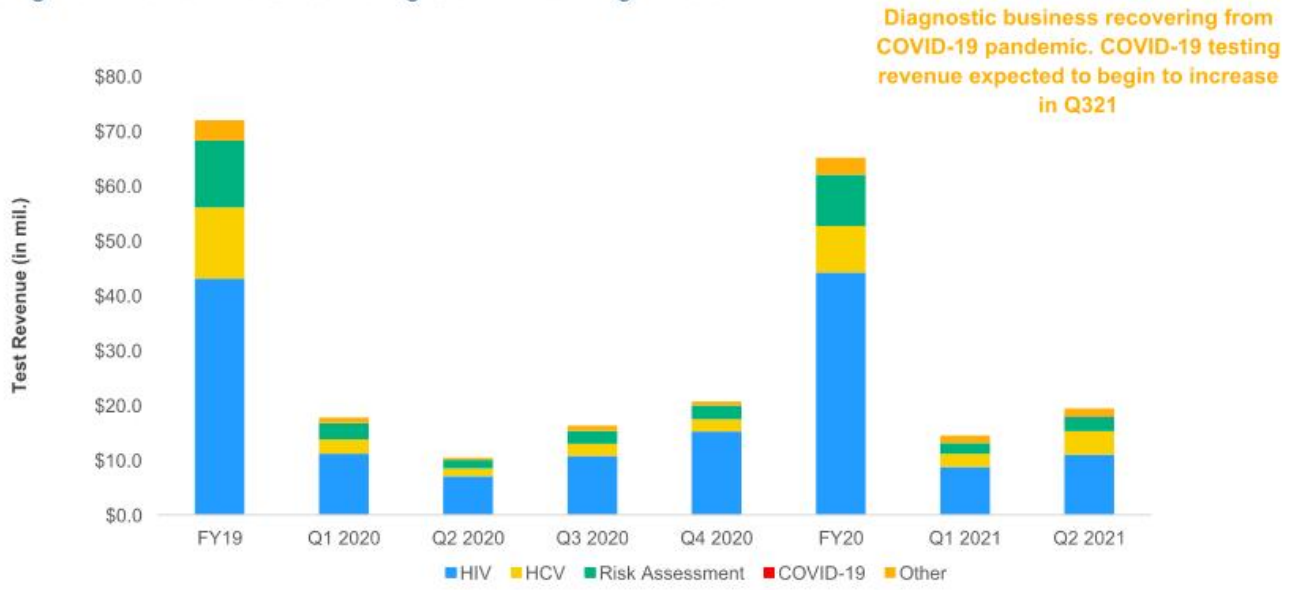
InteliSwab™

- Home testing opportunity
- Retail pharmacy
- Partnerships with businesses and schools
- Government testing
- International expansion



Revenue in Key Diagnostic Testing Categories

Recovering From Pandemic & Launching COVID-19 Antigen Test



A woman with grey hair, wearing a white lab coat, is working in a laboratory. She is holding a test tube in her right hand and a petri dish in her left hand, appearing to be in the process of transferring liquid. The background shows laboratory equipment and a window. The image has a blue and yellow color gradient overlay.

Molecular Solutions

A Global Leader in Sample Collection & Service Solutions for Multi-omic Customers

WHO WE SERVE

Provider of best-in-class, proprietary sample collection systems and services to major academic, clinical, and consumer genomics focused labs



Direct-to-patient laboratories



Clinical Genomics



Academic Labs



Consumer Genomics

END MARKETS GROWING IN MID-TEENS



WHAT WE DO



Sample collection kits across a variety of specimen types and applications



Data and fulfillment services



Multi-omic research & testing services (initial focus in microbiome)



Building a Comprehensive Portfolio of Solutions/Services

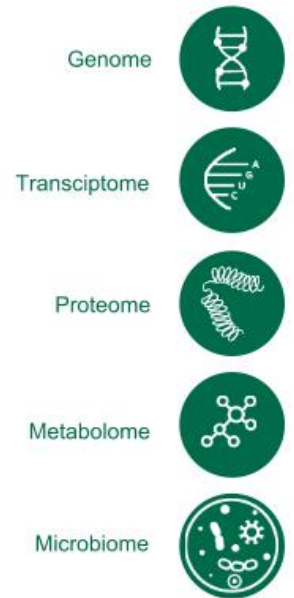
Samples

- Oral*
- Gut*
- Vaginal*
- Urine*
- Skin*
- Blood
- Other

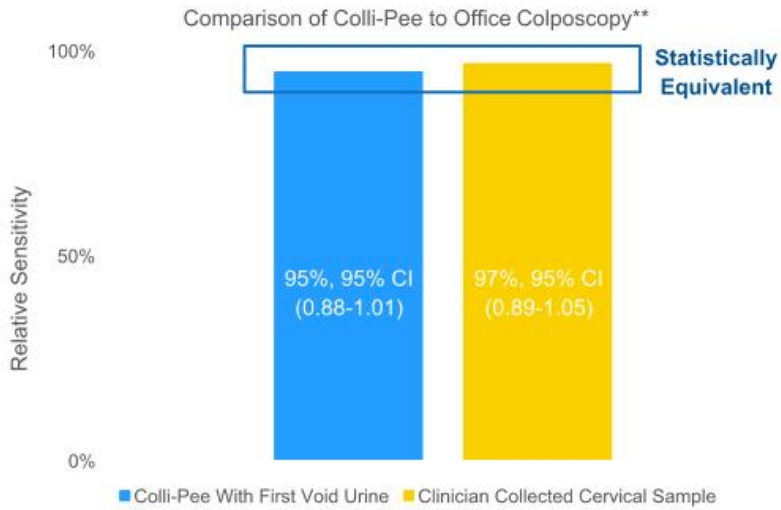
* Currently marketed solutions



Multi-omics



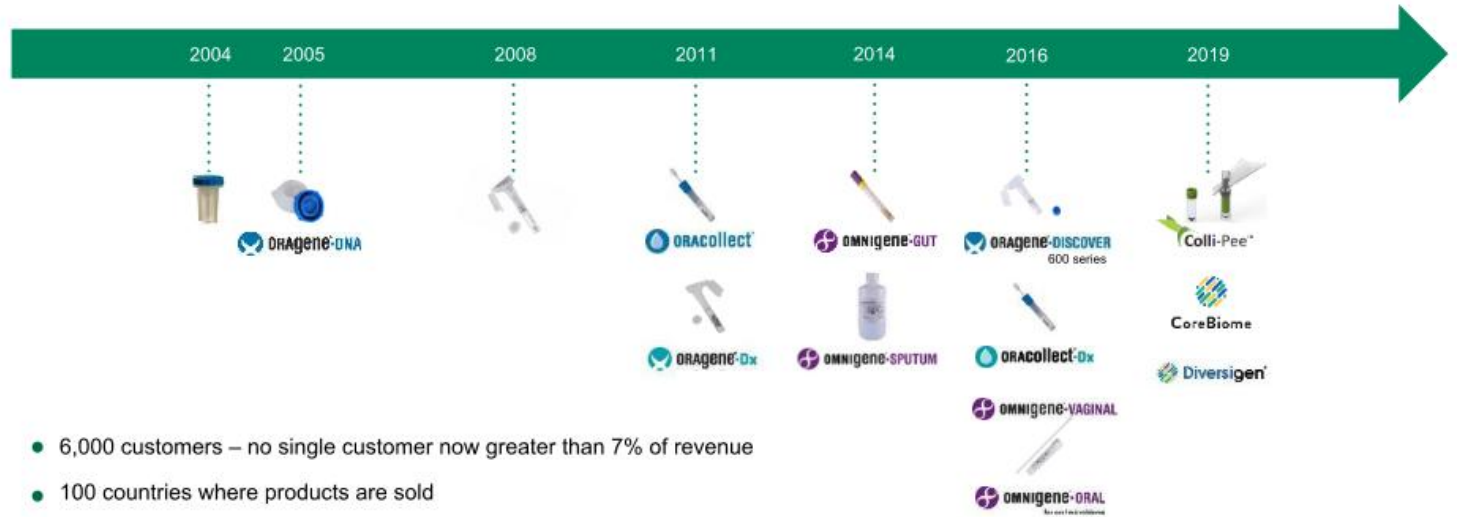
Colli-Pee®*, New Innovation in Sample Collection; Addressing Global HPV Screening Market



*Colli-Pee® is a research use only product and has not obtained regulatory approval
**Van Keer et al., <https://doi.org/10.1016/j.ygyno.2021.06.010>



Accelerating Expansion Into New Sample Types, Multi-omic Research Areas & Services



- 6,000 customers – no single customer now greater than 7% of revenue
- 100 countries where products are sold
- 3,000 peer reviewed research publications supporting technologies



All-in-one Solutions for Self-collection of Samples for Molecular COVID-19 Testing

- All-in-one, easy, reliable and non-invasive self-collection of high quality RNA
- ORAc collect®·RNA and OMNIgene®·ORAL have received EUAs, interim authorization from Health Canada, and are CE-IVD marked
- Eight customers to date* have received EUAs incorporating our sample collection products
- OMNIgene·ORAL named one of TIME magazine's best inventions of 2020

*As of 8/31/21

**OR-100/OM-505 are the formats for the US market. Outside of the US, we use the ORE-100/OME-505 formats.

Validating With Partners

 ORAc collect·RNA



OR-100**

 OMNIgene·ORAL



OM-505**

 ORAgene·Ox



OGD-500



Expanding 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



Building a Leadership Position in High-Growth Microbiome Testing Services Market



Largest provider of microbiome testing services to pharma – >30 biopharma collaborations



Increasing use of microbiome testing in applications such as cosmetics, animal health, & consumer testing



Future applications could include research services, tests, and companion diagnostics for pharma



The microbiome is increasingly being found to influence many diseases and biological processes

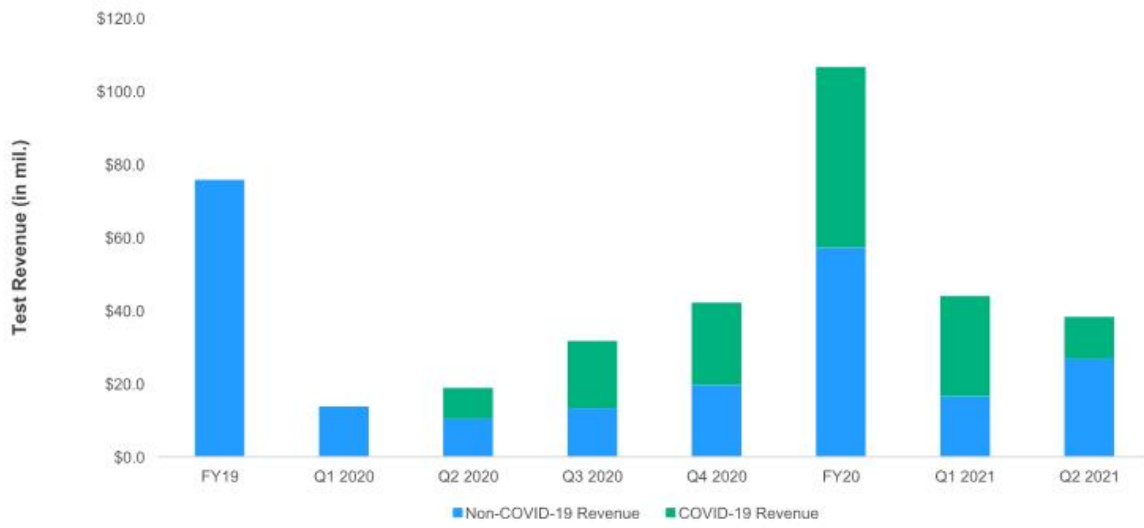


\$400 million microbiome testing market estimated to be growing at 15%+



Strong Core Growth in Molecular Solutions

2Q21 One of Strongest Quarters Ever from Genomics & Microbiome Services



Capital Deployment / Strategic Partnerships



Using robust balance sheet to create revenue and shareholder value



\$229 million in cash on balance sheet* with no debt



Four completed acquisitions 2019-2020



Continue to seek acquisitions that are accretive to our innovation-based growth strategy



Evaluating companies/technologies in both diagnostics and molecular solutions

* Cash and cash equivalents, short-term investments, and long-term investments as of June 30, 2021



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

