

## 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, 2019, Quarterly Reports on Form 10-Q for the quarters ended March 31, 2020, June 30, 2020, and September 30, 2020 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.

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## **Company Snapshot**



Sampling tools, services and diagnostics to understand what's in us, on us, and around us.



\$148 million in net revenue in 2019<sup>1</sup>



Active business development program



470 employees



\$263.7 million in cash<sup>2</sup> on balance sheet; no debt

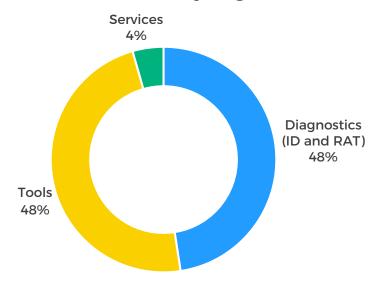


Offices in U.S., Canada and Belgium



Products registered in 89 countries





<sup>&</sup>lt;sup>1</sup> Excludes net revenue of cryosurgical business, which was divested in August 2019

<sup>&</sup>lt;sup>2</sup> Cash and cash equivalents, short-term investments, and long-term investments as of September 30, 2020

### **Investment Rationale**



#### Multiple Near-term COVID-19 Opportunities and Long-term Growth Drivers

- Well positioned for global COVID-19 response: two oral fluid self-collection devices for molecular testing received EUAs + CE-IVD marks and are in wide use; EUA application submitted for lab-based oral fluid antibody test; rapid antigen self-test under development
- Investment in manufacturing capacity and improved production efficiency continues
- Continued expansion in global markets with OraQuick HIV Self-Test and OraQuick HCV test
- Market leading microbiome products and services offer tremendous growth potential
- \$263.7 million in cash<sup>1</sup> on balance sheet and no debt supports ongoing business development activities that have generated four acquisitions and one divesture since January '19

## Improving Global Access to Accurate Healthcare Information



Experts in sample collection, preservation and diagnostics

- Over 20 years of proprietary knowledge in oral fluid testing enables self collection and rapid in-home results
- Broad, well-established channels of distribution across global public health, academic and research institutions, laboratories, employers, hospitals, physician offices, pharmacies and direct-to-consumer
- Leadership in infectious disease, genomics and emerging microbiome fields
- Innovative technologies to collect and analyze molecular samples

## Capitalizing on Next-generation Health and Wellness Technologies



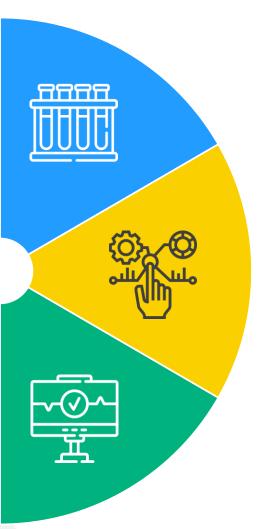
- Innovative sampling tools, services and diagnostics help people understand what's in us, on us, and around us
- Unlocking access to accurate essential information that advances global health and well-being
- Driving access to multiple layers of information and data to understand health, wellness and disease states
- Differentiated products with competitive profiles in large attractive markets - many in their early days



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### **OraSure Solutions**





#### Sampling

Sample collection & stabilization devices to drive discovery and access



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

#### **Services**

Data analytics and AI, multiomic view to health & wellness



Study design

Customization

- Analysis
- Single-order fulfillment
- Consulting

#### **Diagnostics**

Selection of high value/ actionable testing





- Infectious disease
- Substance abuse testing

Wet lab & sequencing

## Innovation and Expertise in Infectious Disease Diagnostics



 Our technologies are the ideal platform for the emerging trends in diagnostic testing

Directly suited for the current COVID-19 testing dynamic
 Leveraging our proven experience with HIV Self-Test and Rapid Ebola Antigen

Test to develop a Coronavirus Antigen Rapid Self-test

 Our unique platform for HIV and HCV provides accurate and easy-to-administer testing methods

Bringing our innovation and expertise in infectious disease diagnostics and sample collection to the fight against COVID-19 and the global eradication of HIV

## **Three Distinct COVID-19 Opportunities**



- Oral Fluid Collection Devices for COVID-19 Molecular Testing
  - Sample collection products included in multiple EUAs and lab validated workflows; incorporated into diverse range of back to school and back to work programs nationwide
  - ORAcollect®·RNA and OMNIgene®·ORAL have received EUAs and are CE-IVD marked
  - \$27M in revenue recorded through Q3 2020

#### COVID-19 ELISA Antibody Test

- Potential to be the first COVID-19 antibody test to use oral fluid samples
- EUA application submitted and under review
- Oral fluid collection is quick, painless, and non-invasive, and requires less human contact in comparison to blood draw, minimizing exposure to potentially infected individuals

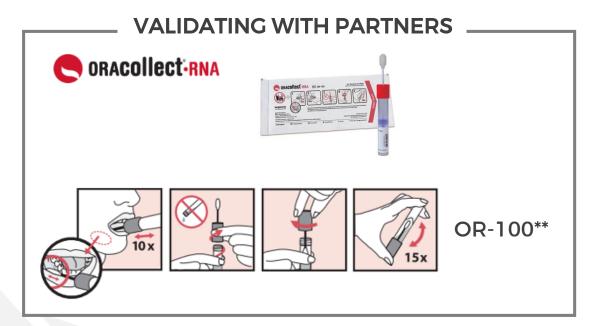
#### OraQuick Coronavirus Rapid Antigen Self-test

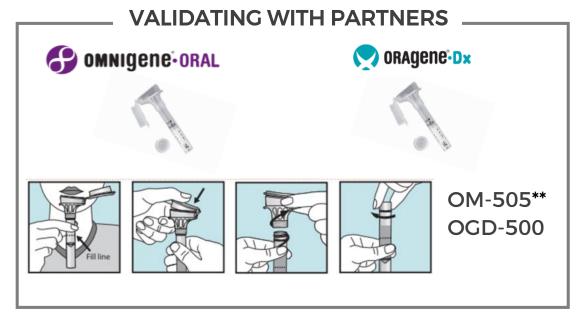
- Would use a nasal sample easily collected from the lower nostril to maximize accuracy and convenience
- Initial launch expected to be Professional Test; second phase expected to be Prescription Self-test;
   third phase expected to be for Over-The-Counter use in asymptomatic individuals
- Expected EUA submission for Professional Test in Q1 2021, with launch to follow authorization
- Prescription Self-Test and OTC Self-Test EUA submissions to follow as soon as possible thereafter

# All-in-one solutions for self-collection of samples for molecular COVID-19 testing



- All-in-one, easy, reliable and non-invasive self-collection
- High quality DNA and RNA
- Ambient temperature stability
- Compatible with high throughput processing
- ORAcollect®-RNA and OMNIgene®-ORAL have received EUAs and are CE-IVD marked
- Six customers to date\* have received EUAs incorporating our sample collection products





### Sars-Cov-2 Oral Fluid Antibody Test

- No oral fluid COVID-19 antibody tests authorized for sale in U.S. to date
- Easy and non-invasive self-collection
- ELISA Microplate lab-based oral fluid test
- Short turn-around time and high-throughput
- Ideal for surveillance data
- BARDA contract to develop
- EUA application submitted
- Research Use Only (RUO) product available for sale currently with numerous labs in validation

#### **EUA SUBMITTED**

**Collect Sample with OraSure Device** 



Insert the device into the buffer



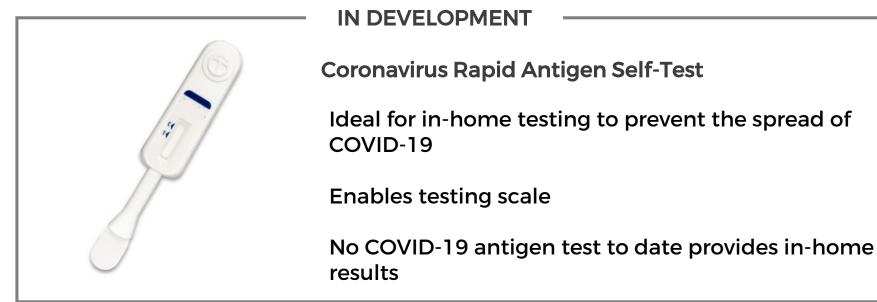
Sample sent to lab where ELISA test is run



## OraQuick Coronavirus Rapid Antigen Self-Test



- Game-changing test to detect active COVID-19 infection **anytime**, **anywhere** with direct results available a short time later at point of collection
- No instrumentation or laboratory analysis needed to interpret results
- Based on proven OraQuick® platform (HIV, HCV, Ebola)
- Targeting EUA submission in Q1 2021 for Professional Test
- · Expanding manufacturing capacity to meet anticipated demand, ahead of EUA



# OraQuick Coronavirus Rapid Antigen Self-Test: Three Products Covering Various Use-Cases



#### **Professional Test**

Rx
Self-Swab
Healthcare practitioner
reads result

Drive-Thru Sites

Physician offices, Employer/University Health Centers, Pharmacy clinics



#### **Rx Self-test**

Rx Self-Swab Consumer reads result

Consumer Home Use via Pharmacy Rx

Employers for Home or Off-site Testing

Education

**Nursing Homes** 

#### **Over-the-counter Test**

OTC
Self-Swab
Consumer reads result

Consumer Home Testing

#### Travel / Entertainment





# Expansion of Manufacturing Capacity to Meet Anticipated Demand for COVID-19 Opportunities



#### **OraQuick Coronavirus Rapid Antigen Self-Test**

#### Today Q1 2021

Current capacity for **35 million**OraQuick test per year
including HIV, HCV and Ebola
tests+

Installation of new lines will expand total capacity for all tests to **55 million** tests per year

Further expansion will allow
70 million total tests per
year including HIV, HCV and
Ebola

Q3 2021

#### **COVID-19 Molecular Sample Collection**

#### Today

Current capacity for **35**million units per year including non-COVID kits\*

Q2 2021

Installation of new lines will increase total capacity for all kits to **75 million** units per year

Q3 2021

Further expansion will allow 80 million total kits per year including non-COVID

#### Sars-Cov-2 Oral Antibody Collection Device

#### Today

Q4 2021

Current capacity for 10 million units per year including existing products++

Installation of new lines will expand total capacity to **20 million** tests per year including existing products

## **Trailblazer in HIV Self-Testing**



## ORAQUICK® HIV SELF-TEST





- 21% of the 38 million people with HIV do not know their status
- Safe, accurate, convenient point-of-care and in-home HIV tests key to identifying HIV positive patients and linking them to care
- OraSure is International HIV Self-Test market share leader with oral fluid self-collection and in-home result
- Opportunities in Africa with UNITAID STAR program expansion, Europe, Eastern Europe, Central Asia and Latin America

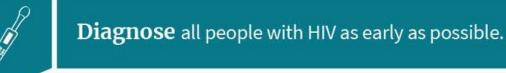
First and only rapid HIV in-home test approved by FDA First and only WHO-prequalified rapid oral HIV self-test

## Well-Positioned to Play an Important Role in the Eradication of HIV in the U.S.



### ENDING THE HIV EPIDEMIC: THE PLAN FOR AMERICA

- The Plan for America continues with \$267 million in FY 2020 funding and meaningful increase proposed for FY 2021
- Reaching the difficult to reach is key to achieving plan goals
- Rapid testing is an important tool
- OraSure has the only FDA-approved OTC selftest in the U.S.
- UrSure acquisition adds PrEP adherence testing to portfolio



**Treat** people with HIV rapidly and effectively to reach sustained viral suppression.





**Prevent** new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

**Respond** quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.



#### **COVID-19 IMPACT**

- CDC is encouraging funded sites to use in-home self-testing for HIV in order to continue testing while complying with COVID-19 safety restrictions.
- Public health departments are increasing purchases of our FDA approved in-home HIV test

## **Hepatitis C**





- 81% of the estimated 71 million people with chronic Hepatitis C do not know their status
- Antiviral medications can now cure 95%+ of those infected but access to diagnosis and treatment is low
- Opioid crisis is fueling the Hepatitis C epidemic
- OraSure makes the first and only FDA-approved, CLIA-waived rapid HCV test\*
- \$10 million in FY 2020 funding to diagnose infectious disease from the opioid epidemic. The opioid and infectious diseases program authorized by Congress for up to \$40 million; the administration has requested additional funding for FY 2021.
- \$341 million for CDC's viral hepatitis surveillance & prevention awards, including testing, being issued to states and major jurisdictions
- OraSure's HCV POC test will play an important role in reaching the hard-to-reach people who are driving a majority of the infections
- Anticipate an eventual return to more normal levels of revenue after COVID-19 begins to resolve

## **Opportunities in Substance Abuse Testing**



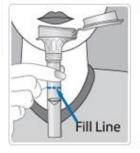


- New federal guidelines permit oral fluid drug testing
- SAMHSA estimates oral fluid testing will grow to 25% of total testing by 2025
- OraSure pioneered oral fluid testing for substance abuse
- Socially distanced, easier, less costly and more efficient sample collection

### **DNA Genotek: The Magic Behind Human Genomics**



### DNAgenotek™















DNA Genotek "has done for DNA collection what Google did for Web searches: made it ridiculously simple and efficient." - TIME Magazine

## Microbiome Impact on Healthcare





## The microbiome is believed to influence many diseases and biological processes

Gastrointestinal diseases, Type 1&2 Diabetes, skin conditions, the urinary tract, women's health and neonatal health

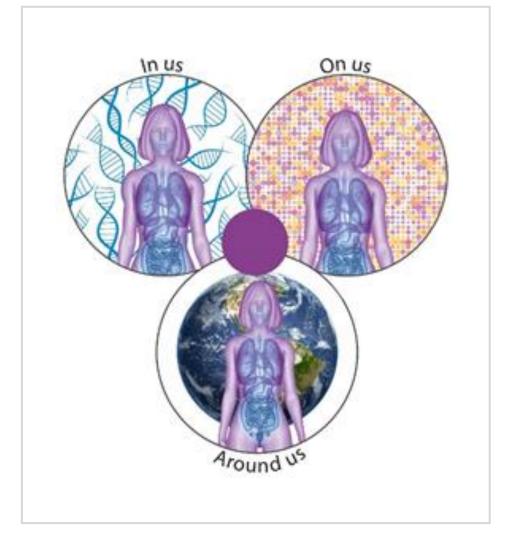


## It provides a means of intercepting disease and personalizing treatments

Diagnostics, therapeutics and preventive medicine are all enabled with this new perspective



Multiple research reports project mid-teens growth for the microbiome market from 2019-2024



## Services: Unmatched Offering From Sample to Answer

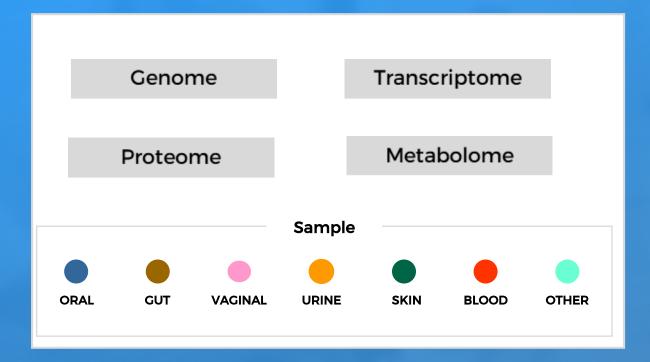


- Blue-chip customer base and technical innovation in microbiome analysis and DNA Genotek's microbiome sampling kits
- Consolidated CoreBiome and Diversigen services under Diversigen brand
- Combined operation offers science-driven, customized solutions for metagenomics sequencing, bioinformatics, and statistical analysis for the study of the microbiome
- Diversigen represents experts with 100+ years of microbiome experience and 300+ scientific publications with ~100,000 citations
- Integrating lab operations in Minnesota

## **Multiomics: New Health Paradigm**



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Multifactorial examination of an individual's health

- Informing health, wellness, infectious disease, chronic disease and cancer
- Introduced first and only commercially available device for in-home, self-collection of fecal samples for metabolomics

End-to-end quality in sampling, services, and bioinformatics

## **Business Development**





Using robust balance sheet to create revenue and shareholder value



Considering infectious disease possibilities as well as molecular



\$263.7 million in cash on balance sheet<sup>1</sup> with no debt



Target rich environment



Four completed acquisitions 2019-2020



Committed to doing the right deal, for the right price, at the right time



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