



# OraSure Technologies

INVESTOR PRESENTATION

MARCH 2021

**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 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.

# Company Snapshot



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



\$172 million in net revenue in 2020



Active business development program



570 employees



\$257 million in cash<sup>1</sup> on balance sheet; no debt

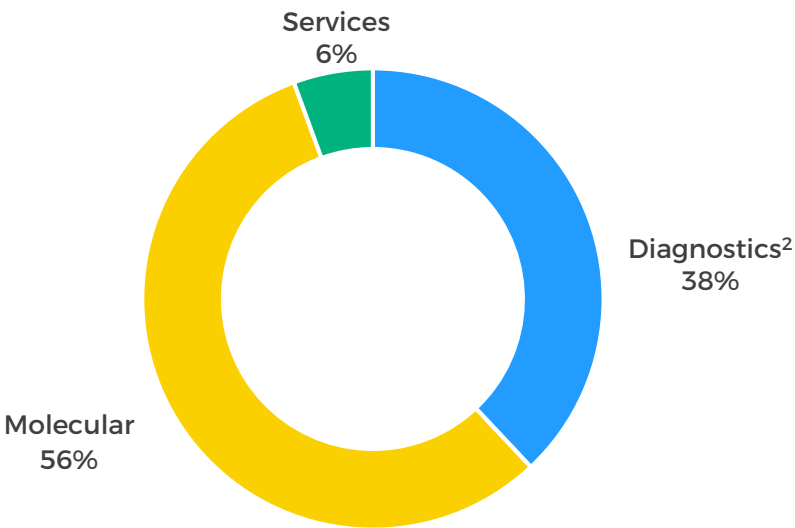


Offices in U.S., Canada and Belgium



Products registered in 89 countries

2020 Revenue by segment



<sup>1</sup>Cash and cash equivalents, short-term investments, and long-term investments as of December 31, 2020

<sup>2</sup> Infectious Disease and Risk Assessment Testing

# 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; rapid antigen self-test development and clinical studies completed, preparing for Q1 EUA submission; lab-based oral fluid antibody test clinical study completed, finishing additional studies for EUA resubmission
- ✓ 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
- ✓ \$257 million in cash<sup>1</sup> on balance sheet and no debt supports ongoing business development activities that have generated four acquisitions and one divestiture since January '19

<sup>1</sup> Cash and cash equivalents, short-term investments, and long-term investments as of December 31, 2020

# 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



# OraSure Solutions



## Diagnostics

Selection of high value/  
actionable testing



OraSure Technologies, Inc.

- ✓ Infectious disease
- ✓ Substance abuse testing

## Sampling

Sample collection & stabilization  
devices to drive discovery and  
access

**DNA**genotek™



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

## Services

Data analytics and AI, multiomic  
view to health & wellness



- ✓ Study design
- ✓ Customization
- ✓ Single-order fulfillment
- ✓ Wet lab & sequencing
- ✓ Analysis
- ✓ Consulting

# 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**

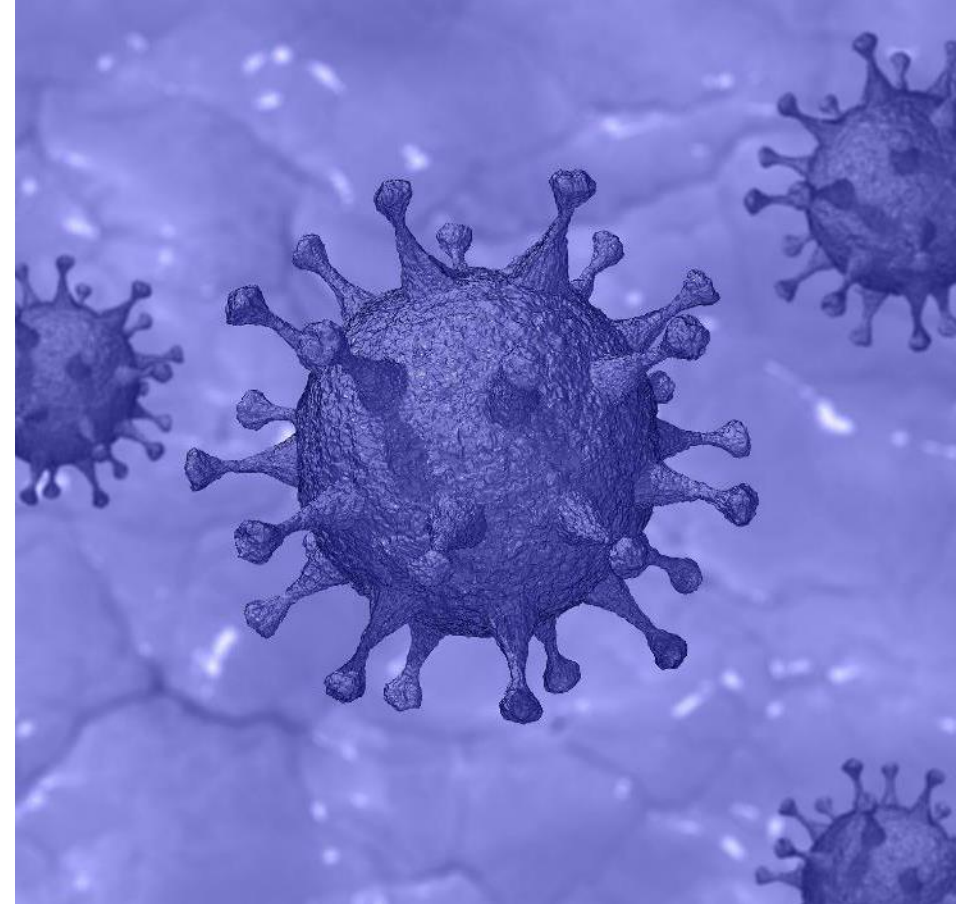
Bringing our innovation and expertise in infectious disease diagnostics and sample collection to the fight against COVID-19 and the global eradication of HIV



# Three Distinct COVID-19 Opportunities



- Sample Collection Devices for COVID-19 Molecular Testing
- COVID-19 Rapid Antigen Self-test
- COVID-19 Oral Fluid Antibody ELISA
  - ✓ Convenient, pain-free self-collection
  - ✓ Increased access to testing
  - ✓ Less burden on healthcare systems
  - ✓ Minimized exposure risks to healthcare workers
  - ✓ Conserve much-needed PPE



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

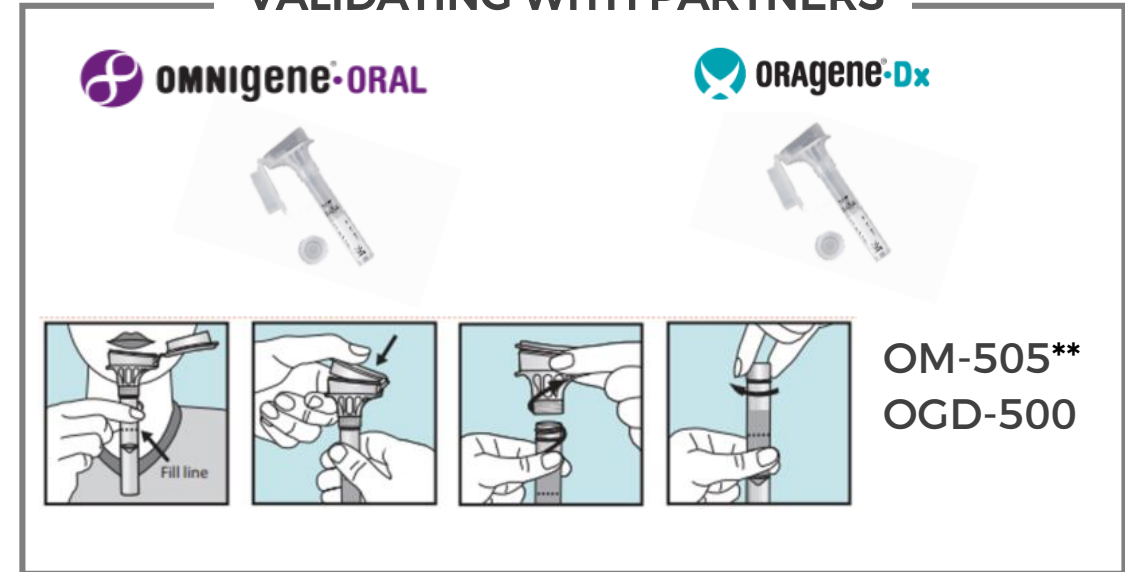


- All-in-one, easy, reliable and non-invasive self-collection of high quality DNA and RNA
- Ambient temperature stability
- Compatible with high throughput processing
- ORAcollect®.RNA and OMNIgene®.ORAL have received EUAs, interim authorization from Health Canada, and are CE-IVD marked
- Eight customers to date\* have received EUAs incorporating our sample collection products
- OMNIgene·ORAL named one of TIME magazine's best inventions of 2020

## VALIDATING WITH PARTNERS



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\*As of 2/28/21

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

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# COVID-19 Rapid Antigen Self-Test



Ideal for In-home testing to prevent the spread of COVID-19

Lower nasal collection not dependent on scarce NP swabs

Simple collection method, “lab on a swab”

Enables testing scale

- Simple, easy-to-use 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) with over 80 million tests sold
- Targeting EUA submission in Q1 2021
- Expanding manufacturing capacity to meet anticipated demand, ahead of EUA

# OraSure's COVID-19 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*

# Sars-Cov-2 Oral Fluid Antibody Test



Collect Sample with OraSure Device



Insert the device into the buffer



Sample sent to lab where ELISA test is run



- No oral fluid COVID-19 antibody tests have received Emergency Use Authorization 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
- On track to resubmit as two separate EUAs, with additional data as requested by FDA
- Product currently sold as Research Use Only (RUO) and in use by customers



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



## OraQuick Coronavirus Rapid Antigen Self-Test

Today	Q1 2021	Q3 2021	Q2 2022
Current capacity for <b>35 million</b> OraQuick test per year including HIV, HCV and Ebola tests+	Installation of new lines will expand total capacity for all tests to <b>55 million</b> tests per year by the end of Q1	Further expansion will allow <b>70 million total</b> tests per year	Further expansion will allow <b>120 million total</b> tests per year

## COVID-19 Molecular Sample Collection

Today	Q2 2021	Q3 2021
Current capacity for <b>35 million</b> units per year including non-COVID kits*	Installation of new lines will increase total capacity for all kits to <b>75 million</b> units per year	Further expansion will allow <b>80 million total</b> kits per year including non-COVID

## Sars-Cov-2 Oral Antibody Collection Device

Today	Q4 2021
Current capacity for <b>10 million</b> units per year including existing products++	Installation of new lines will expand total capacity to <b>20 million</b> tests per year including existing products

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+Approximately half of this capacity is devoted to HIV, HCV, and Ebola testing \*Approximately 7 to 8 million units expected to be used for non-COVID applications

++ Approximately 3 million for existing products

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# Trailblazer in HIV Self-Testing



**ORAQUICK<sup>®</sup>**  
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

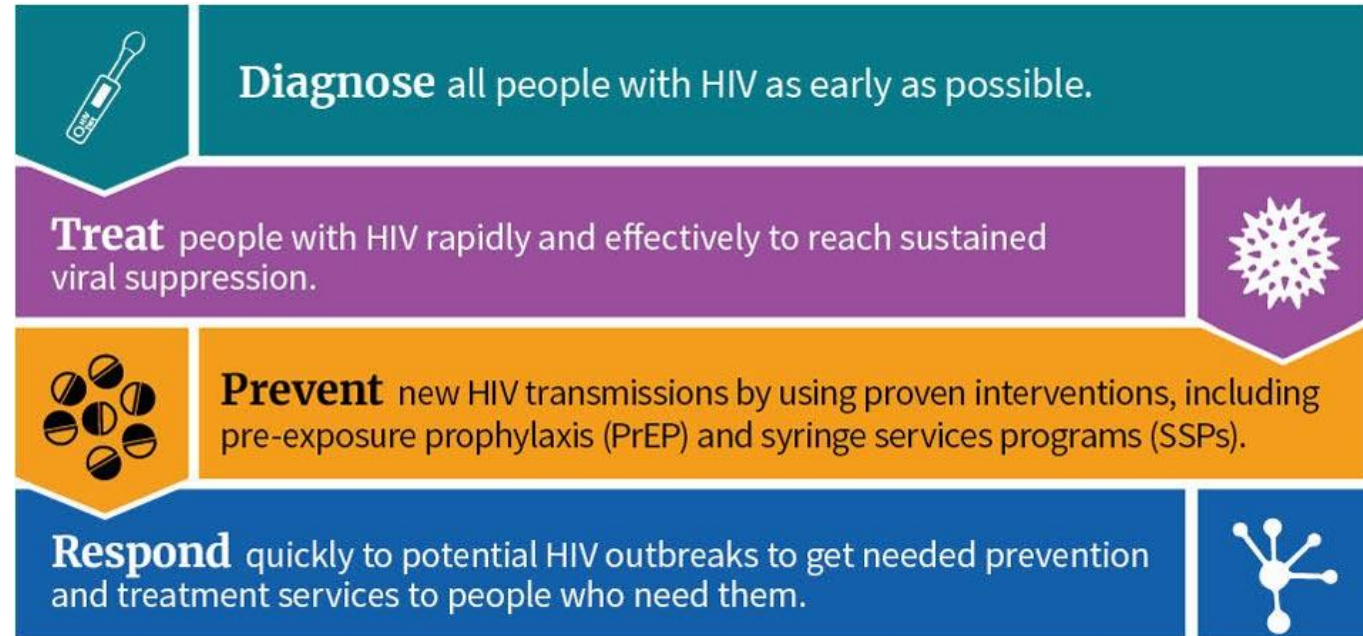
**First and only rapid HIV OTC test approved by FDA**  
**First and only WHO-prequalified rapid oral HIV self-test**

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



## ENDING THE HIV EPIDEMIC: THE PLAN FOR AMERICA

- FY 2021 federal budget includes \$386 million for EHE implementation, up from \$267 million in FY 2020.
- Reaching the difficult to reach is key to achieving plan goals
- Rapid testing is an important tool
- OraSure has the only FDA-approved OTC self-test for HIV in the U.S.
- UrSure acquisition adds PrEP adherence testing to portfolio



## 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



- OraSure makes the first and only FDA-approved, CLIA-waived rapid HCV test\*
- 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
- \$39.5 million for the Division of Viral Hepatitis at CDC, an increase of \$500,000 over FY 2020
- \$13 million for Infectious Diseases and the Opioid Epidemic at CDC, an increase of \$3 million over FY 2020
- 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



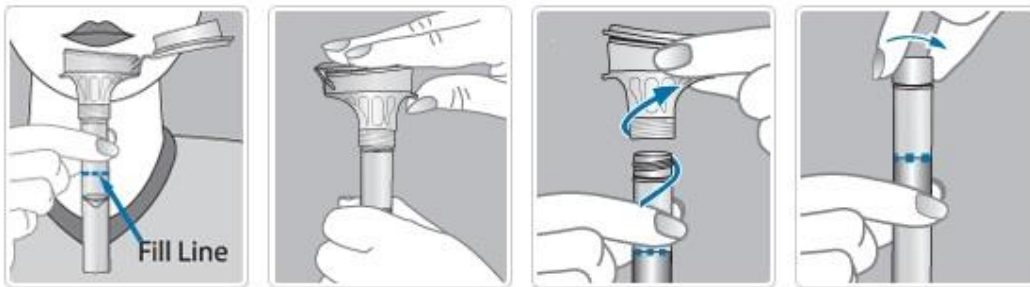
- ✓ New federal guidelines permit oral fluid drug testing
- ✓ SAMHSA estimates oral fluid testing will grow to 25% of total testing by 2025
- ✓ OraSure pioneered oral fluid testing for substance abuse
- ✓ Socially distanced, easier, less costly and more efficient sample collection

*Product shown is under development to meet SAMHSA guidelines.  
Currently for Forensic Use Only.*

# DNA Genotek: The Magic Behind Human Genomics



**DNAgenotek™**



- ✓ Pioneer in DNA/RNA sample collection, stabilization and preparation products
- ✓ Technology stabilizes DNA for long periods of time at ambient temperatures
- ✓ Increased interest in sample collection due to COVID-19

**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

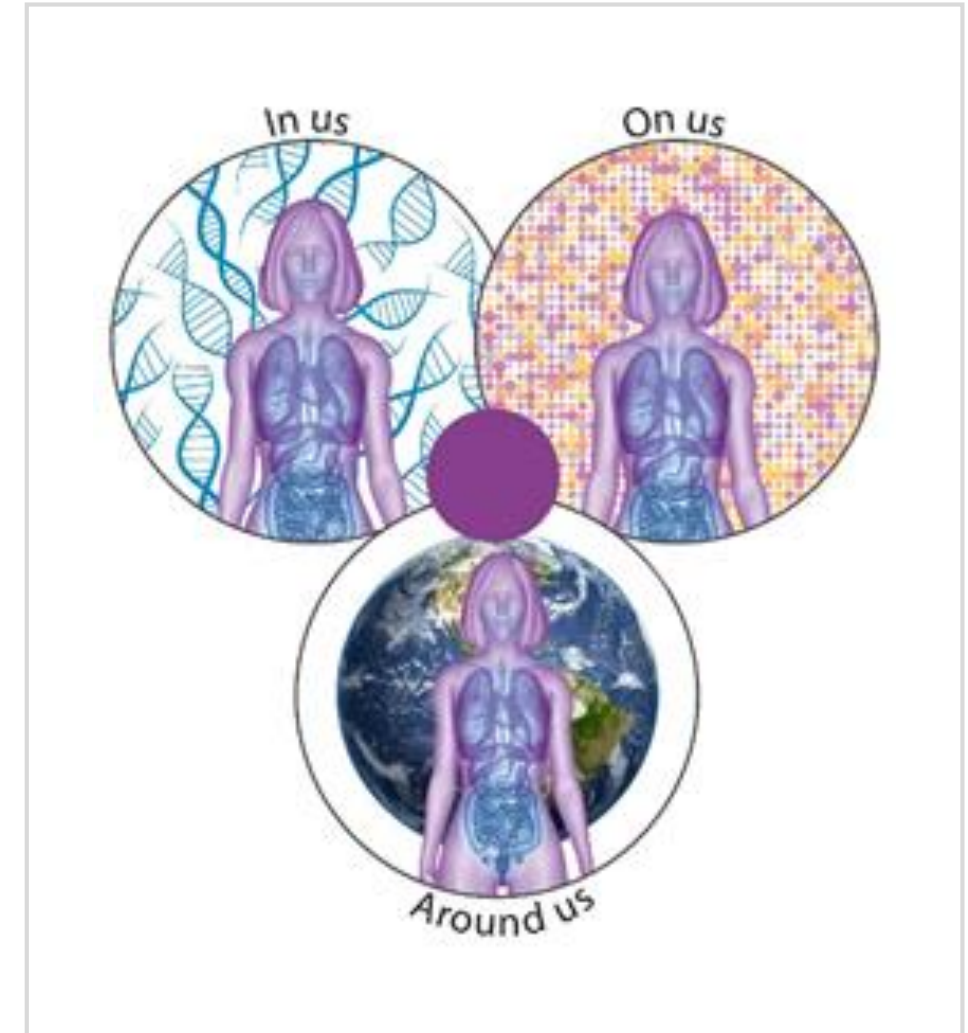


**It provides a means of intercepting disease and personalizing treatments**

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



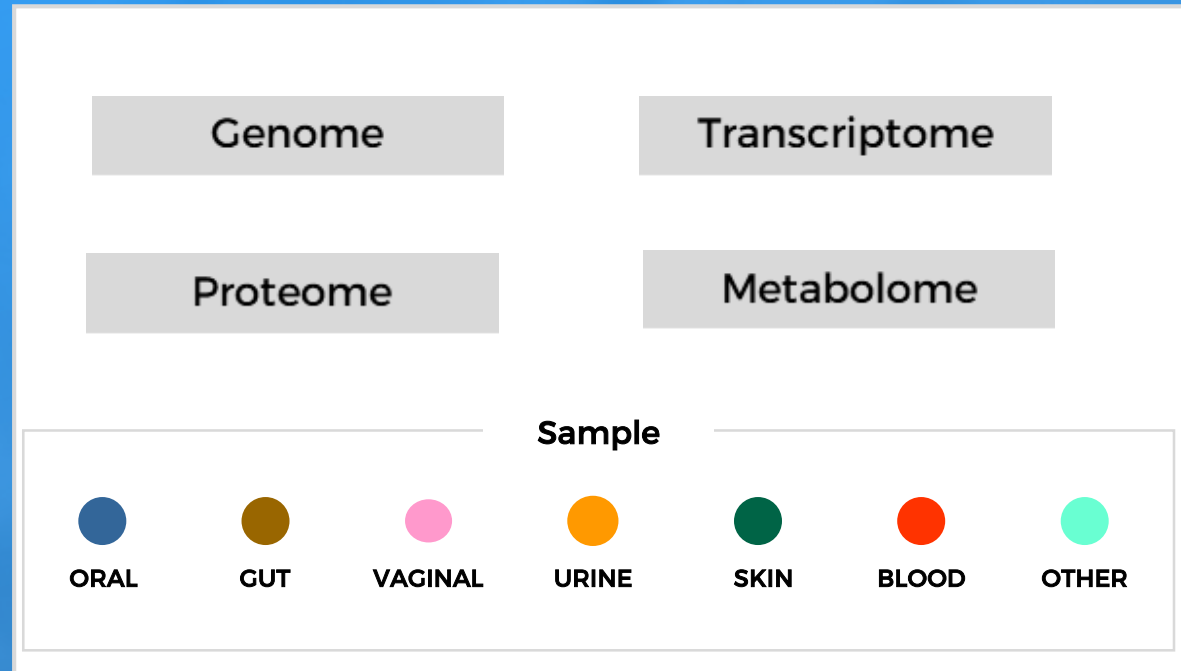


# Services: Unmatched Offering From Sample to Answer



- ✓ 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
- ✓ Integrated lab operations in Minnesota

# Multomics: New Health Paradigm



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



\$257 million in cash on balance sheet<sup>1</sup> with no debt



Four completed acquisitions 2019-2020



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



Considering diagnostic possibilities as well as molecular

<sup>1</sup> Cash and cash equivalents, short-term investments, and long-term investments as of December 31, 2020

# Summary



- Business momentum is strong
- Significant COVID-19 opportunity is robust part of our business for now and the foreseeable future
- Molecular collection devices driving significant revenue
- COVID-19 Antigen and Antibody tests on the road to commercialization
- OraSure is poised for continued and sustained growth
- Our work with COVID-19 will help accelerate our growth significantly

**We expect to emerge from the pandemic a stronger and larger company**