



# OraSure Technologies

INVESTOR PRESENTATION

JUNE 2020

**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, 2019, Quarterly Report on Form 10-Q for the quarter ended March 31, 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.

# Improving Global Access to Accurate Healthcare Information



## Experts in oral fluid 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, laboratories, employers, hospitals, physician offices, pharmacies and direct-to-consumer
- ✓ Well positioned to address COVID-19 in 3 areas:
  - Unique rapid antigen test, using oral fluid and providing a result in-home
  - ELISA-based lab test, using oral fluid self-collected
  - Saliva collection and preservation devices used for molecular PCR testing
- ✓ Leadership in genomics and emerging microbiome field
  - Innovative technologies to collect and analyze molecular samples

# Company Snapshot



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



\$176 million cash<sup>2</sup> on balance sheet; no debt

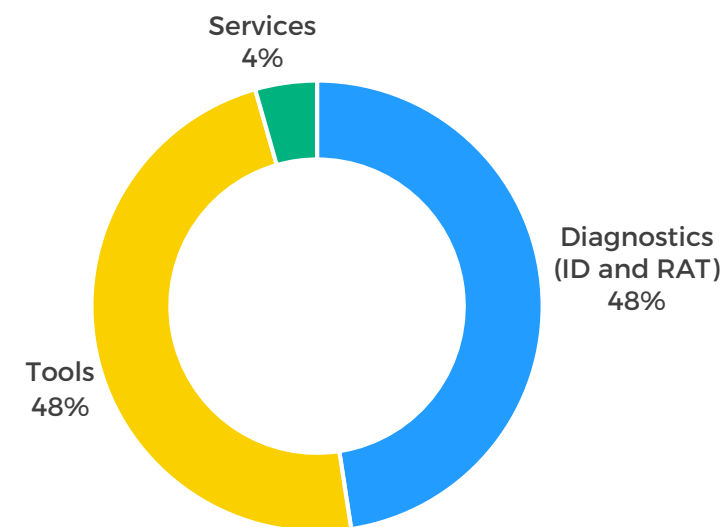


Offices in U.S., Canada and Belgium



Products registered in 89 countries

2019 Revenue by segment<sup>1</sup>



<sup>1</sup> Excludes net revenue of cryosurgical segment, which was divested in August 2019

<sup>2</sup> Cash and cash equivalents, short-term investments, and long-term investments as of March 31, 2020

Note: Other revenue consists of royalty income and funded research and development, grants, and reimbursement of certain costs

# Cash proceeds from June 2020 offering: \$95 million



## Proceeds will be used to:

- ✓ Expand manufacturing capacity for existing and in-development COVID-19 testing products
- ✓ Fund potential acquisitions of new businesses, technologies or products
- ✓ Fund product development, commercialization and manufacturing costs
- ✓ Support general corporate purposes

# 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
- ✓ Single-order fulfillment
- ✓ Wet lab & sequencing
- ✓ Analysis
- ✓ Consulting

## Diagnostics

Proprietary oral fluid diagnostics



- ✓ Infectious disease
- ✓ Substance abuse testing

# Q1 Highlights



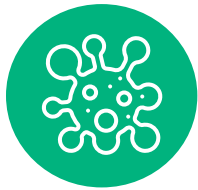
**\$31.6 million net revenues**  
Up 16% vs. Q1 2019<sup>1</sup>



**\$176 million in cash<sup>2</sup> and no debt**



**Multiple opportunities from COVID-19**



**International HIV net revenues up 74% vs. Q1 2019**



**Molecular collection products and services net revenues grew by 25% vs Q1 2019**



**Genomics net revenues up 14% vs. Q1 2019**



**Laboratory services business net revenues up 237% vs. Q1 2019**

<sup>1</sup> Excludes net revenue of cryosurgical segment, which was divested in August 2019  
<sup>2</sup> Cash and cash equivalents, short-term investments, and long-term investments as of March 31, 2020

# 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



# Innovation and Expertise in Infectious Disease Diagnostics



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

Oral fluid sample types enable greater access and benefits over other sample types

- 
- **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 pan-SARS-coronavirus antigen rapid in-home 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

# Global Leadership in Infectious Disease Diagnostics



Lateral Flow Platform

- ✓ Solving the most complex diagnostic challenges
- ✓ Legacy of innovation and first-to-market products
- ✓ Point of care tests for HIV, HCV and Ebola; pan-SARS coronavirus antigen test under development
- ✓ Ideal solution for low-resource settings

# Rapid In-Home Pan-SARS Coronavirus Antigen Testing



- BARDA contract to develop a pan-SARS-coronavirus antigen rapid in-home self-test
- Based on our proven OraQuick platform (HIV, HCV, Ebola)
- Rapid in-home self-test that uses oral fluid samples
- Direct results in minutes vs hours or days
- No instrumentation or trained personnel required to administer the test or to read results
- Ideal for screening scenarios for individuals with or without symptoms
- Enables testing scale
- Aiming for September EUA and launch

## IN DEVELOPMENT



**Rapid Oral Fluid Pan-SARS coronavirus antigen test**

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

**No other COVID-19 test to date provides in-home results**

# COVID-19 ELISA Antibody Testing



- BARDA contract to develop ELISA Microplate lab-based oral fluid test
- Easy and non-invasive self-collection
- Short turn-around time and high-throughput
- Ideal for surveillance data
  - How many infected
  - Return to work programs
- Aiming for initial product sales and EUA this summer



## IN DEVELOPMENT

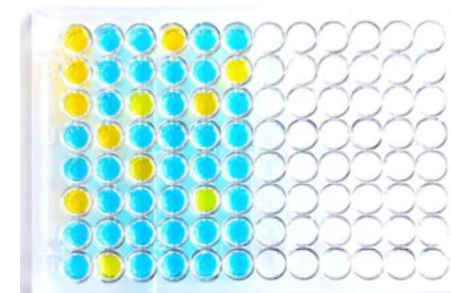
Collect Sample with OraSure Device



Insert the device into the buffer



Lab processes the sample and runs an ELISA test



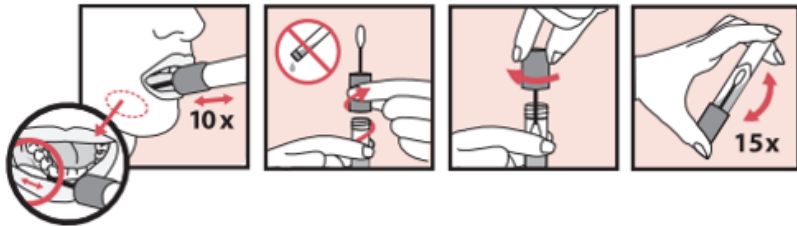
# All-in-one solutions for self-collection of samples for molecular COVID-19 testing



- All-in-one, easy, reliable and non-invasive self-collection
- High quality DNA and RNA
- Ambient temperature stability
- Compatible with high throughput processing
- Three customers to date\* have received EUAs incorporating our sample collection products with more expected to follow

## VALIDATING WITH PARTNERS

**ORACollect<sup>®</sup>RNA**



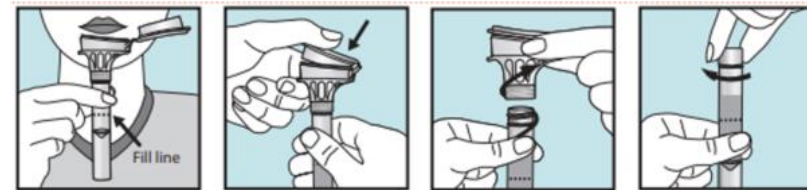
OR-100\*\*

## VALIDATING WITH PARTNERS

**omnigene<sup>®</sup>ORAL**



**ORAgene<sup>®</sup>Dx**



OM-505  
OGD-500

\*As of 6/10/20

\*\*OR-100 is the format for the US market. Outside of the US, it is the ORE-100 format.

# 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



Global HIV Self-Test market expected to grow at 45% CAGR over next 5 years



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 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 \$716 million 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 self test in the U.S.

## 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
- Positive impact on In-Home test sales expected



# 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 2020 federal budget to diagnose infectious diseases as a result of the opioid epidemic
- 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

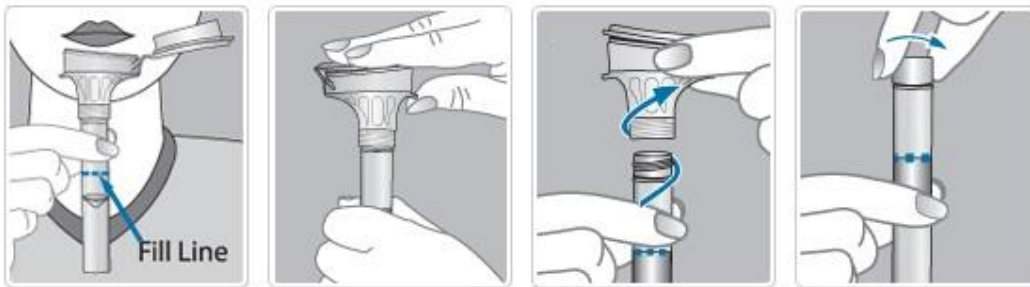


- ✓ New federal guidelines permit oral fluid drug testing
- ✓ SAMHSA estimates oral fluid testing will grow from 7% today to 25% of total testing by 2025
- ✓ OraSure pioneered oral fluid testing for substance abuse
- ✓ Easier, less costly and more efficient sample collection

# 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

# Genomics Market



Academic researchers studying everything from autism to obesity



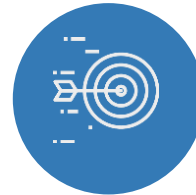
Commercial includes ancestry, animal, lifestyle and disease risk management



Market moving from genealogy to disease risk management



Providing new solutions for COVID-19



FDA generic 510(k) clearance for Oragene Dx collection kit



Genomics business grew 14% in Q1 2020 vs Q1 2019  
31 net new customers

# Genetic Testing Opportunities



## Ancestry

A genetic test that provides ancestry information

Typically offered direct to consumer



## Disease Risk Management

A genetic test that provides information about disease risk

Requires some form of practitioner intervention



## Lifestyle

A genetic test that provides lifestyle information only

Typically offered direct to consumer



## Animal

A companion animal genetic test

Typically offered direct to consumer

Oragene•DX family of products received 510(k) general clearance in Q1

# 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

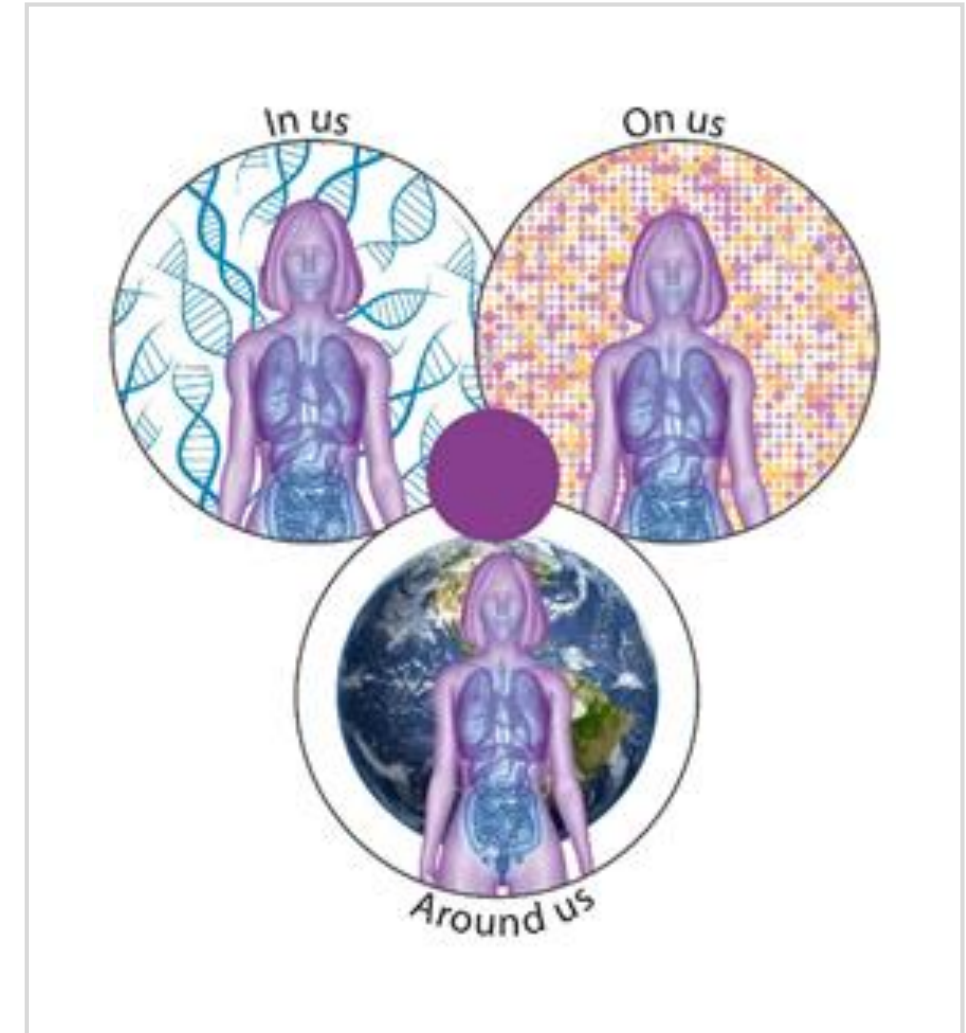


**It provides a means of intercepting disease and personalizing treatments**

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



# 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 offering science-driven, customized solutions for metagenomics sequencing, bioinformatics, and statistical analysis for the study of the microbiome

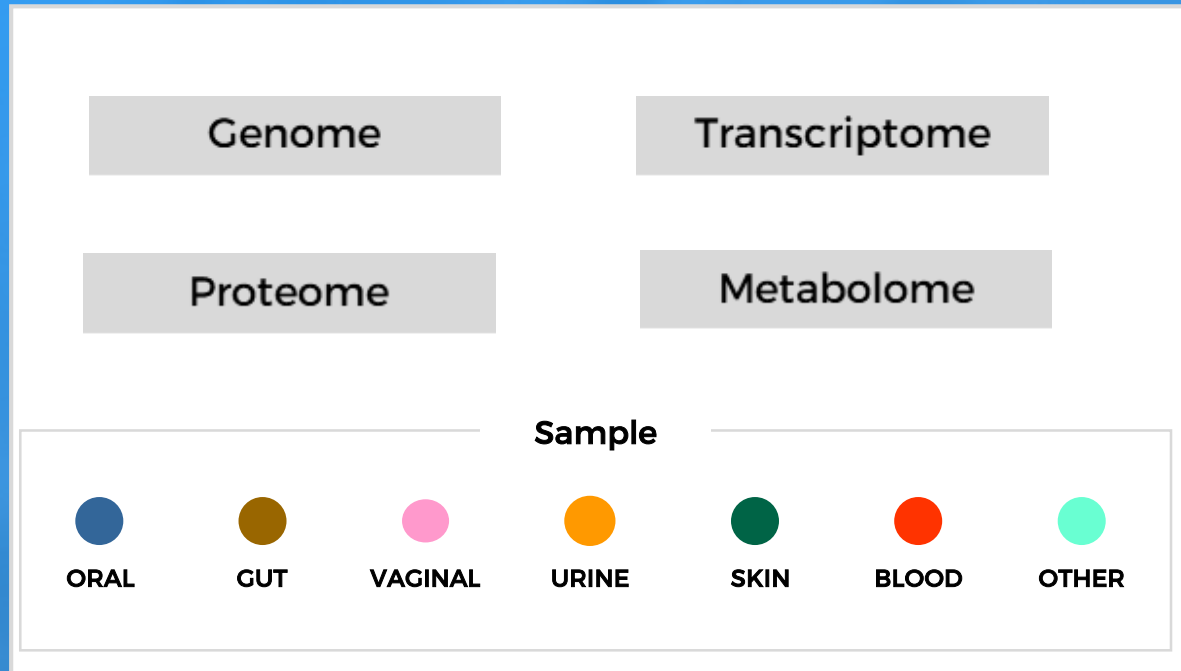


Diversigen represents experts with 100+ years of microbiome experience and 300+ scientific publications with ~100,000 citations



Integrating lab operations in Minnesota

# Multimomics: New Health Paradigm



Multifactorial examination of an individual's health



Informing health, wellness, infectious disease, chronic disease and cancer



Number of customers using both our genomic and microbiome products and services for the first time increased 44% in Q1 20 vs Q1 19

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

# Business Development



Using robust balance sheet to create revenue and shareholder value



\$176 million in cash<sup>1</sup> with no debt



Three completed acquisitions in 2019



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



Considering infectious disease possibilities as well as molecular



Target rich environment



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

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

# M&A strategy has enhanced our capabilities



January 4, 2019

- ✓ CoreBiome's highly scalable and reproducible BoosterShot™ platform allows researchers to efficiently run high-resolution DNA sequencing on thousands of microbiome samples
- ✓ Optimally addresses future microbiome research needs, captures new segments and expands our leadership position in this dynamic market



January 4, 2019

- ✓ Colli-Pee device easily collects biomarker-rich first-void urine
- ✓ Key applications with high-growth screening opportunities such as prostate cancer, human papilloma virus and chlamydia



November 6, 2019

- ✓ Provides science-driven, customized solutions for metagenomics sequencing, bioinformatics, and statistical analysis for the study of the microbiome
- ✓ The powerful combination of Diversigen's strength, expertise, and focus on customer service along with CoreBiome's technical innovation in microbiome analysis and DNA Genotek's innovative sampling kits gives us industry-leading product and service offerings from sampling to rich analytics to drive actionable insights



May 29, 2020

- ✓ Provides laboratory based and in-development point of care tests to measure adherence to HIV pre-exposure prophylaxis medications
- ✓ The addition of UrSure will complement our work with HIV diagnostics enabling us to cover the spectrum from HIV prevention adherence to screening

# Investment Rationale



## Multiple Long Term Growth Drivers & Near Term COVID-19 Opportunities

- ✓ **Leadership position in infectious disease diagnostics and molecular sample collection/stabilization**
- ✓ **Comprehensive solution offering encompassing tools, services and diagnostics**
- ✓ **Continued expansion in global markets with OraQuick HIV Self-Test and OraQuick HCV test**
- ✓ **Well positioned for global COVID-19 response with existing oral fluid sample self-collection devices, and in-development self-collection antibody test and at-home antigen self-test**
- ✓ **Market leading microbiome products and services offer tremendous growth potential**
- ✓ **Genomic and microbiome products and services are a foundation for leadership in multiomics**
- ✓ **Investment in manufacturing capacity and improved production efficiency continues**
- ✓ **Consistent focus on our innovation growth strategy**
- ✓ **\$176 million of cash<sup>1</sup> 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 March 31, 2020