

## **OraSure Technologies**

**INVESTOR PRESENTATION** 

DECEMBER 2020

**DNAGENOTEK** *Movosanis* **U**rSure

### **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 gualified 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 guarters 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. 2019 Revenue by segment<sup>1</sup>

**Active business** 



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



470 employees



Offices in U.S., Canada and Belgium



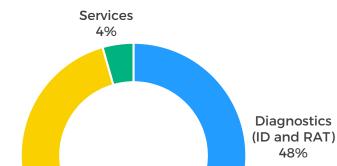




\$263.7 million in cash<sup>2</sup> on balance sheet; no debt



Products registered in 89 countries





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

<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 being pursued 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



### **OraSure Solutions**





#### Sampling

Sample collection & stabilization devices to drive discovery and access

**DNAGENOTEK**<sup>™</sup> ∜novosanis

#### **Services**

Data analytics and AI, multiomic view to health & wellness

**Diversigen** 



Multiple samples/analytes

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Wet lab & sequencing

Customization

Single-order fulfillment

Consulting

Analysis

Diagnostics

Selection of high value/ actionable testing



Infectious disease



## 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<sup>®</sup>·RNA and OMNIgene<sup>®</sup>·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; will be resubmitted as separate EUAs for assay and collector with additional data requested by FDA
- 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

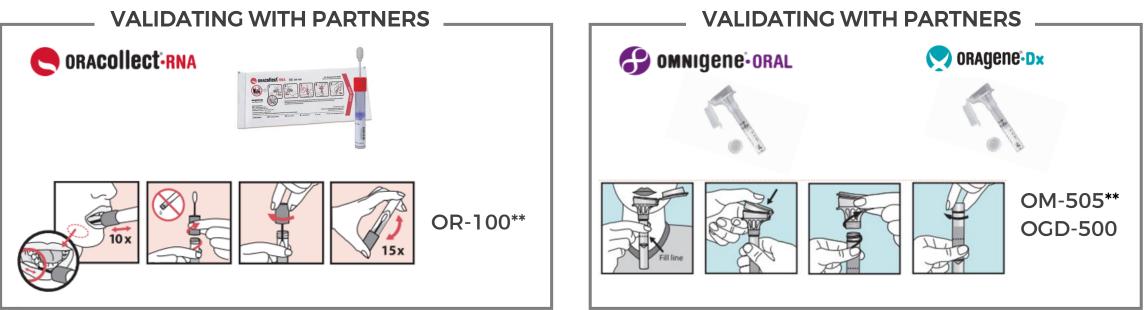
- Would use a nasal sample easily collected from the lower nostril to maximize accuracy and convenience
- Initial launch expected to be Professional Test; second phase expected to be Prescription Self-test; third phase expected to be for Over-The-Counter use in asymptomatic individuals
- Expected EUA 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

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



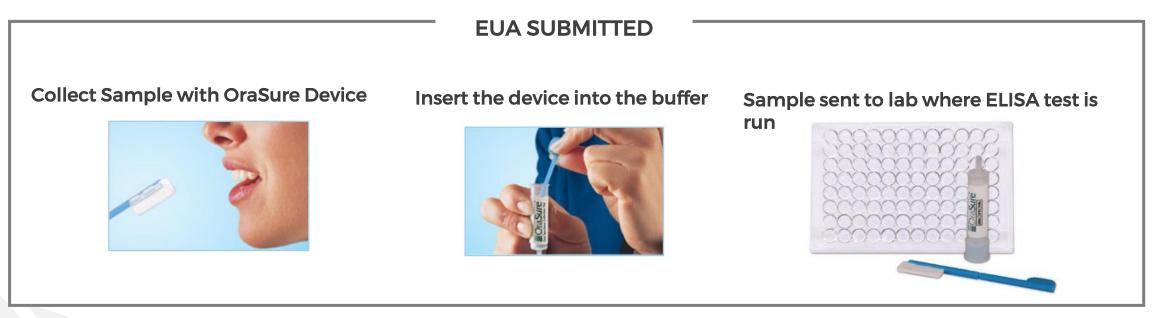
- All-in-one, easy, reliable and non-invasive self-collection
- High quality DNA and RNA
- Ambient temperature stability
- Compatible with high throughput processing
- ORAcollect<sup>®</sup>·RNA and OMNIgene<sup>®</sup>·ORAL have received EUAs and are CE-IVD marked
- Six customers to date\* have received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



\*As of 12/18/20 Confidential \*\*OR-100/OM-505 are the formats for the US market. Outside of the US, we use the ORE-100/OME-505 formats.

### 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; will be resubmitted as separate EUAs for assay and collector with additional data requested by FDA
- Research Use Only (RUO) product available for sale currently with numerous labs in validation





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### **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<sup>®</sup> platform (HIV, HCV, Ebola)
- Targeting EUA submission in Q1 2021 for Professional Test
- Expanding manufacturing capacity to meet anticipated demand, ahead of EUA

	- IN DEVELOPMENT
	Coronavirus Rapid Antigen Self-Test
2	Ideal for in-home testing to prevent the spread of COVID-19
A	Enables testing scale



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



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#### 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

Travel / Entertainment



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

OTC Self-Swab Consumer reads result

Consumer Home Testing



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



OraQuick Coronavirus Rapid Antigen Self-Test

Today	Q1 2021	Q3 2021
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	Further expansion will allow <b>70 million total</b> tests per year including HIV, HCV and Ebola

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

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

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

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	Today	Q4 2021
	units per year including	expand total capacity to <b>20 million</b> tests per year including existing

Confidential +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

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



### ORAQUICK<sup>®</sup>





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 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

**Diagnose** all people with HIV as early as possible.

**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.



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### **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

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total testing by 2025

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SAMHSA estimates oral fluid testing will grow to 25% of

OraSure pioneered oral fluid testing for substance abuse

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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**







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

Fill Line

### **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

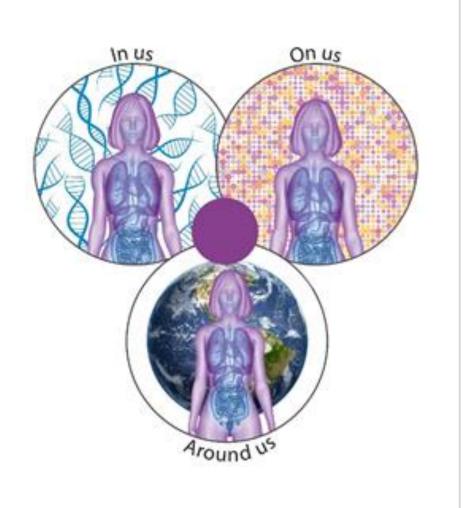


#### It provides a means of intercepting disease and personalizing treatments

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



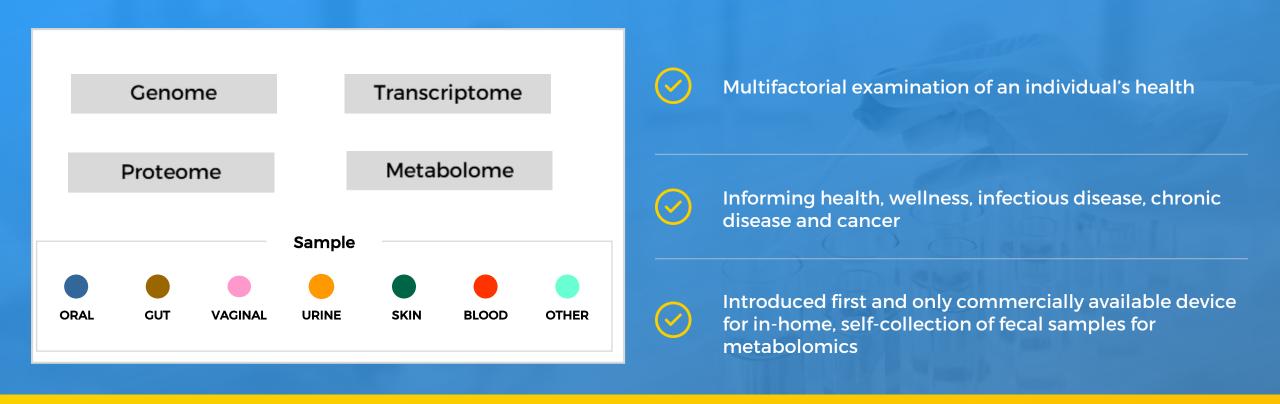
Diversigen represents experts with 100+ years of microbiome experience and 300+ scientific publications with ~100,000 citations



Integrating lab operations in Minnesota

### **Multiomics: New Health Paradigm**





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

### Using robust balance sheet to create revenue and shareholder value

**Business Development** 

Considering infectious disease possibilities as well as molecular



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



Four completed acquisitions 2019-2020

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



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

Target rich environment

