

# OraSure Technologies

## Corporate Deck

### December 2022



OraSure Technologies, Inc.

DNAgenotek™



Diversigen®



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# Our Goal and Operating Mantra

Great Opportunities & Addressable Challenges

## OraSure's Goal

### **“Transforming health through powerful insight”**

Effortless point-of-care diagnostic testing, sample collection  
& stabilization, laboratory services ...

... connecting healthcare to people by increasing access,  
affordability, and quality of care

## How We Will Operate

### **Innovating & operating with disciplined execution & accountability**

To adapt and transform our business

To build credible, sustainable, and long-term profitable growth

To deliver value to patients, customers, employees, and shareholders



# We Focus Where The Future of Healthcare is Going



**Move to Point-of-Care  
Home Testing**



**Growth of  
Personalized  
Medicine**



**Healthcare  
Consumerism**



# Corporate Strategic Imperatives

Simultaneously advancing on all fronts to drive shareholder value

## Strengthen our Foundation



- 1) Create a path to sustainable profitability
- 2) Strengthen balance sheet

## Elevate our Business



- 3) Reinvigorate our core growth ... expand innovation pipeline & partnerships
- 4) Align structure with business needs & inspire talent

## Accelerate our Growth



- 5) Spur new segment expansion ... including M&A to bolster growth

**Innovating & operating with disciplined execution & accountability**



# End-to-End Solutions that Encompass Tools, Services and Diagnostics



## Healthcare POC Diagnostics

Selection of high value / actionable testing

- ✓ Infectious disease – COVID-19, HIV, HCV
- ✓ Substance abuse testing – Workplace, Insurance Risk

## Molecular Sample Collection

Sample collection & stabilization devices to drive discovery and access

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

## Microbiome Services

Data analytics and AI, multi-omic view to health & wellness

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



# Diagnostic Products



# 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"><li>• IntelliSwab™ COVID-19 Rapid Test</li></ul>	<ul style="list-style-type: none"><li>• Designed to be one of the simplest tests on the market</li></ul>	N/A	<ul style="list-style-type: none"><li>• Test has EUA in the professional, prescription self test, and over-the-counter settings</li></ul>	≈ 1B tests (2022)	≈ 5B (2022)	> 60% antigen globally	Variable
HIV	<ul style="list-style-type: none"><li>• OraQuick® HIV</li></ul>	<ul style="list-style-type: none"><li>• Only FDA approved test for over-the-counter home testing</li><li>• Saliva based test</li></ul>	1.2M / 38M	<ul style="list-style-type: none"><li>• 13-64 at least once in their life</li><li>• Those with risk factors tested annually or every 3-6 months</li></ul>	30-40M	80-100M	20-25%	5-7%
HCV	<ul style="list-style-type: none"><li>• OraQuick® HCV</li></ul>	<ul style="list-style-type: none"><li>• Simple highly accurate test using finger stick blood</li></ul>	2.4M / 71M	<ul style="list-style-type: none"><li>• Testing at least once in a lifetime</li><li>• All adults born between 1945-1965</li><li>• Patients with high risk factors</li></ul>	8-10M	75-90M	15-20%	5-7%
Substance Abuse	<ul style="list-style-type: none"><li>• Intercept® Oral Fluid Drug Testing System</li></ul>	<ul style="list-style-type: none"><li>• Ability to use oral fluid as the sample collection and visually ensure compliance</li></ul>	N/A	<ul style="list-style-type: none"><li>• Employer screening</li><li>• Drug treatment and pain management</li><li>• Insurance screening</li></ul>	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

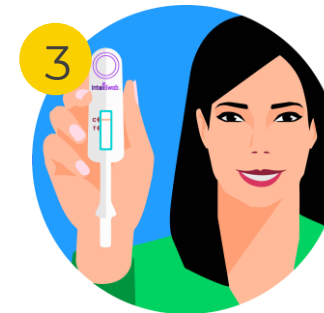
- Authorized by FDA for OTC, Prescription Home Use and Professional Point-of-Care CLIA-Waived use
- Accuracy comparable to other point-of-care offerings (84% sensitivity / 98% specificity)
- Convenient sample collection with <1 min. of hands on time; results in 30 min. More than 98% of users find InteliSwab 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





# Infectious Disease Testing: HIV

Creating HIV Solution Covering All Phases of HHS and Global Response Plan, and Aligned to \$6bn in Global Funding

## ■ Diagnose with OraQuick®

- Perfect for outreach settings where HIV continues to exist and spread
- First and only rapid HIV OTC test approved by FDA (PMA)
- First and only WHO-prequalified rapid oral HIV self-test
- **Global HIV Self-Test market share leader** with oral fluid self-collection and in-home result
- Clinically Proven: 99.3% sensitivity, 99.8% specificity (oral, FDA PMA)

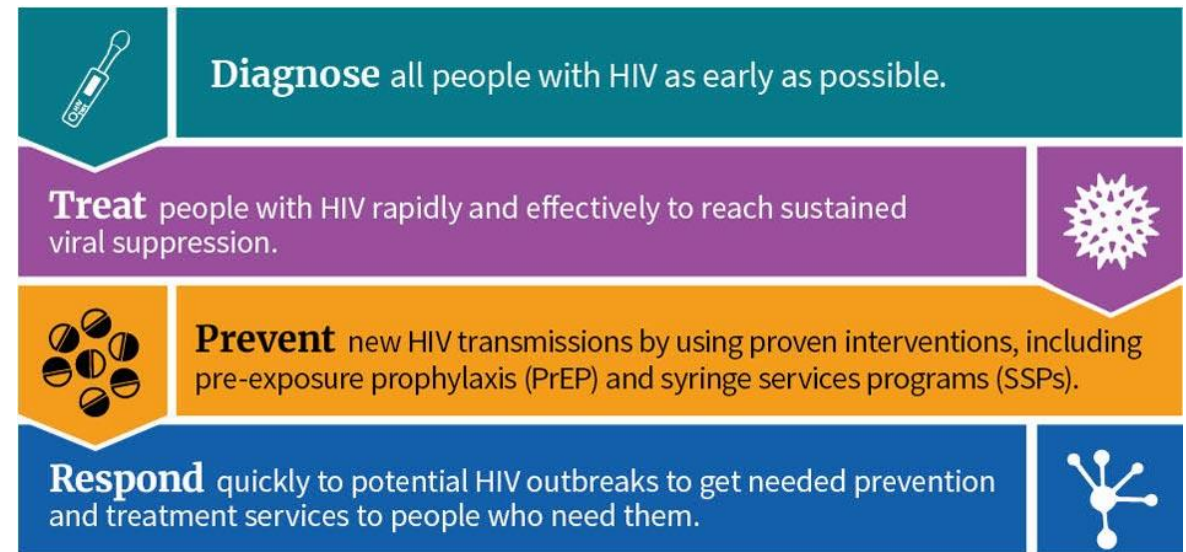
## ■ Ensure Prevention with SureQuick™

- First of its kind diagnostic test for PrEP adherence with additional assays in development

## ■ Ensure Treatment and Stop the Spread with SureQuick™

- Same PrEP adherence tests will also detect adherence to ARV drugs

## US HIV Federal Response Strategy from HIV.gov



38mm people worldwide have HIV  
and 16% do not know their status<sup>1</sup>

1. HIV.gov



# Infectious Disease Testing: HCV

HCV Testing Has Significant Upside with 43mm People Undiagnosed, the Opioid Epidemic Driving Infections, and Treatments to Cure if Caught Early Enough

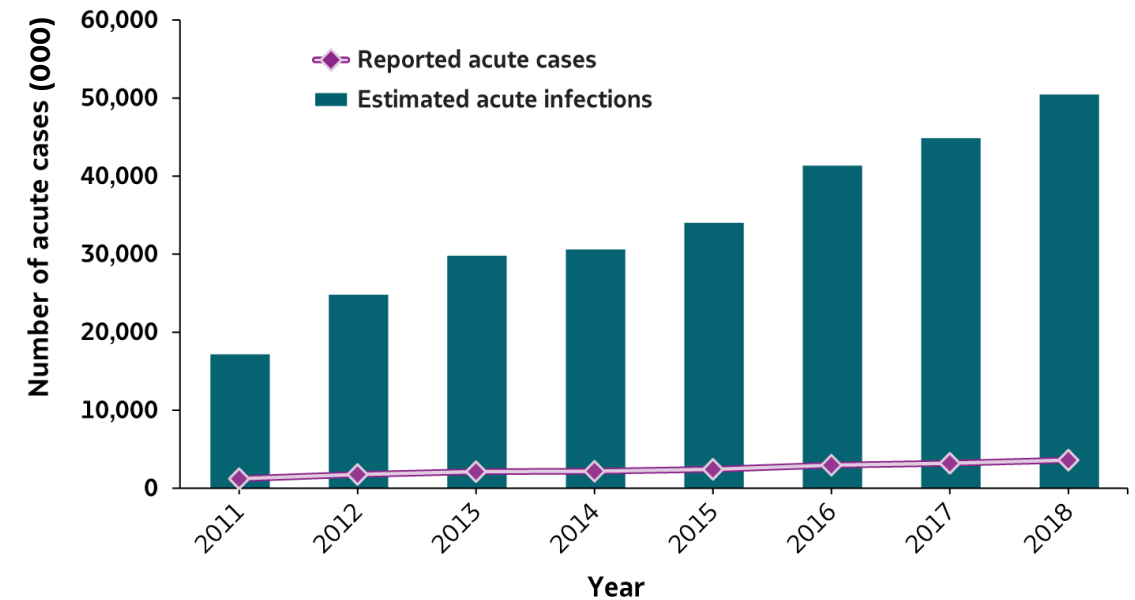
- **Government Tailwinds Support Rapid Testing**

- US issued “Viral Hepatitis Roadmap to Elimination” in 2021 promoting HCV screening
- WHO HCV Self-Test guidelines

- **OraQuick® HCV is Unique**

- Only oral fluid test in the world
- Only rapid POC test in the US, results in 20 minutes
- Clinically proven with 99.5% sensitivity, 99% specificity (blood; US FDA PMA)
- Clinically proven with 98.1% sensitivity; 99.6% specificity (saliva; CE, WHOPQ)

## HCV: Cases Are Growing While Testing Lags<sup>1</sup>



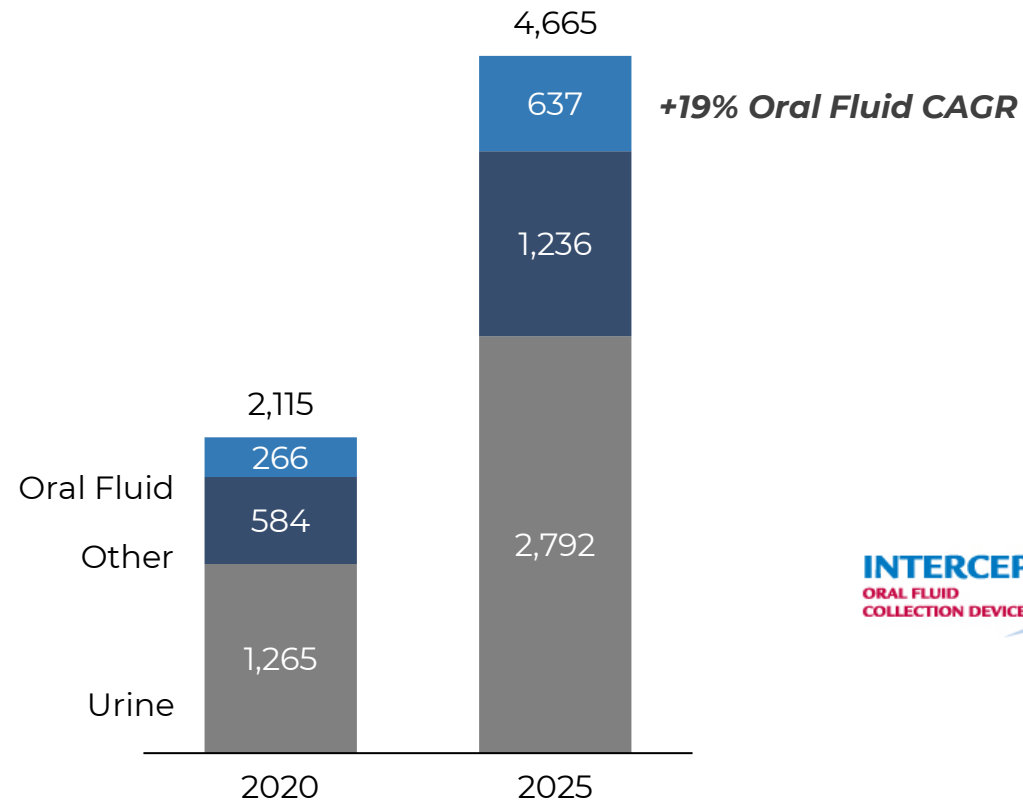
1.

Centers for Disease Control and Prevention

# Substance Abuse Testing: Oral Fluid

\$2bn North American Market Growing at 17% CAGR, with Upside for Oral Fluid Tests as Employers Move from Urine to Oral Testing

## N.A. Drug Testing Market (\$mm)



- **Large, High-Growth Market Supporting Oral Fluid Testing**
  - SAMSHA guideline changes allow oral fluid
- **OraSure Has Several Product Offerings**
  - Self-collected and observed collected oral fluid devices with proprietary chemistries
  - Volume indication to ensure sample adequacy
  - ELISA and high-throughput laboratory assays including marijuana, cocaine, PCP, opiates, amphetamines, barbiturates, benzodiazepines and methadone



Source: Drug Screening Market, Global Forecast to 2025: Markets and Markets, November 2020

A woman with long grey hair, wearing a white long-sleeved shirt, is shown from the chest up. She is holding a small clear plastic bag with both hands, and a small glass vial with a white cap is visible inside the bag. She is looking down at the bag with a focused expression. The background is a kitchen with a white oven and a window. The image has a blue and yellow gradient overlay.

# Multi-omic Kits and Services



# The 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



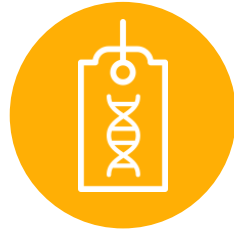
Direct-to-  
patient  
laboratories



Clinical  
Genomics



Academic  
Labs



Consumer  
Genomics

END MARKETS GROWING AT DOUBLE-DIGIT RATES

## WHAT WE DO



Sample collection kits across a variety of specimen types and applications



Data and fulfillment services



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

# Our Collection Products

**DNAGENOTEK®**



Saliva



Swab



Microbiome &  
Metabolomics



Animal



- Reliable **self-collection** at home or in professional settings
- Long-term **room temperature sample stability** for years
- Spit and sponge-based kits
- Chemistries for **DNA and RNA** available
- **Diagnostic and Research Use Only** options also available
- Reagents for preparation also available

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 **Colli-Pee**



Infectious  
Diseases



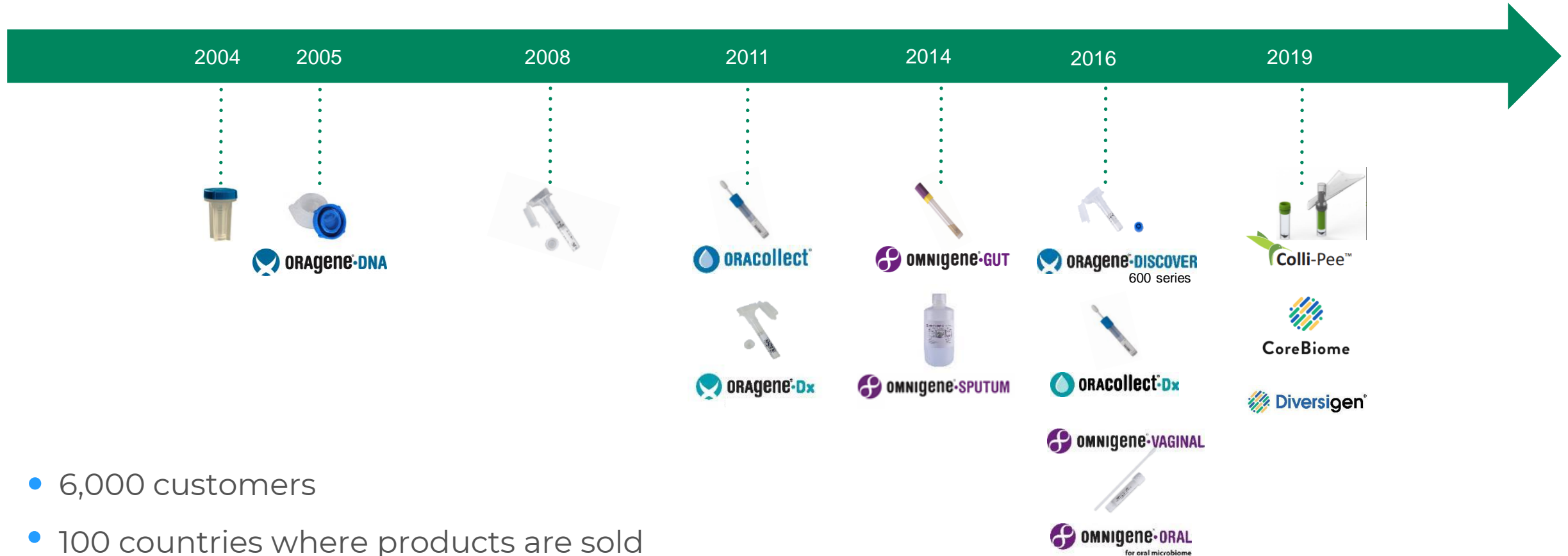
Oncology



- Non-invasive, **volumetric** collection of first void urine (4-45ml)
- Easy-to-use; ideal for home collection
- Can be prefilled with Novosanis' proprietary chemistries
- Preservatives enable **longer storage** and shipment of urine at room temperature



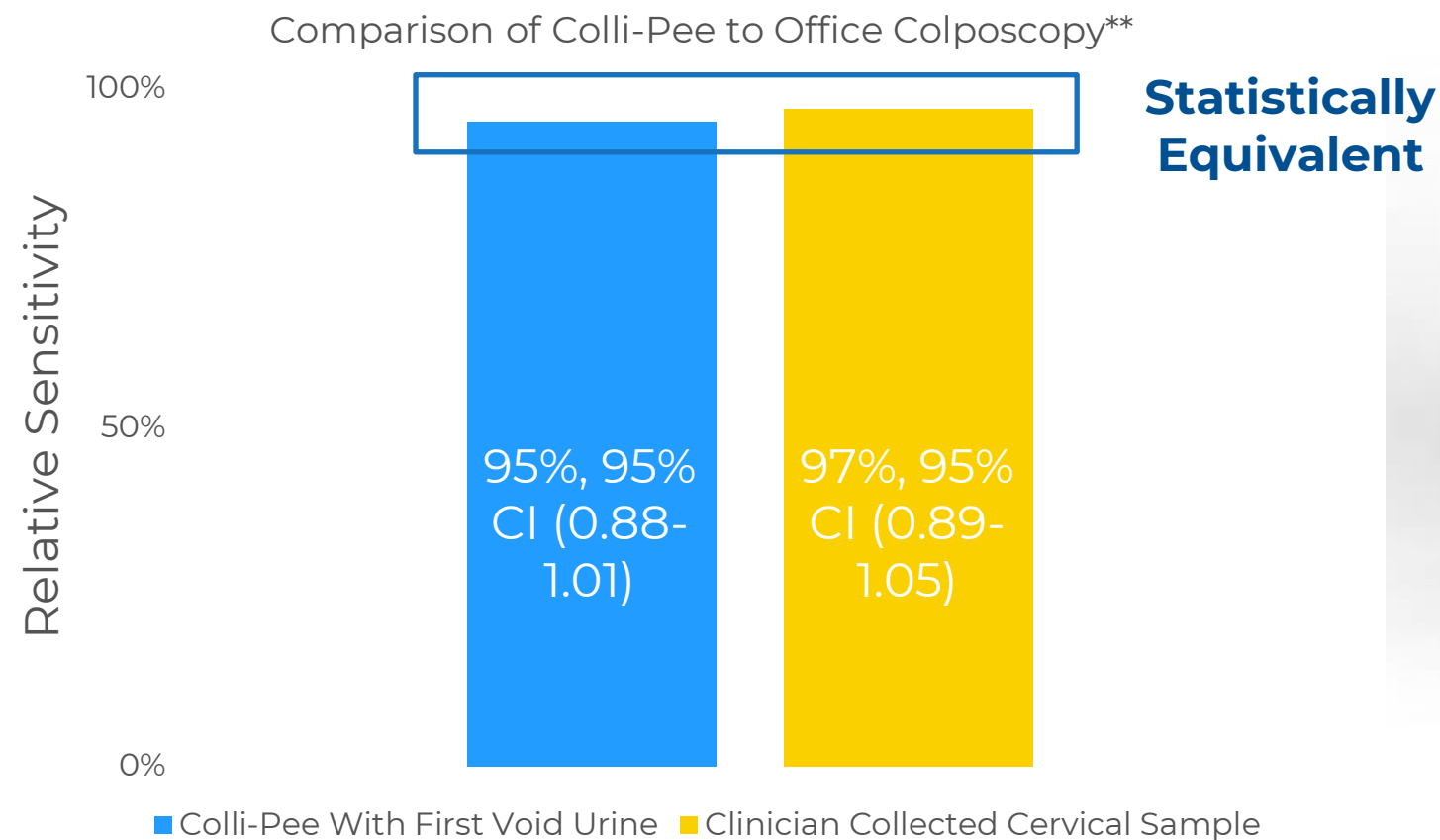
# Accelerating Expansion Into New Sample Types, Multi-omic Research Areas & Services



- 6,000 customers
- 100 countries where products are sold
- 3,000 peer reviewed research publications supporting technologies



# Colli-Pee®\*, New Innovation in Sample Collection; Addressing Global HPV Screening, STD, & Oncology Markets



\*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>





# Services & Analysis: Diversigen

100+ Years of Microbiome Experience with 300+ Scientific Publications & 100K+ Research Citations

## Human Health



- Discovery & Clinical Research
- Diagnostics & Live Biotherapeutics
- Fecal Microbiota Transplantation (FMT)
- Pathogen Surveillance

## Agriculture



- Crop Yield
- Soil Amendment
- Animal Health
- Feed Conversion Ratios

## Environmental Monitoring



- Environmental Science: Food Safety
- Oil & Gas

## Skin



- Personalized Beauty & Cosmetics
- Atopic Dermatitis & Acne Vulgaris
- Wound & Tissue Healing

Nucleic Acid Extraction

Shallow & Deep  
Shotgun Sequencing

Amplicon Sequencing

Bioinformatic  
Services

Strain  
Analysis

Viral Metagenomic  
Sequencing

Mouse Microbiome  
Profiling

Germ-Free Mouse  
Study Services

Absolute Quantification

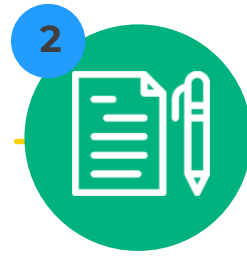
Metal  
Services



# Expanding Competitiveness Through Multiple Strategies



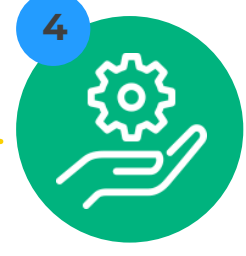
Expanding intellectual property portfolio through filed patents and technology acquisitions



Long-term contracts with major customers providing forward visibility



Increased regulatory approvals in conjunction with commercial partners



Customer kit specialization and increased service scope



# Financials & Summary



OraSure Technologies, Inc.

DNAgenotek™

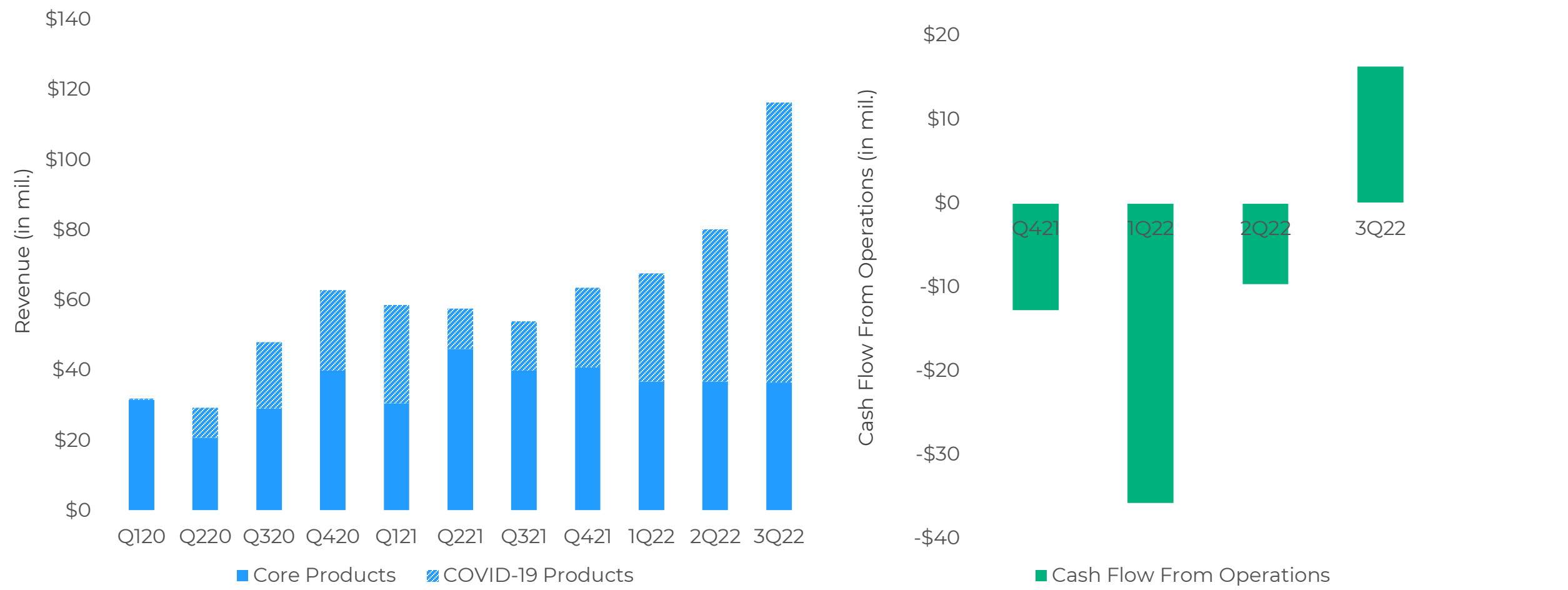


Diversigen®



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# Strong Revenue Growth and Improving Cash Generation





# Summary

- Commercially tied to high growth areas of healthcare such as consumer/clinical genomics and shift to direct-to-patient/near patient testing
- Focused on COGS improvements and streamlining internal cost structure
- Opportunity to reinvigorate core growth through leveraging new enterprise capabilities and partnerships
- Strong backdrop for cash generation from COVID-19 testing and improving cost structure that will finance future organic and inorganic growth

