



OraSure Technologies, Inc.

Corporate Fact Sheet

Headquarters

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Website: www.orasure.com

Subsidiaries:

Diversigen: www.diversigen.com
DNA Genotek: www.dnagenotek.com
Novosanis: www.novosanis.com

Stock Symbol: NASDAQ: OSUR

Executive Officers:

- Stephen S. Tang, Ph.D., President and Chief Executive Officer
- Roberto Cuca, Chief Financial Officer
- Kathleen G. Weber, Executive Vice President, Business Unit Leader, Molecular Solutions
- Lisa Nibauer, Executive Vice President, Business Unit Leader, Diagnostics
- Jack E. Jerrett, Senior Vice President, General Counsel, Secretary and Chief Compliance Officer
- Michele Miller, Vice President, Finance, Controller and Assistant Secretary

Company Overview:

OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate, essential information. Together with its wholly owned subsidiaries, DNA Genotek, Diversigen and Novosanis, OraSure provides its customers with end-to-end solutions that encompass tools, services and diagnostics. The OraSure family of companies is a leader in the development, manufacture, and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular services solutions designed to discover and detect critical medical conditions.

OraSure's first-to-market, innovative products include rapid tests for the detection of antibodies to HIV and Hepatitis C (HCV) on the OraQuick® platform; sample self-collection and stabilization products and laboratory and analytical services for molecular applications; and oral fluid laboratory tests for detecting various drugs of abuse.

The Company is bringing its expertise to the COVID-19 battle with a rapid antigen test, InteliSwab™ COVID-19 Rapid Test, which has been authorized by the FDA, and an oral fluid antibody test, which is under development. In addition, its sample collection devices are being used for the collection, both in at home and professional settings, and transport of samples for COVID-19 molecular testing.

OraSure's portfolio of products is sold globally to clinical laboratories, hospitals, physician's offices, clinics, public health and community-based organizations, research institutions, government agencies, pharma, commercial entities and direct to consumers.

OraSure Technologies – Product Offerings:

MOLECULAR SOLUTIONS

The Molecular Solutions business unit focuses on delivering high-quality products and services in the realms of human genomics, animal genomics, viral screening and surveillance and microbiome discovery.

Molecular Sampling Tools

Self-collection sampling products are designed to maximize reach and access to samples enabling research, health risk screening, consumer and animal genomics and diagnostic applications.

- The Oragene[®] family of products is designed for the non-invasive self-collection and stabilization of DNA from saliva. Oragene[®]Dx is the first saliva collection device to receive FDA 510k general clearance for prescription and over-the-counter/DTC in vitro diagnostic testing of human DNA.
- The ORACollect[®] family of products is designed for non-invasive DNA self-collection and stabilization kits using a swab oral sample. ORACollect[®]Dx is the first and only FDA 510k-cleared sponge-based **saliva** collection device to collect and stabilize oral DNA samples.
- The OMNIgene[®] family of products is an all-in-one system for the collection and stabilization of gut, oral, skin, or vaginal microbiome samples. These products are for Research Use Only in the U.S.
- OMNImet•GUT is an at-home collection and stabilization device for metabolomics.
- PERFORMAgene and PERFORMAbiome are designed to collect and stabilize genomic and microbial samples from animals.
- The Colli-Pee[™] device, designed by Novosanis, efficiently and hygienically captures a volumetric first-void urine sample.
- In 2020, the ORACollect•RNA, OMNIgene•ORAL and Oragene•Dx products were validated through various global regulatory mechanisms (U.S. FDA Emergency Use Authorization, Health Canada authorization, and CE/IVD in Europe) for the purposes of Molecular testing (PCR and Sequencing) of the SARS-CoV-2 virus.

Molecular Services

- Diversigen is powering microbiome discovery through sequencing, analysis, and consulting services geared toward the study of the microbiome of living organisms and environments. By working closely with key manufacturers and applying laboratory best practices, Diversigen has developed state-of-the-art techniques to extract high quality nucleic acids from a variety of sample types for subsequent metagenomic analysis. Diversigen's flexible sequencing and computing capacity, combined with ongoing improvement of analytic tools and their applications, allow them to customize unique strategies on a per-project basis. Diversigen takes pride in one-on-one consultation with the customer until complete satisfaction is achieved. The services offered cover the full spectrum from organism detection, to analysis, modification, and consultation.
- The customization and fulfillment services offered through our DNA Genotek subsidiary support the needs of our research and commercial customers. We offer package design, customized inserts, single

order fulfillment, warehousing and tracking to customers requiring assistance in the execution of broad research or population health initiatives.

DIAGNOSTICS

Infectious Disease

OraSure offers several infectious disease tests based on lateral-flow technology. The ease-of-use and reliability of the products make them ideal for use in clinic and in outreach settings, enabling greater access to high-risk individuals. Rapid testing also enables the patient to receive a result in one interaction, thereby allowing them to be linked to care.

- OraQuick® HIV family of products includes rapid testing for HIV that provides an answer in as little as 20 minutes. Its ease of use has led to its adoption across the globe as it enables access to patients that may not go to a clinic for testing, and use in low-resource settings. The family of products includes:
 - OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test – the first FDA-approved, CLIA-waived, rapid point-of-care test that can detect antibodies to both HIV-1 and HIV-2. For use in professional settings.
 - OraQuick® In-Home HIV Test – the first and only oral fluid rapid over-the-counter HIV test approved in the U.S. For self-test use; available online and through retail outlets.
 - OraQuick® HIV Self-Test – the first and only oral fluid rapid test pre-qualified by the World Health Organization. For use in global settings to enable elimination programs and self-testing.
- OraQuick® HCV Rapid Antibody Test – the first FDA-approved, CLIA-waived rapid HCV test. In Europe, it is the only CE-marked approved, point-of-care device that works on oral fluid, whole blood, serum and plasma for HCV. OraQuick HCV is approved for the detection of HCV antibodies for individuals with signs and symptoms or at risk of infection.
- OraQuick® Ebola Rapid Antigen Test is designed to detect viral antigens in fingerstick and venous whole blood from patients presenting with signs and symptoms of Ebola infection in conjunction with epidemiological risk factors. It is also intended for use with cadaveric oral fluid collected from recently deceased individuals with epidemiological risk factors who are suspected to have died of EVD.
- OraSure QuickFlu® Rapid Flu A+B Test – an FDA-cleared and CLIA-waived in vitro rapid qualitative test for the detection of influenza (flu) type A and type B, including H1N1 viral infections.
- OraSure offers diagnostic tests that measure adherence to HIV medications, including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV. This includes laboratory-based tests that can measure levels of the medication in a patient’s urine or blood, as well as several additional point of care products in development.
- InteliSwab™ COVID-19 Rapid Test for Over-the-Counter (OTC) has been authorized for use without a prescription. FDA has also authorized the InteliSwab™ COVID-19 Rapid Test Pro for professional use in point of care (POC) CLIA-waived settings, and InteliSwab™ COVID-19 Rapid Test Rx for Prescription Home Use. These remarkably simple COVID-19 lateral flow tests use samples self-collected from the lower nostrils. InteliSwab’s unique design incorporates a built-in swab fully integrated into the test stick. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution,

and the result appears right on the test stick within 30 minutes, with no instruments, batteries, smartphone or laboratory analysis needed to see the result.

Substance Abuse / Insurance Risk Assessment

OraSure offers a range of products that use oral samples for substance abuse testing. The ease-of-use of these products makes them ideal for workplace, criminal justice, drug treatment centers, pain management and clinical setting screening programs.

- Intercept® Oral Fluid Drug Test – an FDA-cleared laboratory-based oral fluid testing system (Intercept Oral Fluid Collection Device and Intercept Micro-Plate Assays) that enables accurate testing for drugs of abuse, including marijuana, cocaine, PCP, amphetamines and opiates.
- Intercept® i2™ Oral Fluid Collection Device – a next-generation collection device for drugs of abuse with an adequacy volume indicator.
- Q.E.D.® Saliva Alcohol Test – a CLIA-waived and U.S. DOT-approved, rapid, low-cost alternative to alcohol breath or blood testing.

Selected Financial Information:

Years Ended			
(in thousands, except per share amounts)			
(Audited)			
		2020	2019
Revenues		\$ 171,121	\$ 154,605
Net Income (Loss)		\$ (14,922)	\$16,656
Earnings Per share -	Basic	\$ (0.22)	\$ 0.27
	Diluted	\$ (0.22)	\$ 0.27
Number of Shares -	Basic	67,505	61,675
	Diluted	67,505	62,170

Employees: 570 (as of December 31, 2020)

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