UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 29, 2016

OraSure Technologies, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

220 East First Street **Bethlehem, Pennsylvania**	**18015-1360**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: 610-882-1820

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 – Regulation FD Disclosure.

On November 29, 2016, OraSure Technologies, Inc. (the "Company") will host an Analyst Day meeting in New York City, New York, at the NASDAQ MarketSite at Times Square. At the meeting, the Company's senior executive team will make presentations to analysts using slides containing the information attached to this Current Report on Form 8-K as Exhibit 99.1. The fact that these presentation materials are being furnished should not be deemed an admission as to the materiality of any information contained therein. The information contained in the slides is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission filings and other public announcements that the Company has made or may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report.

This information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Management presentation to be used at the OraSure Technologies, Inc. Analyst Day on November 29, 2016.

Signatures

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ORASURE TECHNOLOGIES, INC.

Date: November 29, 2016

By: */s/ Jack E. Jerrett*
Jack E. Jerrett
Senior Vice President, General Counsel
and Secretary

Exhibit Index

Exhibit Number	Description
99.1	Management presentation to be used at the OraSure Technologies, Inc. Analyst Day on November 29, 2016.

OraSure Technologies

Analyst Day
November 29, 2016
Nasdaq MarketSite

OraSure Technologies, Inc.

Agenda

- Welcome and introductions
- Infectious Disease
  - HCV Country-Wide Elimination Programs
  - HIV Self-Testing
  - R&D: Emerging Diseases - Ebola, Zika
  - Tuberculosis (TB)
- Molecular
  - Personal Genomics
  - Microbiome
  - R&D: Sample Optimization
- Financial review / Business Development
- Summary

OraSure Technologies, Inc.

Forward-looking statements

These slides and the associated presentation contain certain forward-looking statements, including statements with respect to revenues, earnings, technology, new products, product performance, markets, clinical development, regulatory filings and approvals, and business plans. Factors affecting these statements include, but are not limited to, the ability to develop new technology, technology changes, ability to fund research and development, required regulatory approvals, product performance and market acceptance of products. Please see the Company's SEC filings, including its registration statements, and the Company's most recent Form 10-K and Form 10-Q, for a more detailed description of specific factors that may cause actual results or events to differ materially from those described in the forward-looking statements. The Company undertakes no duty to update these statements.

Welcome and introductions

Tony Zezzo
Executive Vice President,
Business Unit Lead, Infectious Disease

Brian Smith
Senior Vice President
Business Unit Lead, Molecular

Mike Reed, Ph.D.
Senior Vice President, Research & Development
and Chief Science Officer

Aaron Del Duca
Vice President, Technology
Microbiome Program Lead

Cassandra Kelly-Cirino, Ph.D.
Vice President, Infectious Disease
TB and Emerging Diseases Program Lead

Rafal Iwasiow, Ph.D.
Vice President, R&D, Molecular

OraSure Technologies, Inc.

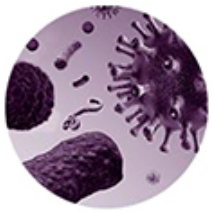
Our company vision

Empower healthcare providers and patients worldwide to improve global health through access to accurate, essential information.

We will accomplish this through a deep understanding of our customers' needs and a commitment to innovative infectious disease and molecular solutions.

Core strategic growth pillars

Grow Infectious Disease business

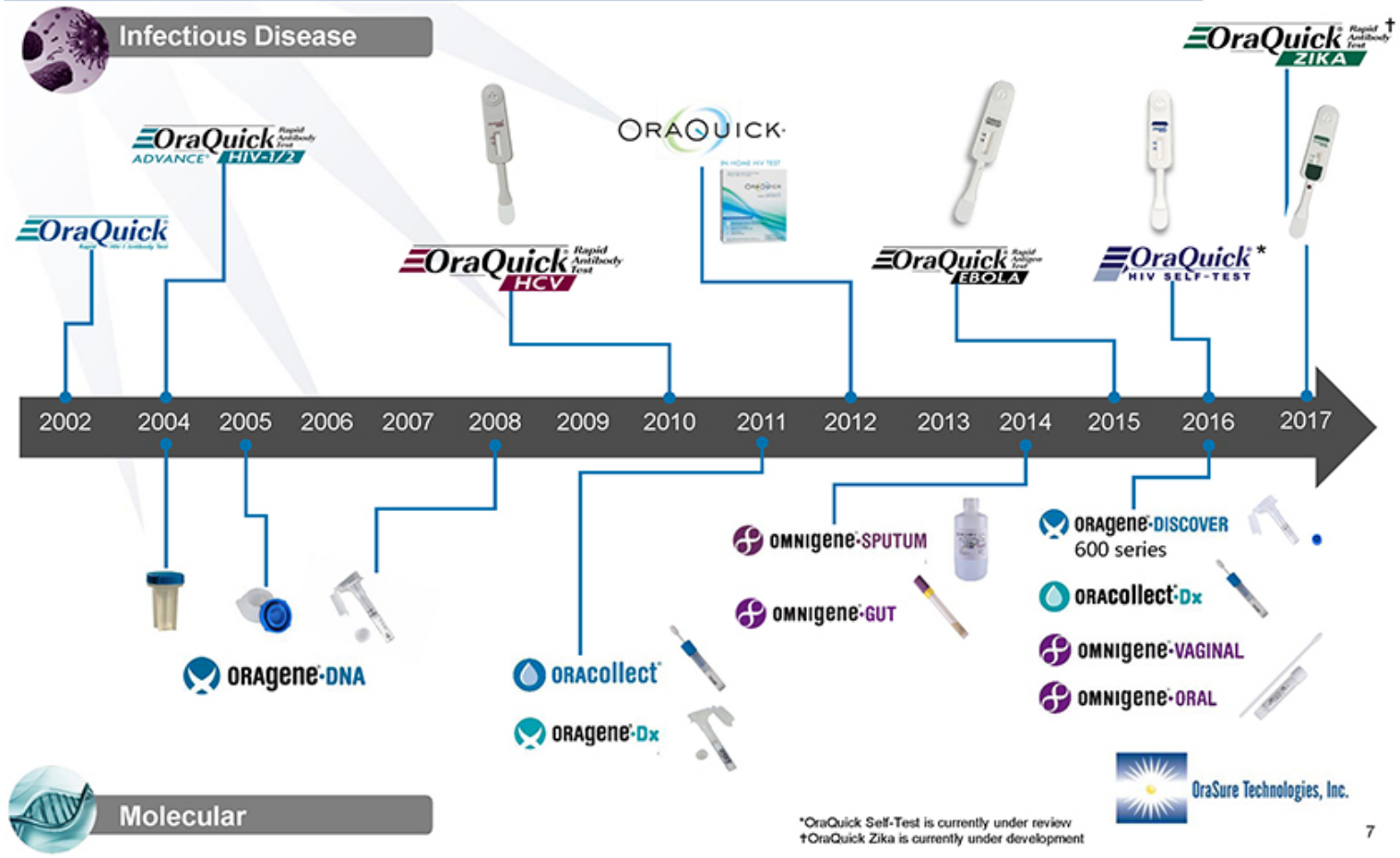


Driving unprecedented global access to our existing and new Infectious Disease diagnostics

Grow Molecular business

Leveraging the strength of our Molecular business into new growth markets, with existing and new technology

Strong platform foundation for growth



*OraQuick Self-Test is currently under review
†OraQuick Zika is currently under development

Core growth strategies

Infectious Disease

- Expand global access to HIV and HCV products through innovative testing programs and collaborations
- Develop and launch new POC diagnostics targeting emerging high burden infectious diseases
- Develop and launch reagent targeting transport and processing of sputum samples to optimize Tuberculosis (TB) diagnosis

Molecular

- Expand beyond sampling to offer incremental value from collection through to reporting via complementary products and services
- Leverage early wins in Asia to replicate success in US
- Focus on standardization and weaving Microbiome into genomics research customer base to drive growth

OraQuick® Rapid Antibody Test HCV

HCV Country-Wide Elimination Programs

Tony Zezzo
Executive Vice President,
Business Unit Lead, Infectious Disease
OraSure Technologies, Inc.

OraSure Technologies, Inc.

HCV opportunities

- 170 million people infected globally, 4-5 million people infected in U.S.
  – The majority of HCV infection remains undiagnosed
- Approved drugs, and those in the pipeline, are driving demand for increased diagnoses and the number of patients initiating therapy
- Significant reduction in the cost of treatment in developing countries
- Availability of a rapid, non-instrument rapid point of care test drives diagnosis through increased testing outside of laboratory

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Source: CDC

OraQuick® HCV Rapid Antibody Test

Quality matters

- **Accurate** – sensitivity and specificity comparable to lab-based immunoassays
- **Versatile** - reach patients outside traditional laboratory testing channels
- **Simple** – extremely easy to use three step process; use with oral fluid outside U.S.
- **20 minute results** – allows for immediate linkage of patient to care and treatment

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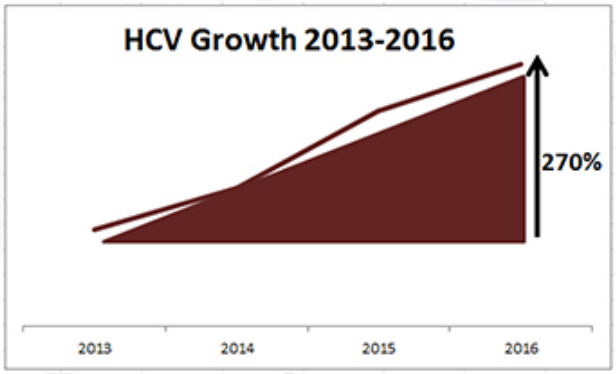
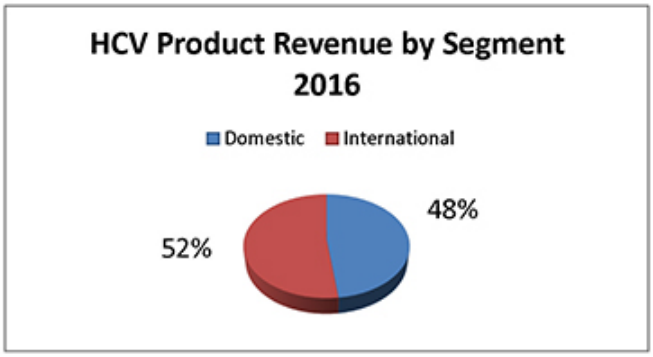
HCV product revenue 2013-2016

Overall Growth



- Product revenue growth of 270%
- CAGR of 28.2%
- Historical revenue drivers:
  - Domestic Public Health
  - Asia and Large International NGO
- Future revenue drivers:
  - Country elimination projects
  - Public Health and drug treatment

Product Revenue Growth



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Eliminate viral Hepatitis by 2030

WHO leading effort to eliminate viral hepatitis by 2030

Map 3-05. Global epidemiology of hepatitis C virus infection[1]

36 countries with national plans to combat hepatitis
33 countries formulating national plans

Source: WHO, Combating Hepatitis B and C to Reach Elimination by 2030, May 2016

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[1]Disease data source: Mohd Hanafiah K, Groeger J, Flaxman AD, Wiersma ST. Global Epidemiology of Hepatitis C Virus Infection: New Estimates of Age-Specific Antibody to HCV and Seroprevalence. Hepatology.

HCV program opportunities (examples)

Country 1

- Country-wide testing campaign over 12 months
- $18 million in value, 90% HCV tests
- Multi-million test kit purchase with additional purchase option

Country 2

- Rural community and migrant worker program by MOH
- Initial pilot order shipped
- Expected volume of 100K+

HCV growth programs

Country 3

- Outreach and remote testing initiative
- Initial order shipped, additional orders anticipated
- Expected volume of 100K+

Country 4

- Test and treat program with local partner
- Initial order 2017 of 50K tests
- Expected volume of 100K+

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Excellent growth prospects

- Recognized bodies (WHO) have prioritized Hepatitis and Hepatitis C for elimination
- Price of HCV therapy is significantly reduced in developing countries
- Large scale test and treat pilots and country elimination programs are being executed
- Recognition that all test and treat programs will need a quality rapid test to optimize success
- OraSure's HCV test is seen as an ideal solution and is being incorporated into test and treat programs

OraQuick® HIV SELF-TEST

HIV Self-Testing

Tony Zezzo
Executive Vice President,
Business Unit Lead, Infectious Disease
OraSure Technologies, Inc.

OraSure Technologies, Inc.

The need and opportunity

- ~100MM HIV rapid tests are deployed annually, funded largely by donor agencies
- 36.7 million people globally were living with HIV (end 2015), only half of those individuals know their status
- The majority of undiagnosed individuals have limited or no access to health services
- Stigma associated with HIV remains an issue
- The down stream costs of these issues has and will financially burden health systems
- Implementation of UNAIDS 90:90:90 initiative to address situation

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Source: unaids

State of HIV self-testing

- The first studies conducted by the London School of Hygiene and Tropical Medicine
- Other studies followed by several notable organizations
- Two important outcomes developed:
  - More people chose to test when offered a self test
  - OraQuick was used in all studies for its quality and ease of use
- UNAIDS sited self testing as an innovation critical to achieving the 90:90:90 goals

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

PATH

3ie International Initiative for Impact Evaluation

BILL & MELINDA GATES foundation

psi

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The OraQuick® HIV self-test

Self-test product contains: Standard OraQuick device and vial, single use stand and a package insert placed in an over-pouch for personal use/carry.

Standard device/vial
+ single use stand

Package insert

Over-pouched
for single use

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OraQuick and self-testing

Competitive advantage

- OraQuick track record of success
- Endorsement from leading KOLs
- Ease of use and oral fluid matrix
- Foundation and validation studies well underway

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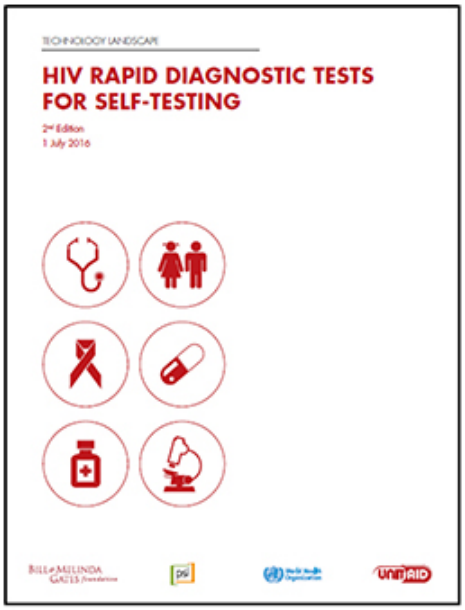
State of HIV self-testing

WHO/UNITAID release landscape report on Rapid HIV self-testing

- Market for HIV self testing tools is clearly growing
  - Drivers are replacement, frequency of testing and uptake of testing
  - Early estimates indicate self testing could easily reach 23M tests annually
- Additional information on demand estimates is expected by the end of 2016
- 16 countries have adopted HIV self testing policies – others are currently developing them
- Growing interest from international donors could make low-cost and quality self-testing tools available faster than ever before



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Key progress to date

- UNITAID/PSI STAR program phase 1 initiated in Zimbabwe, Malawi and Zambia
- Shipped over 400K tests to pilot countries
- Additional studies initiated in 6 countries with early stage interest
- WHO submission received 10/7/2016
- WHO pre-qualification opens up funding through various organizations
- Funding organizations highly interested (Global Fund, PEPFAR, UNITAID)

UNITAID/PSI
HIV SELF-TESTING AFRICA

UNITAID psi World Health Organization LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE LSTM UCL

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Next steps

- Complete Phase 1 (750K units) of UNITAID/PSI initiative and prepare for Phase 2 (1.9M units)
- Continue ongoing discussions with additional 6 countries to deploy once WHO pre-qualification is achieved
- Initiate studies in additional countries

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Summary

- Major funding organizations are showing high interest in self-testing
- Volume growth will be significant over the next few years
- The OraQuick HIV Self-test is very well positioned as the easiest, high quality, oral fluid rapid test available
- Self testing is a critical tool in reaching the undiagnosed in middle and low income countries and toward achieving the 90:90:90 millennium development goal

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R&D: Emerging Diseases – Ebola & Zika

Michael Reed, Ph.D.

Senior Vice President, Research & Development and Chief Science Officer

OraSure Technologies, Inc.

Emerging Diseases

"An emerging disease is one that has appeared in a population for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range" …

World Health Organization

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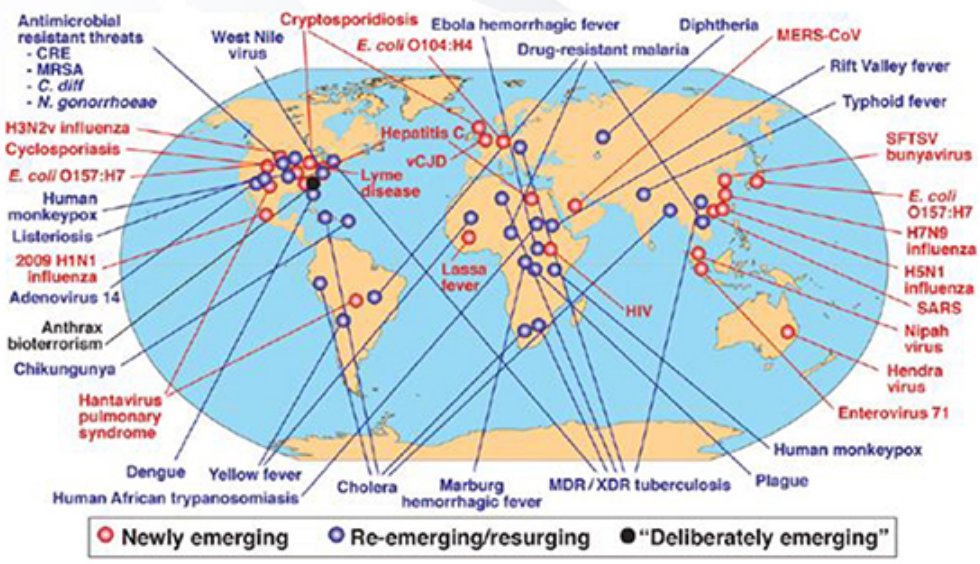
Ideal solution for emerging disease



- First line of defense is identifying and containing infected populations
- Demand for tests is generally small with sudden peaks during outbreaks
- Industry-Public Health collaborations critical to providing robust, rapid solutions

Powerful OraQuick platform ideal for rapid response to Ebola and Zika outbreaks

Being driven by US Government funding of up to $27M

Strong collaborations with the NIH, CDC and BARDA have been key for innovation and delivery

Morens et al., 2004.

OraQuick® Rapid Antigen Test EBOLA

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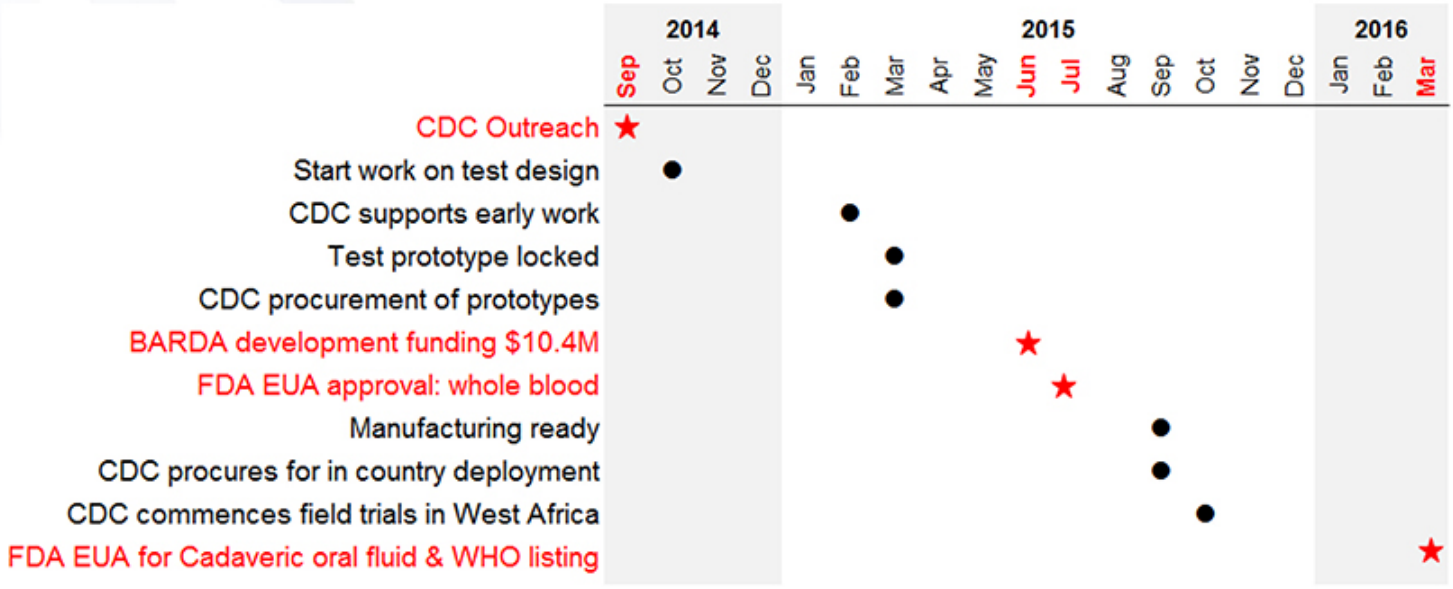
Quick and collaborative crisis response

10 month concept to deployment



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Impact of Ebola program

Providing high impact solution for Ebola control

- CDC has 75 staff in Africa to prevent another Ebola epidemic
- Cadaver testing is critical for outbreak management
- 7 outbreaks since 2014 epidemic have been controlled due to rapid response

Built process muscle

- Rapid innovation and commercialization
- Scale-up capacity for major outbreaks
- “Go to” company for Public Health collaborations

Ebola Outbreaks in West Africa (since 2014 epidemic)

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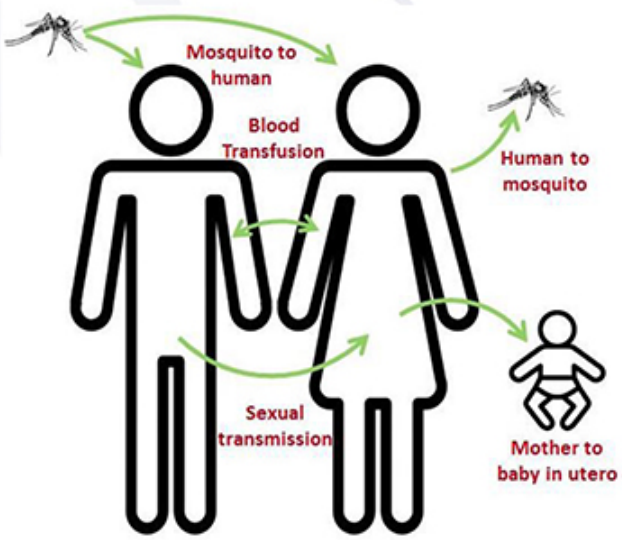
OraQuick® Rapid Antibody Test ZIKA

OraSure Technologies, Inc.

The Zika crisis

"Zika really is unprecedented. Never before have we seen a mosquito-borne virus that can cause birth defects"
Dr. Tom Frieden, CDC Director

Easy transmission



Health effects

- Flu-like symptoms: 20% of all infections
- Congenital birth defects: ~5% of pregnancies
- Guillain-Barre Syndrome: <1% of all infections

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Significant rise in Zika infections

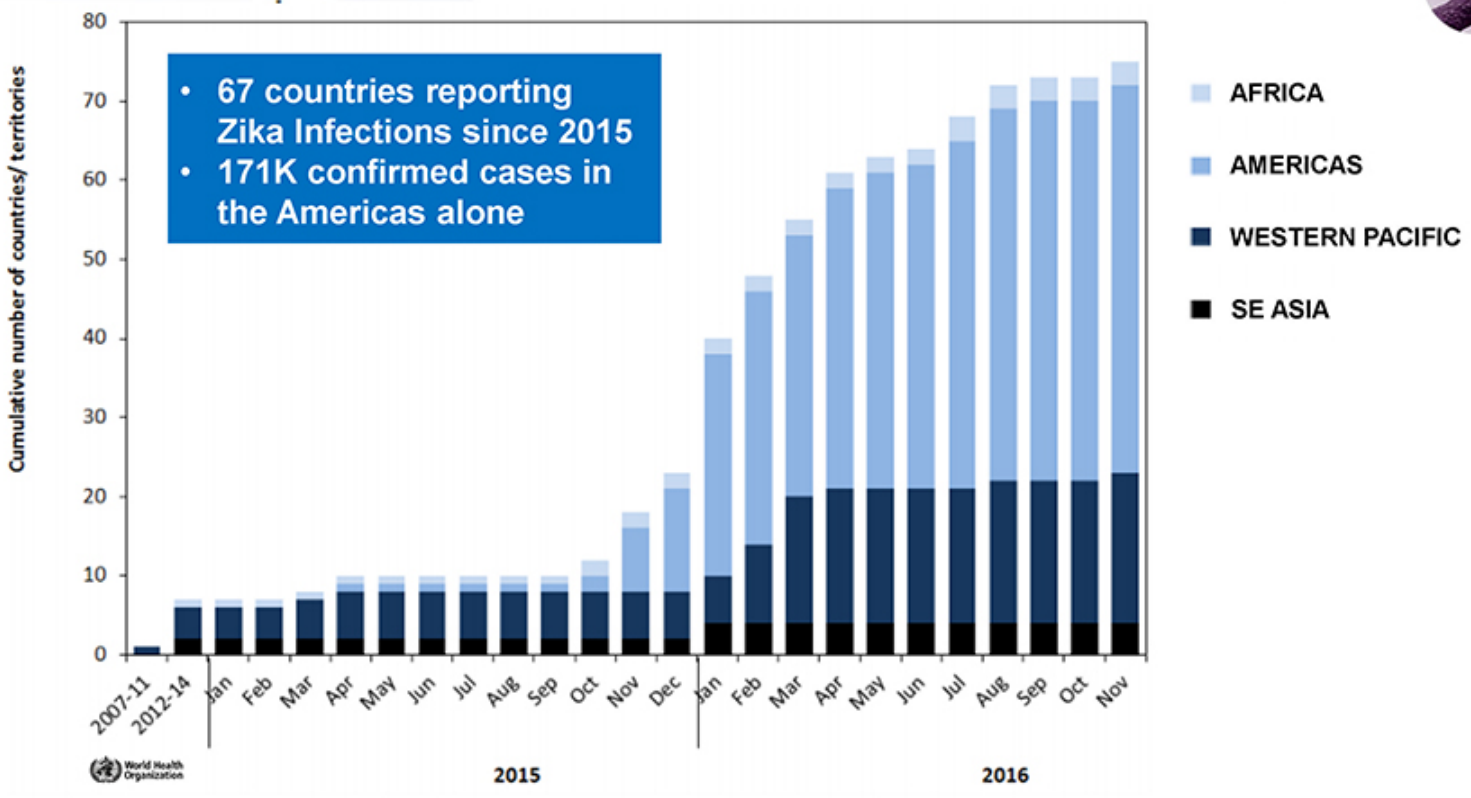

Figure 1. Cumulative number of countries and territories by WHO region[1] reporting mosquito-borne Zika virus transmission for the first time by year (2007–2014), and by month from 1 January 2015 to 9 November 2016

SITUATION REPORT: ZIKA VIRUS, MICROCEPHALY, GUILLAIN-BARRÉ SYNDROME - 17 NOVEMBER 2016

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Zika in the U.S. and territories

Total infections

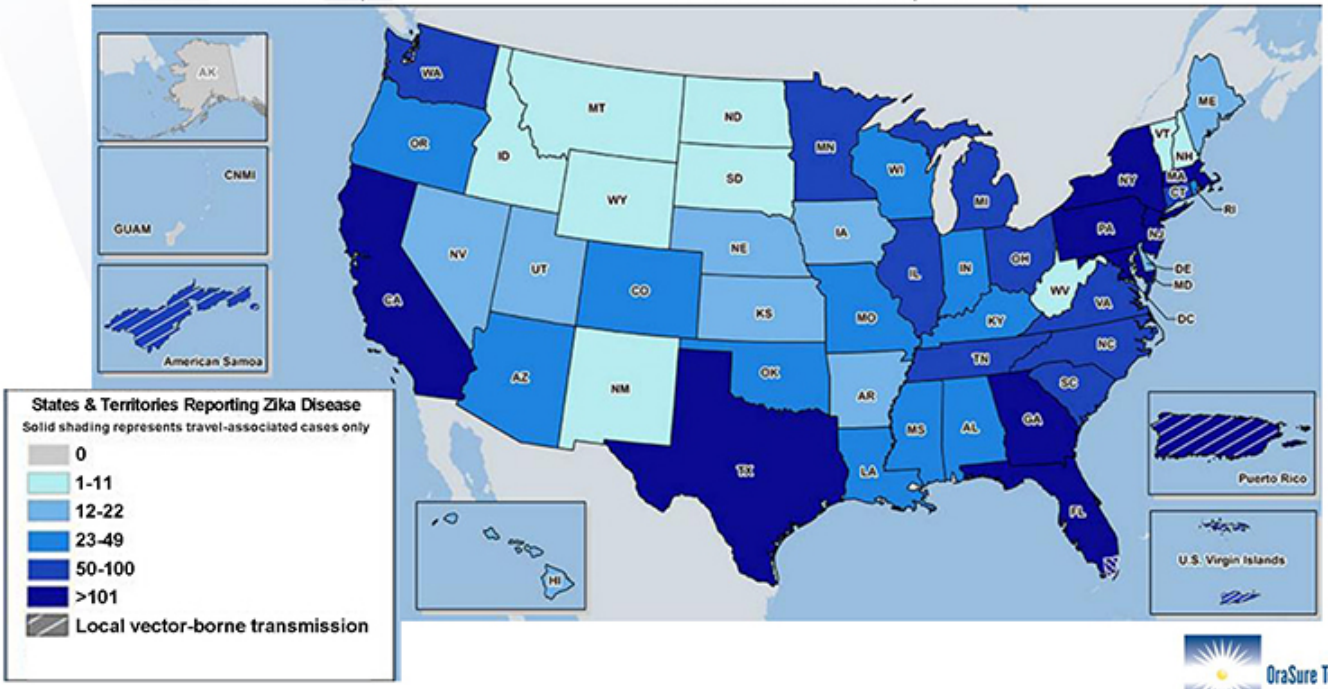
U.S. & D.C.: 4,444

U.S. territories: 32,724

Pregnant women

U.S. & D.C.: 1,114

U.S. territories: 2,561



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Source: https://www.cdc.gov/zika/intheus/maps-zika-us.html#active-florida; November 23, 2016

Zika health impact

"All pregnant women in the U.S. and U.S. territories should be assessed for possible Zika virus exposure at each prenatal care visit."

ACOG Practice Advisory, October 18, 2016

"Regardless of how WHO defines Zika, it is unprecedented, and it's an extraordinary risk for pregnant women."

Tom Frieden, CDC Director

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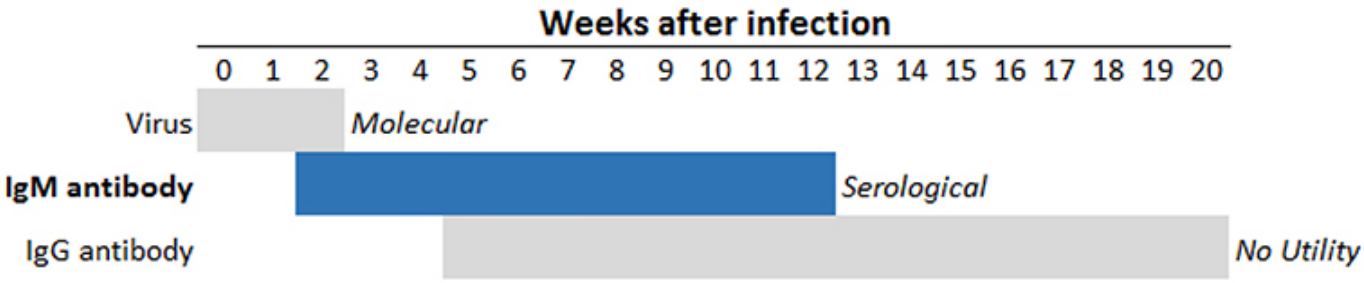
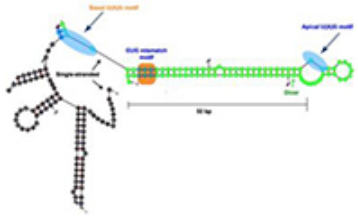
Zika detection needs



Molecular

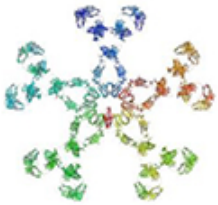


Ricketson (2016) WebMed Central, Mar 24

Zika Genome detection

10 Lab-based EUA tests

Serological



Protein Data Bank

Zika IgM detection

2 Lab-based EUA tests

Unmet need

Zika IgM detection

Point-of-care rapid test

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Awarded $16.6 M BARDA contract

THE WALL STREET JOURNAL.

Retailers Vie for Black Friday Dollars

Stripe's Valuation Nearly Doubles to $9.2 Billion

J&J Approaches Swiss Firm Actelion About Potential Deal

Tech Giants Are Poaching Universities' AI Talent

Czec Makes U on Coal

BUSINESS

OraSure Gets U.S. Contract to Hurry Development of Zika Test

Funding will speed development of oral test kits for the virus

OraQuick Zika Rapid Antibody Test*

Point-of-care value

Rapid results at patient's side
- <30 minute read time
- Relieves Public Health Lab testing burden

Prototype* data

In-house testing with prototype design:
- % positive agreement: 97.3% (36/37)
- % negative agreement: 98.3% (295/300)

Targeting EUA Submission in Q2, 2017

* The OraQuick Zika Rapid Antibody Test is a prototype and not intended for IVD use. Performance characteristics have not been established

OraSure Technologies, Inc.

Unique solution for emerging disease

Robust, flexible & proven platform

Rapid development of high quality tests for outbreak management

Strong partnerships and funding

OraQuick ADVANCE HIV-1/2

OraQuick HIV SELF-TEST

OraQuick HCV

OraQuick EBOLA

OraQuick ZIKA

10 month development to deployment

	2014 Sept	Oct	2015 Feb	Mar	Jun	Jul
CDC Outreach	★					
Start work on test design		●				
CDC supports early work			●			
Test prototype locked				●		
CDC procurement of prototypes				●		
BARDA development contract $10.4M					●	
FDA EUA approval: whole blood indications						★

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

World Health Organization

BARDA

FDA

Tuberculosis (TB)

Cassandra Kelly-Cirino, Ph.D.
Vice President, Infectious Disease
TB and Emerging Diseases Program Lead
DNA Genotek

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TB is an ongoing global crisis ...

TB KILLS

- 4,900 people per day
- One person every 18 seconds
  - 1.8 million died in 2015
  - 400,000 people with HIV+TB
- 28,500 people are infected per day
  - 10.4 million people infected in 2015

Better reporting, diagnosis and access to care will close this gap

Source: WHO

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WHO's end TB strategy

End the global TB epidemic

- Reduce TB deaths by 90%
- Cut new cases by 90% between 2015 and 2035
- Ensure that no family is burdened with catastrophic expenses due to TB

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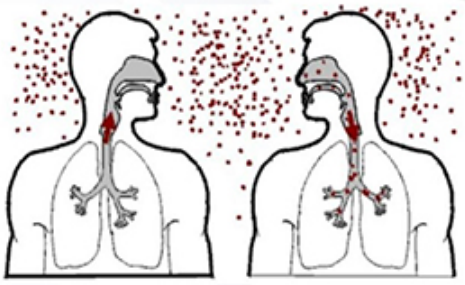
Why is TB eradication such a challenge?



- Easy to catch
  - TB is highly contagious – spread through the air, most often by coughing
- Difficult to reach patients
  - Poor patient access – rural settings with no infrastructure
  - Need to collect, transport and process viable sputum samples
- Hard to diagnose
  - Inefficient laboratory processes
  - Diagnostic tests for TB are insensitive, slow and/or expensive
- Hard to treat
  - Increasing antibiotic resistance

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The crisis gap

- While 6.1 million people had access to quality TB care, 4.3 million missed out in 2016
- 100M sputum samples were collected to find the 6.1 diagnosed cases in 2016
- ~200M sputum samples are needed to find the 4.3M undiagnosed people

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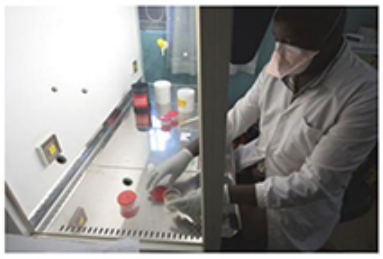
Source: WHO

Current sample method challenges



Sample quality

- Samples need to be shipped on ice or can be putrefied and unusable when they arrive at the lab
- Sample quality directly impacts tests results and diagnosis rates

Failed diagnosis kills …

- Delayed treatment
- Further spread of disease
- More lives impacted

Laboratory inefficiency

- NaOH/NALC used to liquefy samples
- Needs to be mixed and quality controlled daily
- Labor intensive and limits number of samples tested per day

50,000+ labs spend over 12,500,000 hrs/yr preparing a **reagent that we eliminate**

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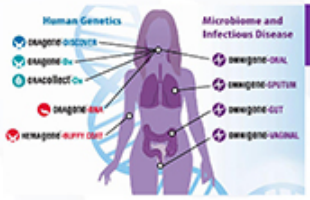
Photo source: www.dw.com and http://www.msf.ca/en/article/new-test-increases-drug-resistant-tuberculosis-diagnosis

Our solution



Leader in Biospecimen Optimization

OMNIgene·SPUTUM

- A reagent designed to maintain MTb viability for 8 days between 39ºF and 104ºF while liquefying and decontaminating sputum samples.
- IP protected
- CE/IVD marked

Sample transport and decontamination reagent

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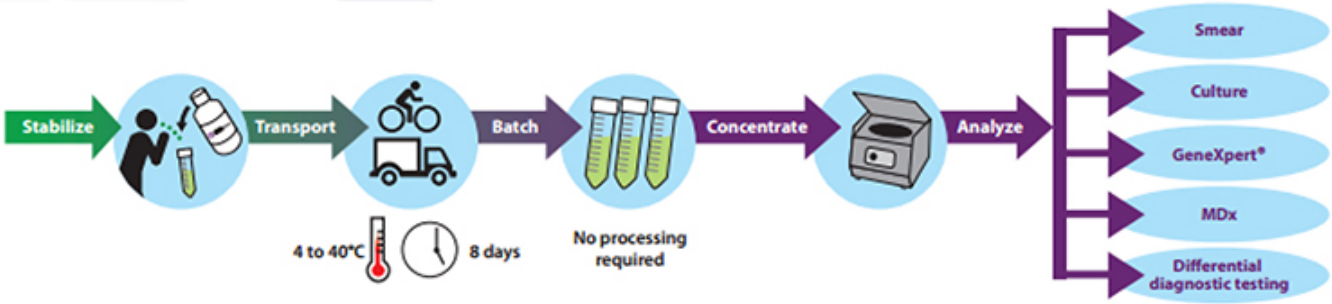
What OMNIgene•SPUTUM solves



- Eliminate need and cost of cold chain transport
- Eliminate samples lost due to putrefaction in transit
- Eliminate daily reagent preparation and quality control testing
- Minimize culture test contamination and failures
  - Nepal study: Improved TB detection by 9% and decreased contamination by 10%
  - Italy-Albania study: reduced contamination by 20%
- Compatible with all diagnostic options

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Market access strategies

#1: Independent Countries, NGO's & Private Labs

- BRICS: Brazil, China, India and South Africa
- NGO's: MSF, KNCV, FHI360, PHI, IOM
- Private labs: India, South Africa, Latin America

#2: Requires WHO Endorsement

- For Global Fund procurement

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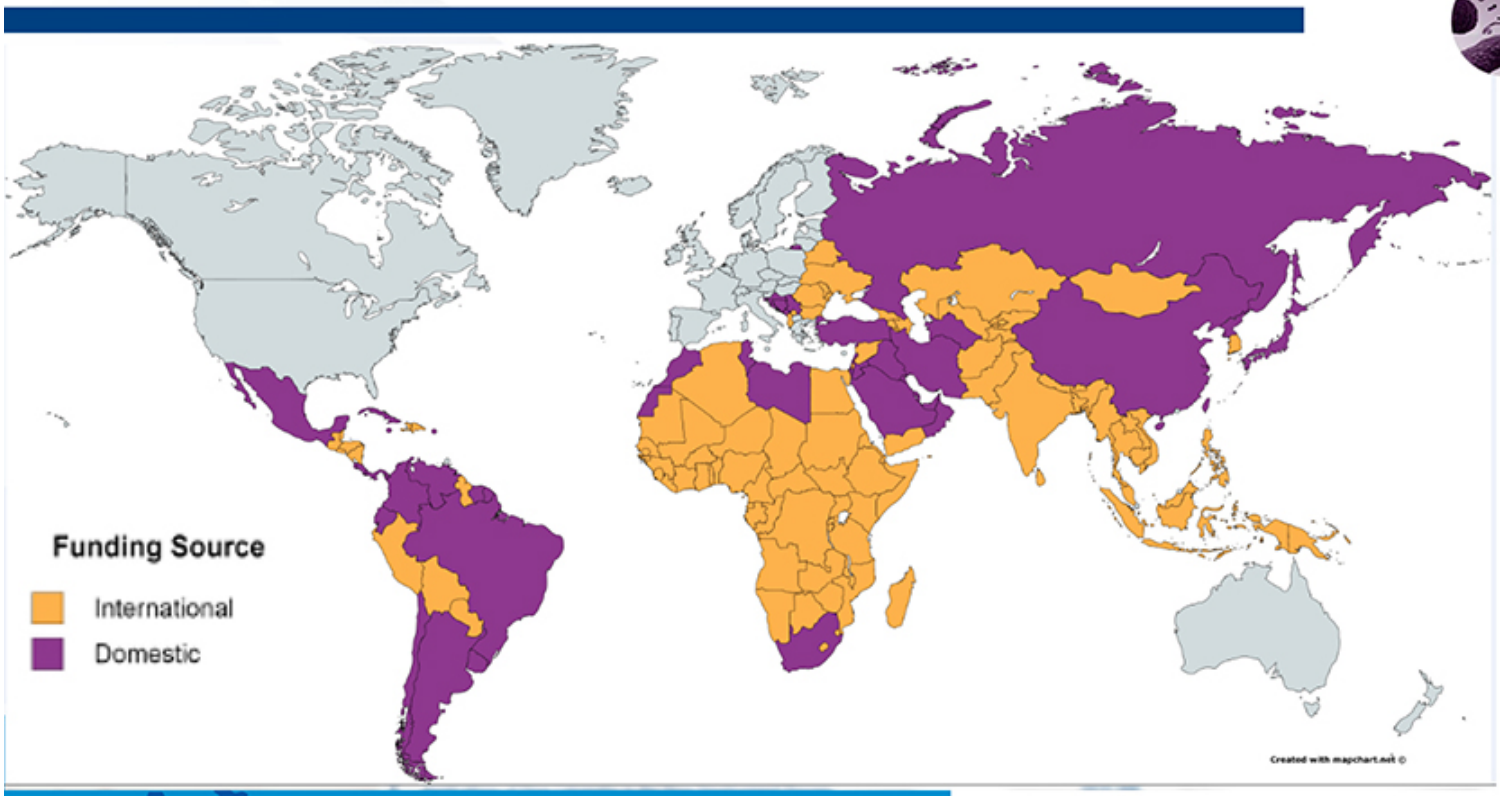
Funding impact



More action and investment in these countries will drive down the TB burden

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Market access plan

In country evaluations to speed adoption upon WHO endorsement

Peer reviewed publication data (open independent funding) ->ongoing 3 complete 1 more submitted

CE/IVD registrations

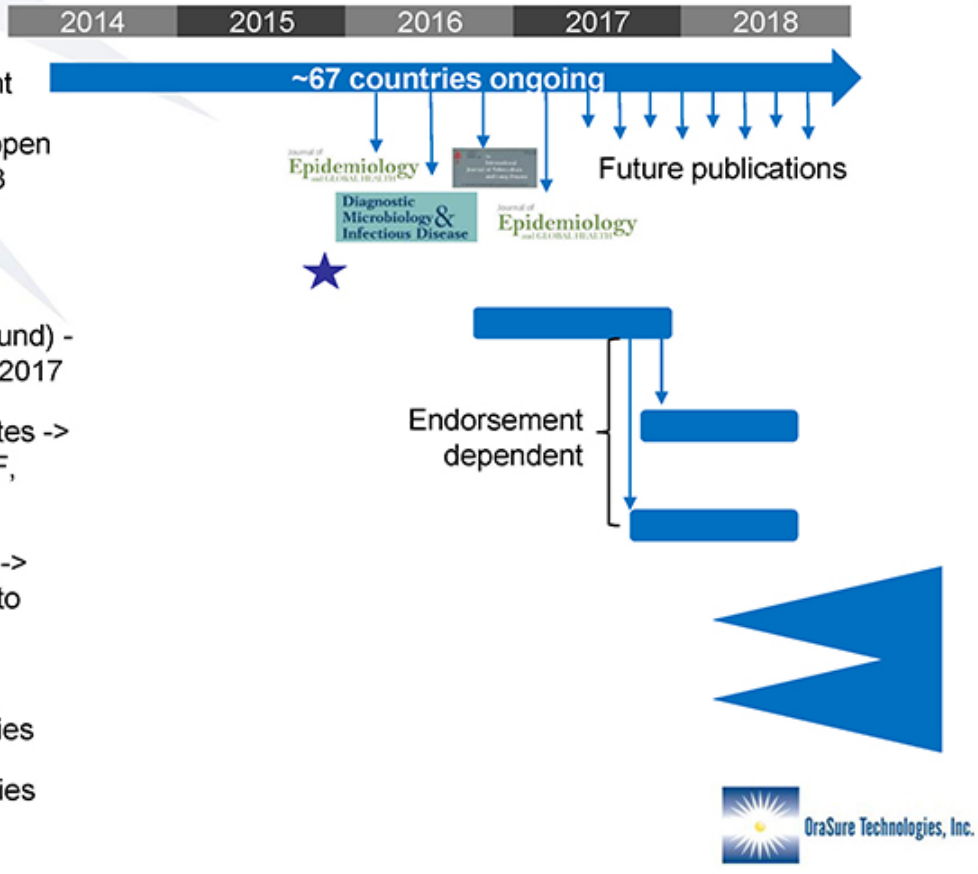
Unlock funding (USAID, Global Fund) ->WHO endorsement – target Q2 2017

Establish global procurement routes -> GDF, Global Fund, MSF, UNICEF, USAID, PEPFAR and FIND

Establish early adopter countries -> working with FIND and STOPTB to identify and ramp early adopter countries

Scale use in early adopter countries

Replicating model to other countries



OraSure Technologies, Inc.

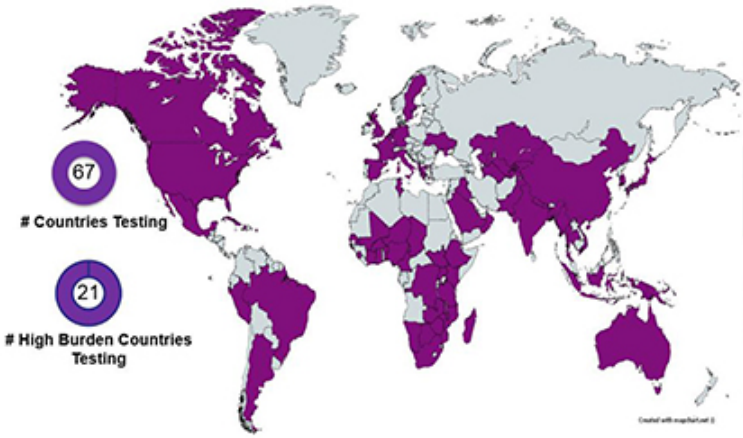
Our unique advantage

Working toward WHO endorsement

Country wide technical validations in progress

Collaborating with key stakeholders

Technical Validations



Publications

Journal of Epidemiology and GLOBAL HEALTH

Diagnostic Microbiology & Infectious Disease

The International Journal of Tuberculosis and Lung Disease

Collaborations

Stop TB Partnership GLOBAL DRUG FACILITY

The Global Fund To Fight AIDS, Tuberculosis and Malaria

FIND Because diagnosis matters

World Health Organization

Q&A

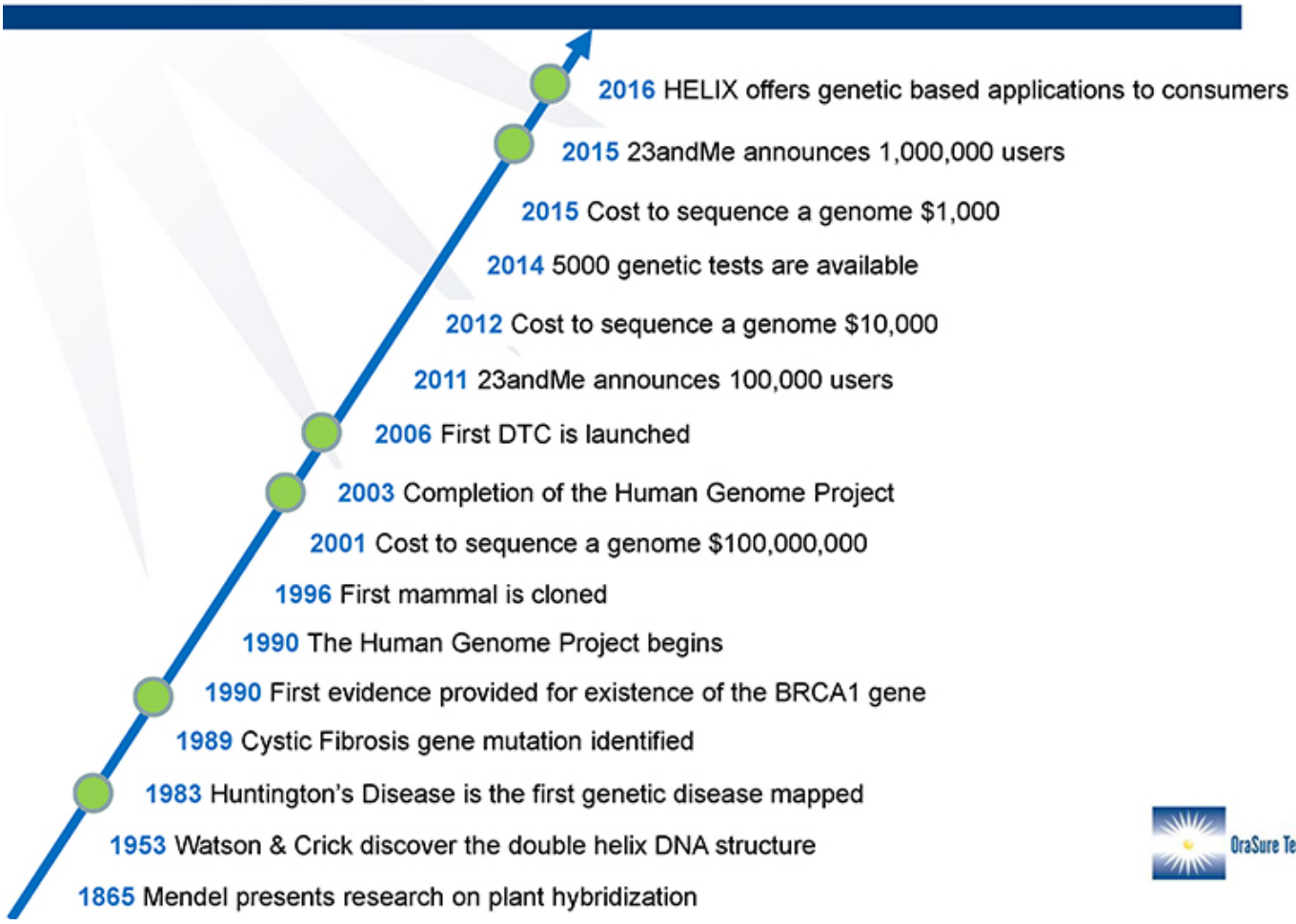
OraSure Technologies, Inc.

Personal Genomics

Brian Smith
Senior Vice President and
Business Unit Lead, Molecular
DNA Genotek

OraSure Technologies, Inc.

Genomics: From Double-Helix to Helix



OraSure Technologies, Inc.

Exponential growth in genetic testing

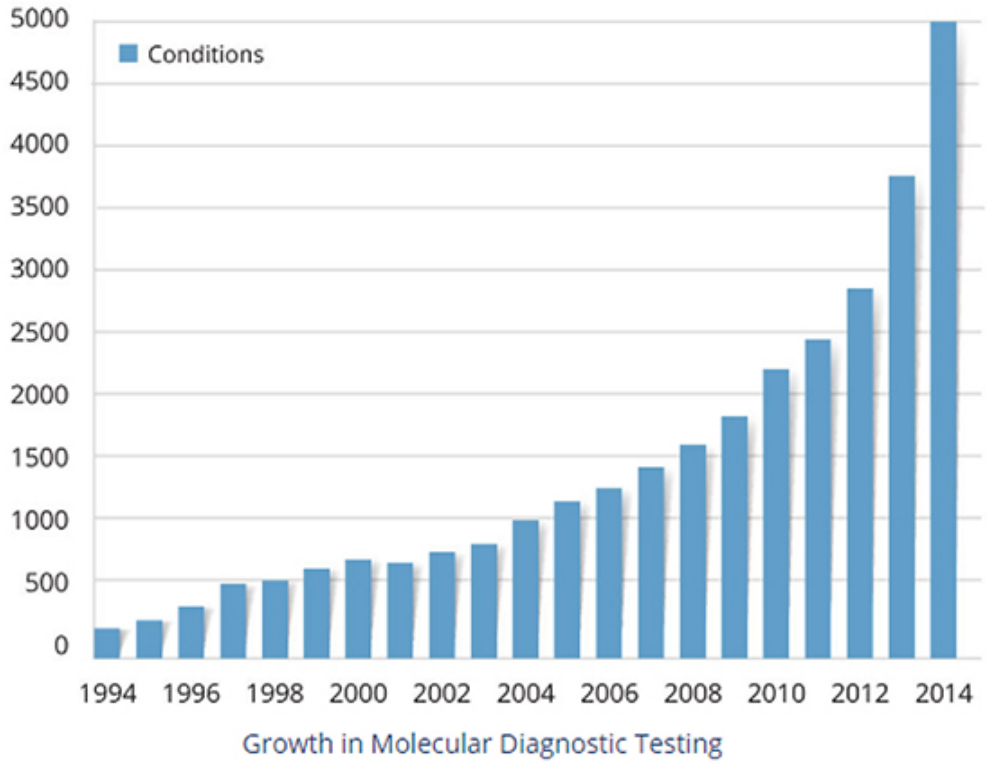


Figure 1. 1994 - 2012 data from GeneTests. In 2013, GeneTests was transitioned to the NBCI's Genetic Testing Registry. 2014 data are as of November 20, 2014.

OraSure Technologies, Inc.

Personal genomics segments

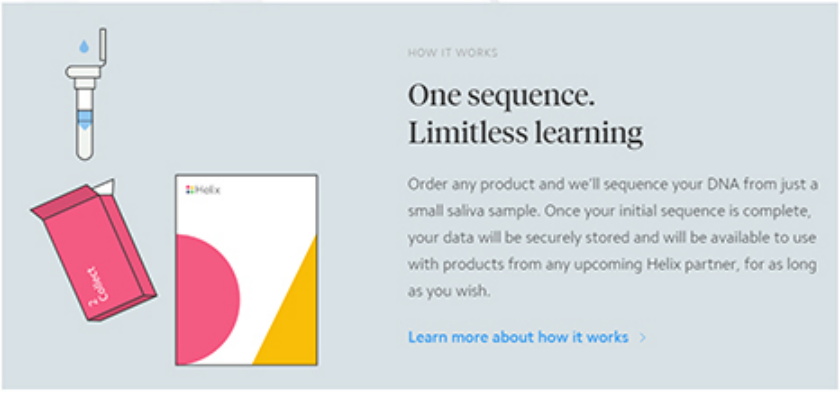
OraSure Technologies, Inc.

HELIX

Helix

BUSINESS INSIDER | TECH INSIDER

A new $100 million company could transform the way we interact with our own DNA



10 Breakthrough Technologies The List+ Years+

DNA App Store

An online store for information about your genes will make it cheap and easy to learn more about your health risks and predispositions.

Availability: this year

by Antonio Regalado

OraSure Technologies, Inc.

Source: www.Helix.com

23andMe

23andMe Genotypes One Millionth Customer

Direct-to-Consumer Genetic Testing Company Reaches Milestone; Increases Potential for Genetic Research

How it works.
It's just saliva.

Provide your saliva sample from home. Mail it back to our lab in the same kit it came in–the postage is pre-paid.

We bring your genetics to you.

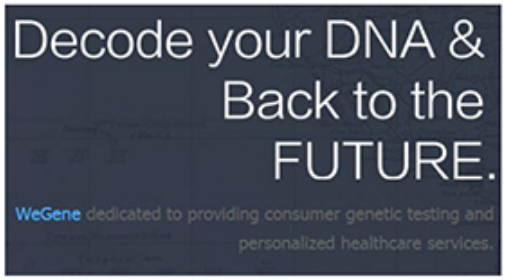
Learn more about how it works.

Source: www.23andMe.com

Growing worldwide market opportunity

Genesis Healthcare.Co

WEGENE



WuXiNextCODE

THE GLOBAL PLATFORM FOR GENOMIC BIG DATA
WuXi NextCODE is a genomic information company using sequence data to improve health for people around the world.

OraSure Technologies, Inc.

Enabling personal genomics

Access to patients/consumers
No established collection infrastructure
Competing with reference labs

Quest Diagnostics™ LabCorp

Reference labs

- Established brick and mortar service clinics for sample collection

23andMe Helix

Emerging Personal Genomics companies

- In clinic or at home access to patients for sample collection
- Personalized experience
- Results back directly or via practitioner

OraSure Technologies, Inc.

The sample enables scalability

Easy to collect, non-invasive

- By individuals at home or at point of care
- By children and the elderly
- By clinicians

Reliable

- Usability lowers failure rates

High quality

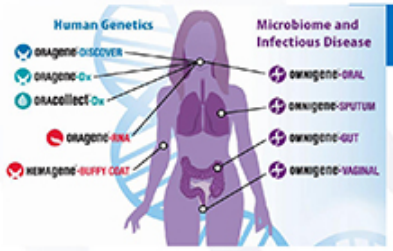
- Increasing trend toward sequencing
- Leverage data across evolving test

Compatible with existing lab protocols

- Liquid samples and intelligent designs support high volume automation

OraSure Technologies, Inc.

Proven solutions
First and only FDA 510(k) cleared devices



~2,000 peer-reviewed publications

6,000+ customers in 100+ countries

Leader in Biospecimen optimization

ORAgene•Dx

ORAcollect•Dx

ISO 13485:2003 FM 506255

CE

FDA

IVD

Oragene•Dx and ORAcollect•Dx are the **only FDA 510(k) cleared devices**† proven for collection, stabilization and ambient temperature transportation and storage of DNA from saliva.

OraSure Technologies, Inc.

† FDA cleared for in vitro diagnostic use with the eSensor Warfarin Sensitivity Saliva Test.

Our unique advantage

Regulatory and quality focus

End-to-end service and support

Collaborating with leaders and innovators in the space

Products

FDA

BSI REGISTERED
ISO 13485:2003
FM 506255

CE

IVD

Service and support

- Customizations
- Donor recruitment
- Logistical support
- Single Order Fulfillment

Customers

23andMe

Helix

HUMAN LONGEVITY, INC.

Microbiome

Aaron Del Duca
Vice President, Technology and
Microbiome Program Lead
DNA Genotek

OraSure Technologies, Inc.

What is the Microbiome?

The human-associated microbiome comprises the trillions of micro organisms that live on us and in us.

OraSure Technologies, Inc.

Genomics vs. Metagenomics

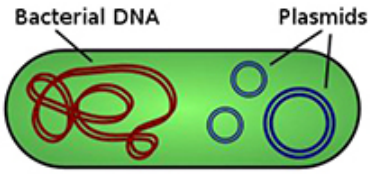
Genomics

- 23,000 genes
- 10M SNPs
- Humans share 99.5%
- More or less static

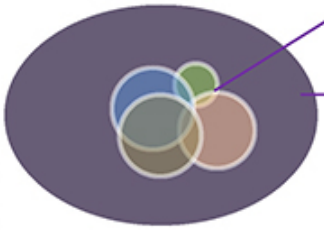
Missing Heritability?

Exome Seq
WGS

Metagenomics



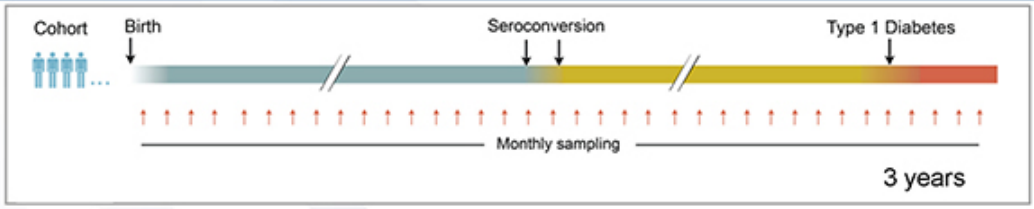
- ≈1000 species identified (gut)
- Collectively, 10M genes
- 40-70% consistently appear in 'core'
- **Dynamic**



16S rRNA Seq
Shotgun
Metagenomics

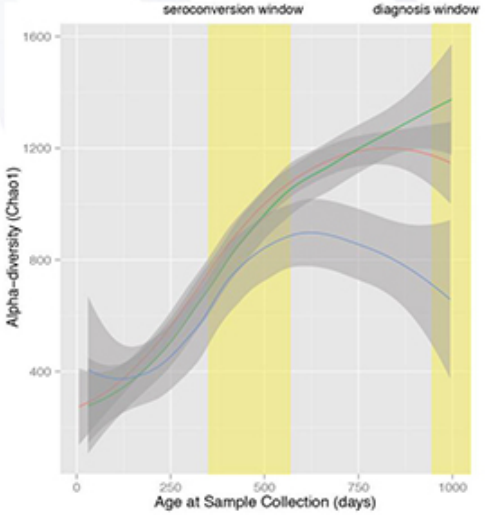
OraSure Technologies, Inc.

Value of microbiome-enabled discovery



Progression to Type 1 Diabetes in infants

HARVARD UNIVERSITY



T1D Status
- control
- seroconverted
- T1D diagnosed

Joslin Diabetes Center

Genes don't tell the whole story!

Longitudinal monitoring essential to understand chronic disease progression

A. Kostic, D. Gevers, R. Xavier, et al.
Cell Host Microbe 2015 Feb 11;17(2):260-73

OraSure Technologies, Inc.

Microbiome impact to healthcare

- It influences extremely high burden/high value medical conditions
  - 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 even preventive medicine are all enabled with this new perspective on health

- Microbiome science is quickly translating from research to clinical applications

OraSure Technologies, Inc.

Early stage, rapid growth opportunity

Fiscal Year	Genomics Projects	Funding
2011	4,955	$ 3,081,216,026
2012	5,314	$ 3,442,245,767
2013	5,436	$ 3,430,237,569
2014	5,573	$ 3,677,078,245
2015	5,370	$ 3,664,397,258
Total	**26648**	**$ 17,295,174,865**
	CAGR =	**3.53%**

Fiscal Year	Microbiome Projects	Funding
2011	189	$ 112,536,253
2012	280	$ 235,128,901
2013	344	$ 205,755,751
2014	478	$ 327,853,816
2015	654	$ 461,844,500
Total	**1945**	**$ 1,343,119,221**
	CAGR =	**32.6%**

- Over $1B in NIH funding allocated to microbiome research in the last 5 years
- $400M contributed from government and industry players toward National Microbiome Initiative in 2016

NIH RePORTER Version: 7.11.0 Funding toward "Microbiome" & "Genomics" as of Aug 2016

OraSure Technologies, Inc.

Leverages population research infrastructure

Fig 1

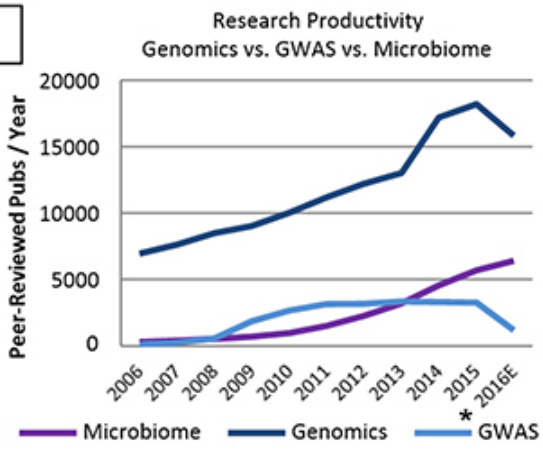
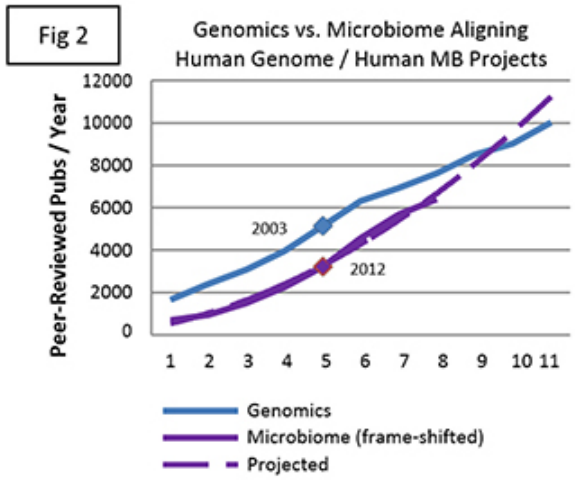


Fig 2



- Overlaying Human Genome Project completion with Human Microbiome Project completion reveals that the Microbiome research field is growing at least as quickly as genomics.
- Best model for Microbiome business is Human Genomics business. Slightly smaller breadth of applicability vs. genomics offset by need for longitudinal sampling

OraSure Technologies, Inc.

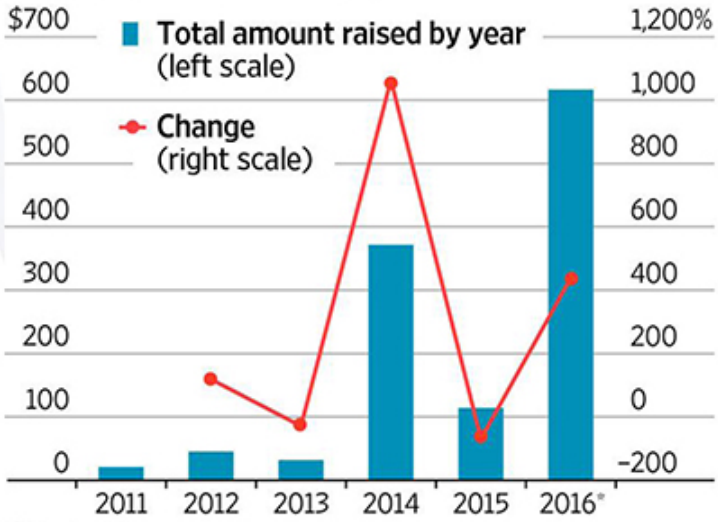
* *Based on June 2016 PubMed literature search for highlighted key terms*

Quickly translating to industry applications

Under the Microscope

Investors pour into microbiome companies

Venture capital investment, in millions



* Year to date

Sources: Dow Jones VentureSource; Securities and Exchange Commission; the companies

Over $1.5B in Venture Capital invested into microbiome start-ups since 2012

OraSure Technologies, Inc.

http://www.wsj.com/articles/microbiome-companies-attract-big-investments-1474250460

Constrained by methods and reproducibility

nature microbiology

CONSENSUS STATEMENT

PUBLISHED: 11 JANUARY 2016 | ARTICLE NUMBER: 15015 | DOI: 10.1038/NMICROBIOL.2015.15

An assessment of US microbiome research

Key challenges:

- Standardized wet lab protocols, high-throughput processing
- Validated bioinformatics pipelines
- Longitudinal and functional studies
- Patient engagement, standardized phenotyping and metadata capture

"The inter-lab comparability of measurements on microbiomes is generally poor."

OraSure Technologies, Inc.

Biospecimen quality dictates data quality

OMNIgene·GUT*

OMNIgene·VAGINAL *

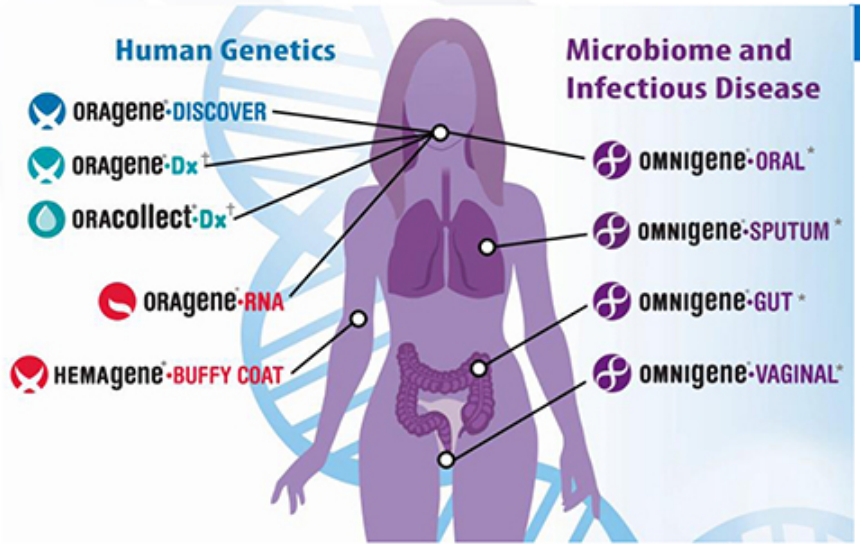
OMNIgene·ORAL*

- Human-factors driven design
- Ambient temperature stable
- Pristine representation of *in vivo* microbiome
- Scalable for high throughput processing

OraSure Technologies, Inc.

*For research use only

Positioned to leverage strengths



DNA Genotek customers

ISO 13485:2003
FM 506255

CE IVD

HUMAN LONGEVITY, INC.

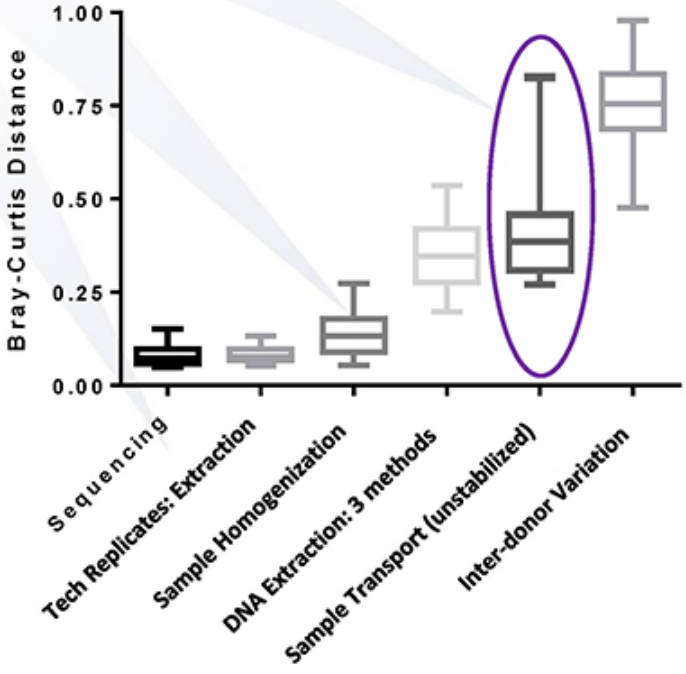
WEIZMANN INSTITUTE OF SCIENCE

DAY TWO

OraSure Technologies, Inc.

† FDA cleared for in vitro diagnostic use with the eSensor Warfarin Sensitivity Saliva Test
* For research use only

Root of the reproducibility challenge



NIST National Institute of Standards and Technology

Study Design

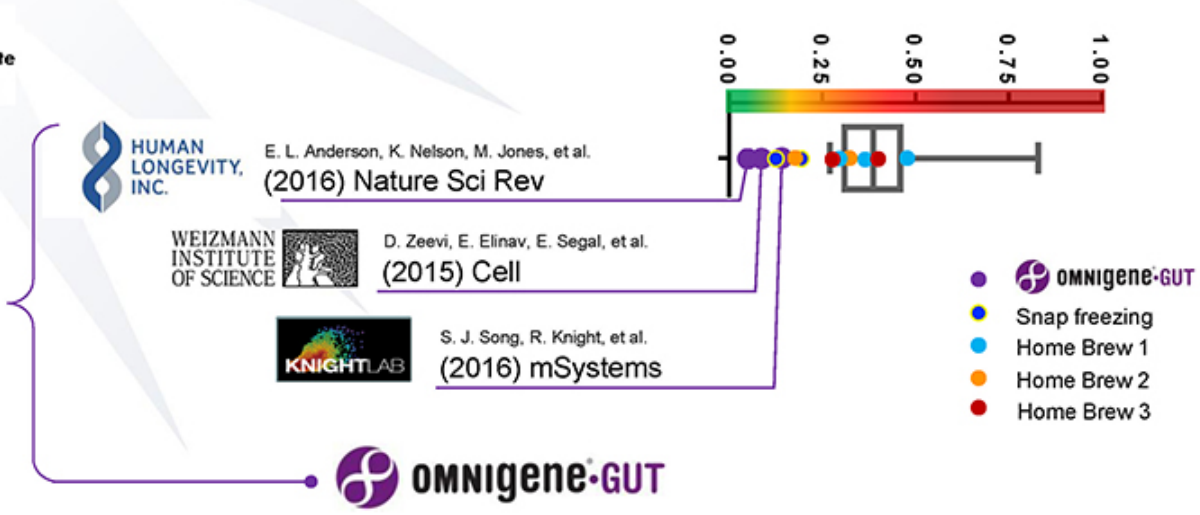
- N = 30 donors
- Collected
- Extracted
- Sequenced

} in triplicate

- **Error is additive!**

OraSure Technologies, Inc.

Establishing the new gold standard



Results: Based on our analyses, the *DNA* Genotek reagent consistently results in higher nucleic acid yields, reduced variation, and increased reproducibility.

Conclusions: Our results show that stabilization of stool microbiome samples with the DNA Genotek reagent is a robust, reproducible and easy to use solution which enables standardized, global collection and storage in microbiome studies.

Constrained by methods and reproducibility

nature microbiology
CONSENSUS STATEMENT
PUBLISHED: 11 JANUARY 2016 | ARTICLE NUMBER: 15015 | DOI: 10.1038/NMICROBIOL.2015.15

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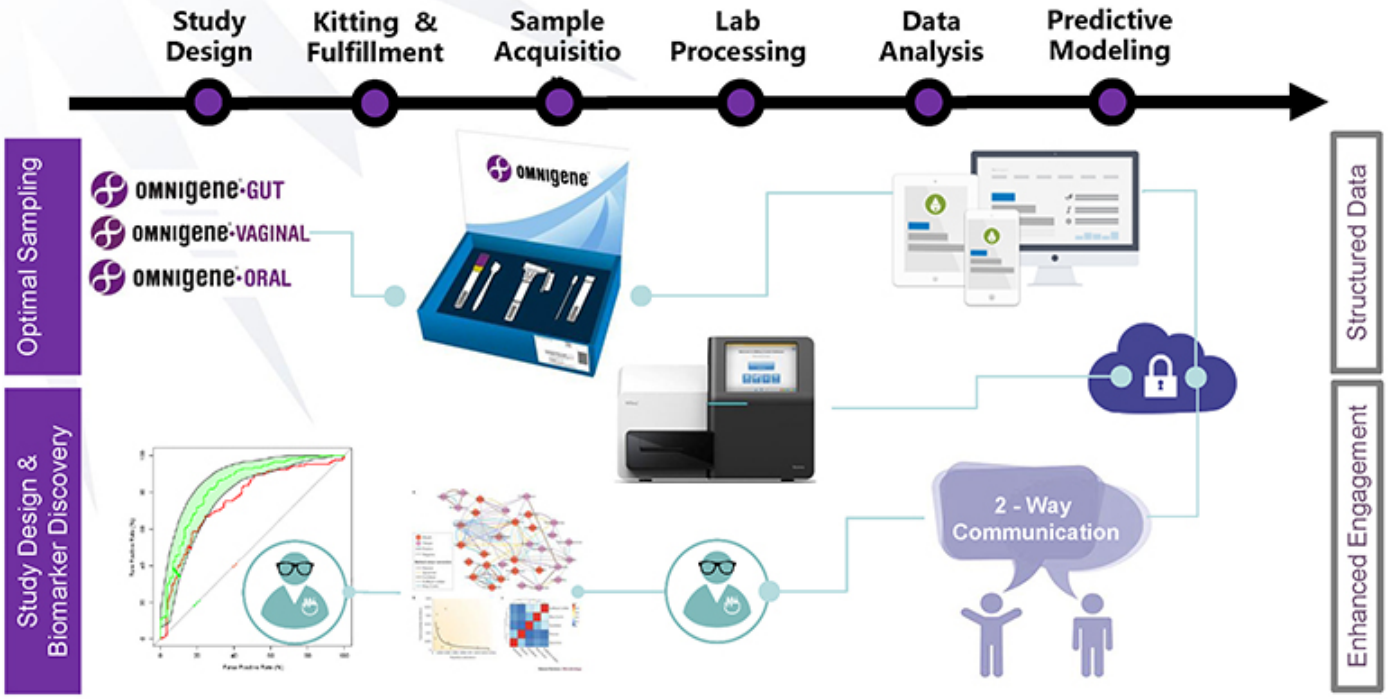
OraSure Technologies, Inc.

Turn-key services from sample to signal

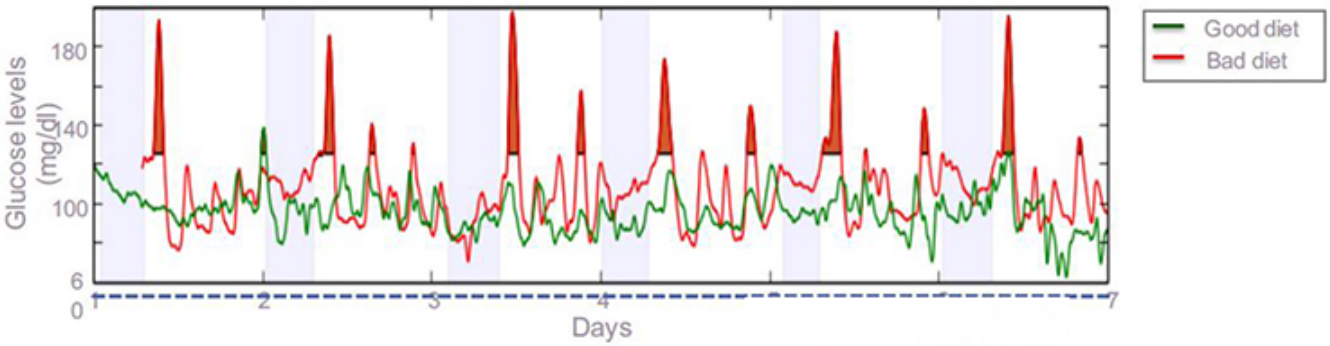


Microbiome-On-Demand™

OraSure Technologies, Inc.

Microbiome impact on personalized medicine?

Cell, Volume 163, Issue 5, p1079–1094, 19 November 2015
E. Segal, E. Elinav, D. Ze'evi, et al.



WEIZMANN INSTITUTE OF SCIENCE

DAY TWO

- Significant difference between glycemic index of ideal and 'non-specific' food choices.
- Glycemic index is highly personal, driven by gut microbes.

OraSure Technologies, Inc.

Our unique advantage

Technical validation of sample quality to results

Leveraging leadership position in academic market

End-to-end service and support

Collaborating with leaders and innovators in the space

HUMAN LONGEVITY, INC.

E. L. Anderson, K. Nelson, M. Jones, et al.

(2016) Nature Sci Rev

WEIZMANN INSTITUTE OF SCIENCE

D. Zeevi, E. Elinav, E. Segal, et al.

(2015) Cell

~2,000 peer-reviewed publications

6,000+ customers in 100+ countries

Microbiome-On-Demand™

- Study Design
- Customizations
- Donor recruitment
- Logistical support
- International regulatory support
- Comprehensive lab services
- Bioinformatics analysis and interpretation

HUMAN LONGEVITY, INC.

DayTwo

R&D: Sample Optimization

Rafal Iwasiow, Ph.D.
Vice President R&D Molecular
DNA Genotek

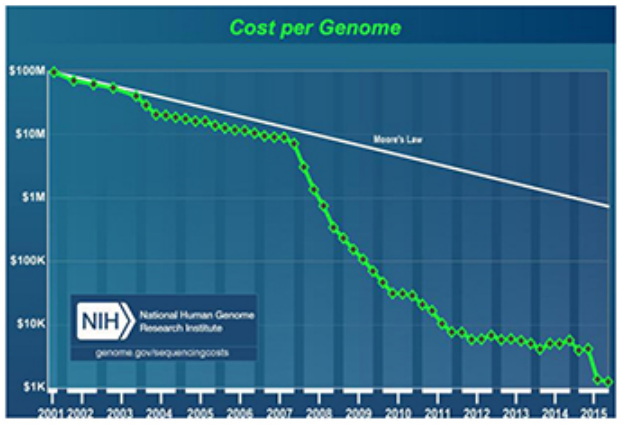
OraSure Technologies, Inc.

Sample quality is paramount

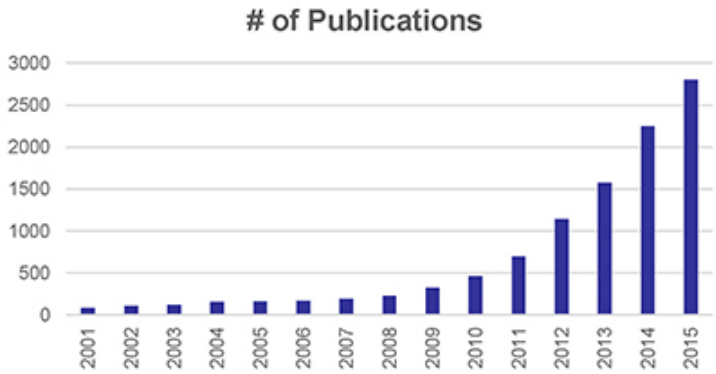
Sample quality is paramount

"**We now have the technical ability to get the wrong answers with unprecedented speed.** If we put the wrong stuff into the front end of our analytical pipeline, we will not only lose the war on cancer, we'll pollute the scientific literature with incorrect data that will take us a long time to sort out. **This is a crisis that requires disruptive innovation.**"

Carolyn Compton, Biorepository Chief
National Cancer Institute, USA
2012

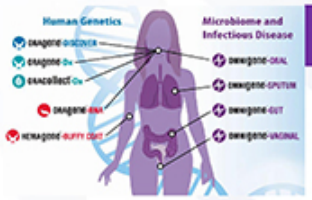


Decreasing cost



Increasing use of sequencing

Our current solutions – optimized samples



~2,000 peer-reviewed publications

6,000+ customers in 100+ countries

ISO 13485:2003
FM 506255

CE

IVD

Leader in Biospecimen Optimization

ORAgene®·Dx ORAcollect®·Dx

OMNIgene®·GUT OMNIgene®·VAGINAL OMNIgene®·ORAL

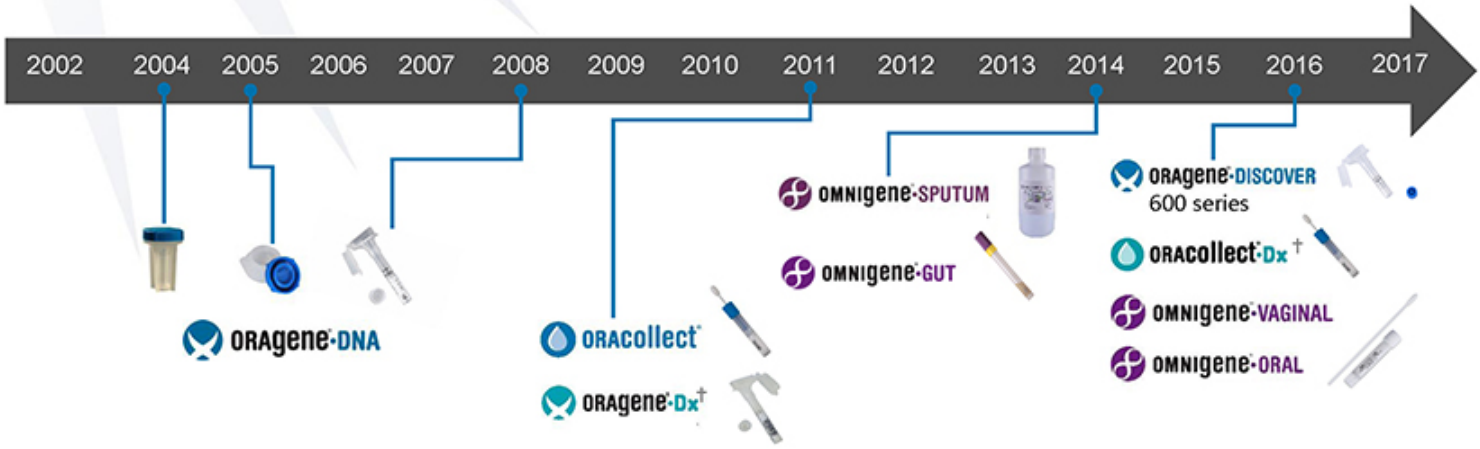
- Easy and reliable collection
- Stabilize and protect the *in vivo* state
- Ship and store at ambient temperature
- Integrate into lab protocols and automation
- High quality DNA/RNA for all applications
- Increase sensitivity and improve results of assays

OraSure Technologies, Inc.

Proven platforms accelerate growth

Molecular Platforms

Combined physical design and reagent to optimize products to address market needs



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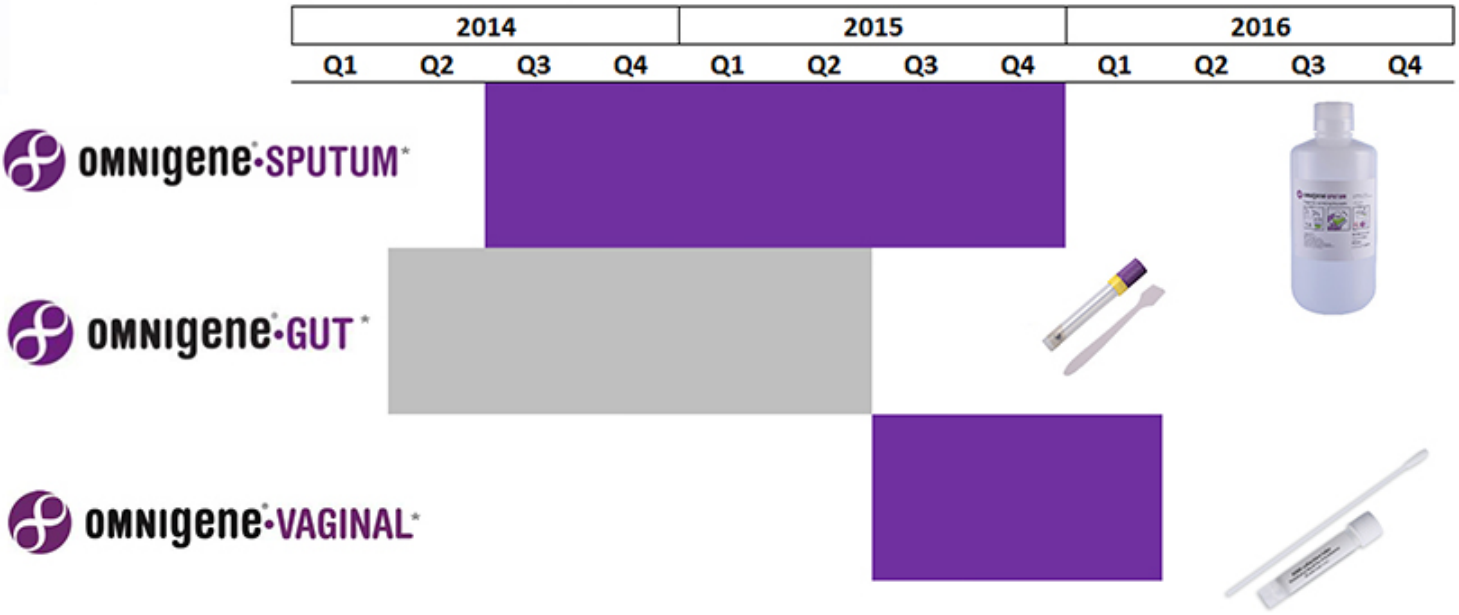
† FDA cleared for in vitro diagnostic use with the eSensor Warfarin Sensitivity Saliva Test

Rapid innovation to meet customer needs



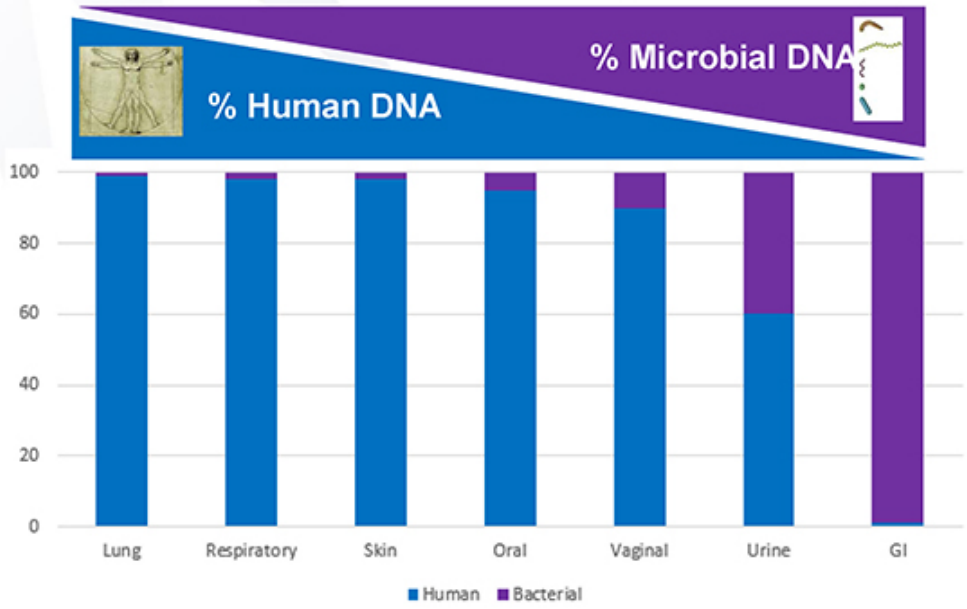
For research use only in the United States.

OMNIgene®•Gut (OM-200), Oragene (OG-500/OG-575/OG-600/OG-675) and OMNIgene®•Sputum are CE marked for In Vitro Diagnostic Use and not available for sale in the U.S.A.

OraSure Technologies, Inc.

Sequencing and multi-sample challenges

Biological samples are diverse and complex

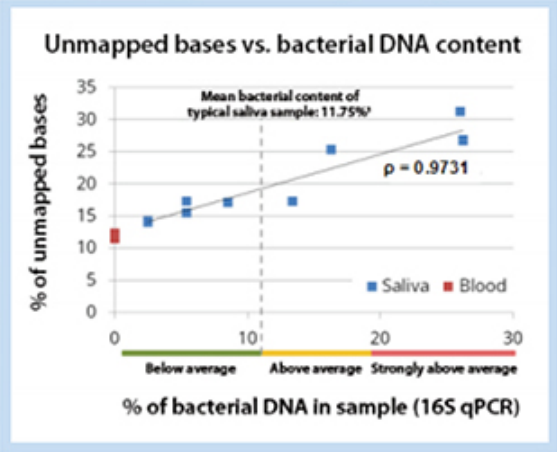


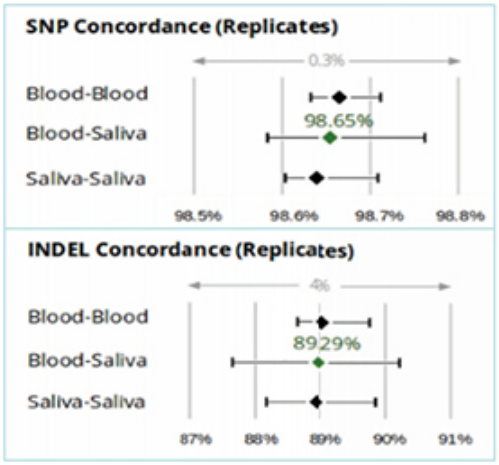
How to stabilize the sample?

- We approach it from the diverse biological perspective of each sample type
- Take control of the environment = take biology out of the equation
  - Disrupt cells
  - Inactivate nucleases
  - Liberate DNA from proteins
  - Provide controlled liquid environment optimized for DNA chemical and enzymatic stability

OraSure Technologies, Inc.

Oragene as a source of DNA for WGS





AGBT 2016 Poster – Broad Institute

"To date, we have sequenced over 1585 saliva *(Oragene)* samples to 30x coverage using the HiSeqX."

"The alignment rates to human suggest bacterial contamination levels ranging from 0-80% with an average of 10%. Given this experience we are confident sequencing patient samples from **saliva can be cost effective and produce high quality results for research and clinical studies**."

OraSure Technologies, Inc.

New platform opportunity

Collect & Stabilize | Transport & Store | DNA Preparation | Process | Results

OMNIgene·GUT

ORAgene·Dx

OMNIgene·VAGINAL

ORAcollect·Dx

OMNIgene·ORAL

OMNIgene·SPUTUM

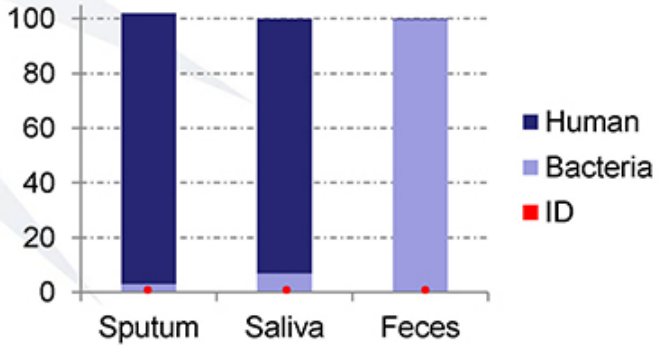
New platform opportunity

Targeted market solutions for optimized sequencing workflow

Upsell for existing customers

OraSure Technologies, Inc.

Optimizing samples for sequencing



Market	Microbial	Benefits/ drivers
Genomics	Depletion	• Optimize for sequencing • Standardize NGS workflows
Microbiome	Enrichment	• Enable NGS applications for low bacterial biomass samples • Optimize for sequencing • Standardize NGS workflows
ID	Target selection	• Increase sensitivity • Enable NGS applications

OraSure Technologies, Inc.

Financial Review / Business Development

Ron Spair

Chief Operating Officer and Chief Financial Officer

OraSure Technologies, Inc.

Business development program

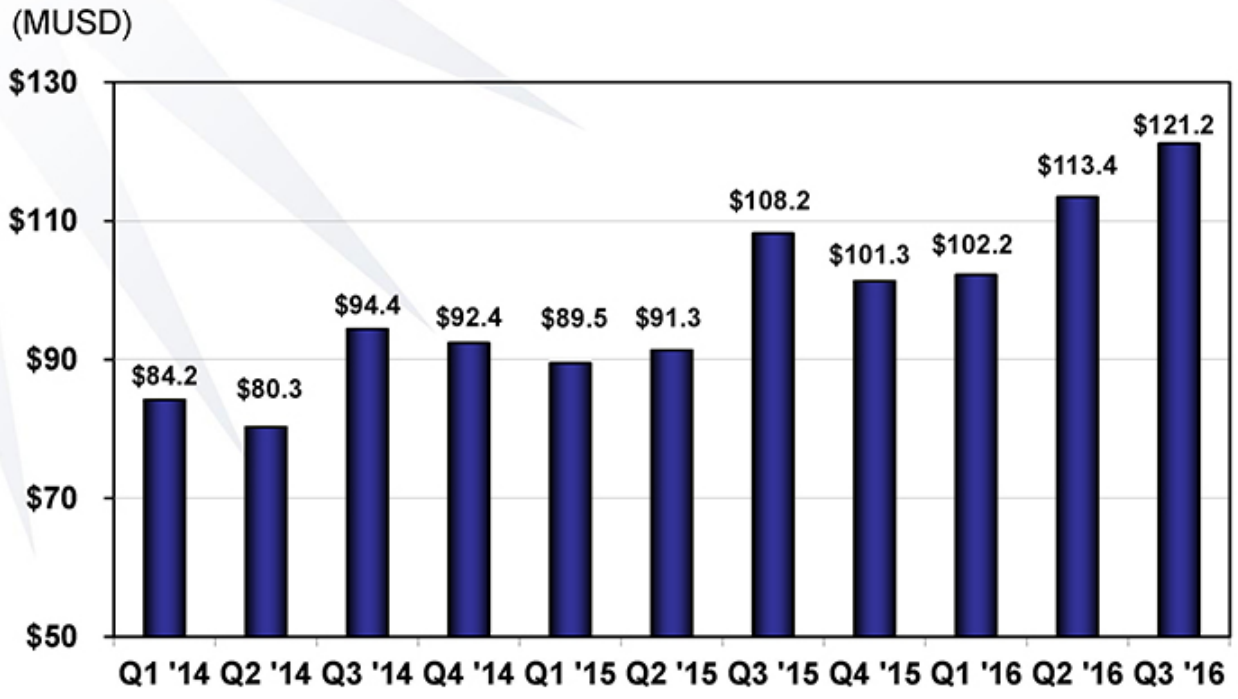
Over $120 million in cash and marketable securities and no debt

Our criteria:

- Seeking opportunity to in-license, partner or acquire a product or company that complements or leverages our existing business
- Focused on sample prep, enrichment, collection, microbiome and infectious disease
- Preferably a late-stage or approved product(s)
- Favorable reimbursement and regulatory profile
- Disciplined buyers

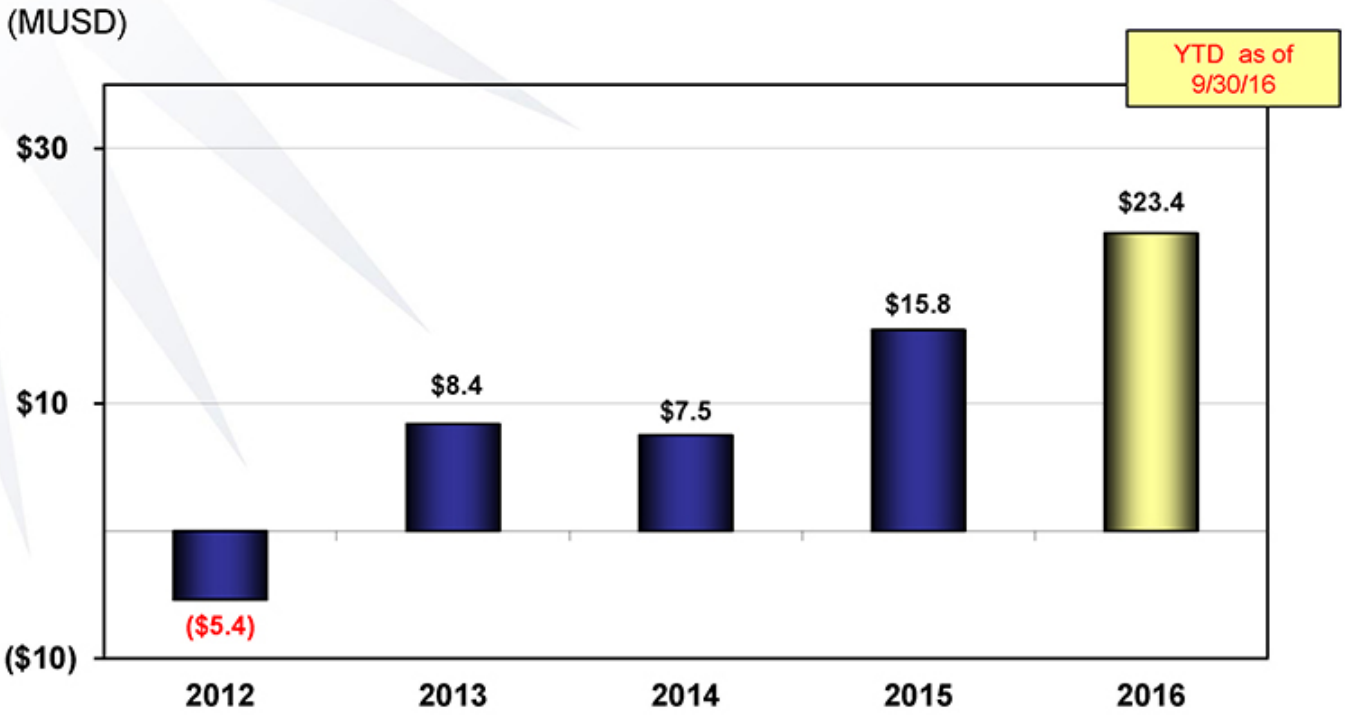
Quarterly cash/Cash equivalents

Q1-2014 – Q3-2016 actual



YOY Cash flow from Operations

2012 actual – Q3 - 2016



OraSure Technologies, Inc.

ID business development strategy

Infectious Disease strategies drive specific business development opportunities to investigate:

- Technology to enhance current lateral flow devices (e.g. digital reader, assay, technology licenses)
- Technologies to expand point of care testing portfolio (lateral flow, POC MDx, other)
- Access to low cost products or enabling technology that may lower manufacturing costs

Molecular business development strategy

Molecular business strategies drive specific business development needs to investigate:

- Collection, stabilization, enrichment and prep technologies that are disruptive and enable innovation in NGS market (small volume blood, liquid biopsy, sample to sequence)
- Analytics that directly support microbiome expansion, and potentially lab services

Executing strategies for growth

Innovation
Proven platforms

Growth
Market Opportunities

Leadership
Strong partnerships, funding and collaborations

OraQuick® HIV SELF-TEST

OraQuick® Rapid Antibody Test ZIKA

ORAgene®·Dx

ORAcollect®·Dx

OMNIgene®·GUT

HIV

HCV

TB

Emerging Diseases

Personal Genomics

Microbiome

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

World Health Organization

BARDA

23andMe

HUMAN LONGEVITY, INC.

Helix

Q&A

Additional information

OraSure Technologies, Inc.

Glossary

BARDA: Biomedical Advanced Research and Development Authority
FIND: Foundation for Innovative New Diagnostics
GDF: Global Drug Facility
IgM: Immunoglobulin M
IOM: International Organization for Migration
KNCV: Royal Netherlands Chemical Society
MSF: Doctors without Boarders
NGO: Non-Government Organization
PEPFAR: President's Emergency Plan for AIDS Relief
PHI: Public Health Institute
PSI: Population Services International
UNAIDS: The Joint United Nations Programme on HIV/AIDS
UNICEF: United Nations International Children's Emergency Fund
UNITAID: Innovative Financing Mechanism for Global Health
USAID: United States Agency for International Development
WHO: World Health Organization