



OraSure Technologies

Business Overview
March 2018



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.



Investment Rationale

- Industry leader in rapid point-of-care infectious disease testing and DNA/RNA sample collection, stabilization and preparation products. Significantly ramping manufacturing capacity for OraQuick and OraGene production
- Several Growth Drivers - with several products in early stages of penetration:
 - Highly competitive molecular sample collection and stabilization devices
 - Growth driven by expanding customer base and broader utilization
 - New products focused on Microbiome and TB offer large growth opportunities
 - Portfolio of new products and programs addressing large global markets
 - Strong demand for OraQuick HIV self test
 - Interest for OraQuick HCV test in conjunction with Hep C eradication programs
 - Rapid Ebola test EUA approved
 - Rapid Zika test in development
- Strong balance sheet with over \$175M in cash, no debt and sustainable profitability
- Active business development program

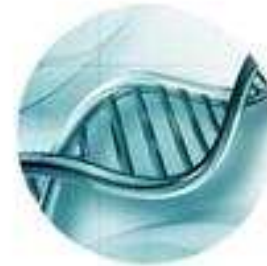


Strategic Growth Pillars

**Grow Infectious
Disease business**

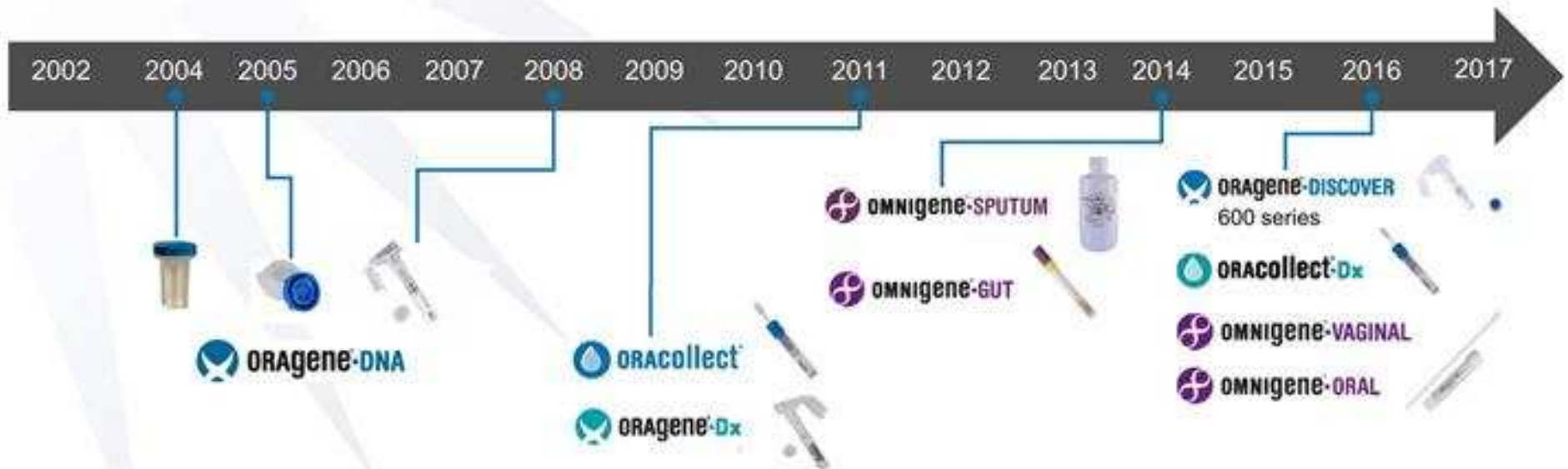


**Grow Molecular
business**





Molecular Platforms



- Flexible and reliable products
- Optimized samples
- Strong IP

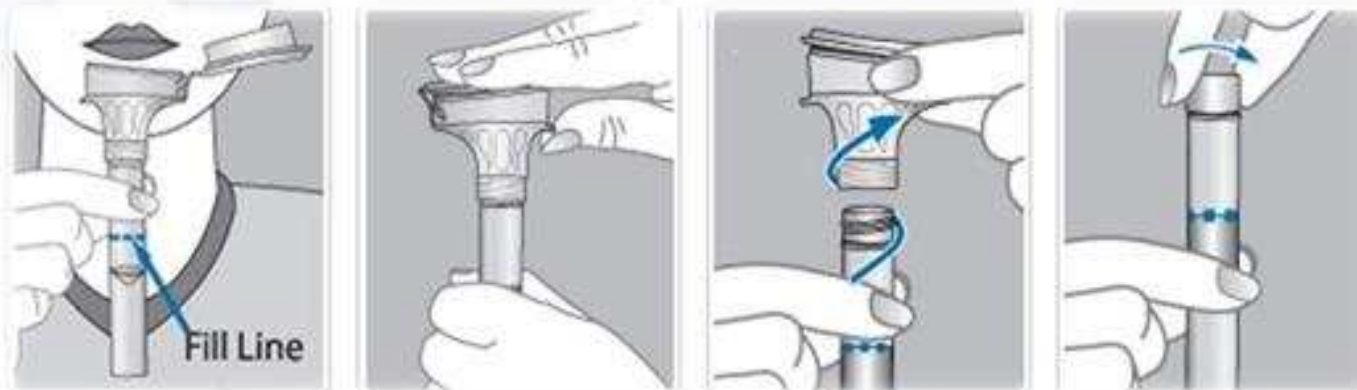
~2,000 peer-reviewed publications

6,000+ customers in 100+ countries



Improving the Method of Sample Collection

Expanded use coming from existing customers and increased demand driven by new genetic testing options and studies



- Oral fluid - anytime, anywhere sample collection
- All-in-one, easy, reliable and non-invasive
- Captures high quality DNA and RNA
- Ambient temperature stability

The only FDA 510(k) cleared device for collection, stabilization and ambient temperature transportation and storage of DNA from saliva.



Exponential Growth in Genetic Testing

Pharmacogenomics



Carrier Screening



Ancestry



Wellness



Health

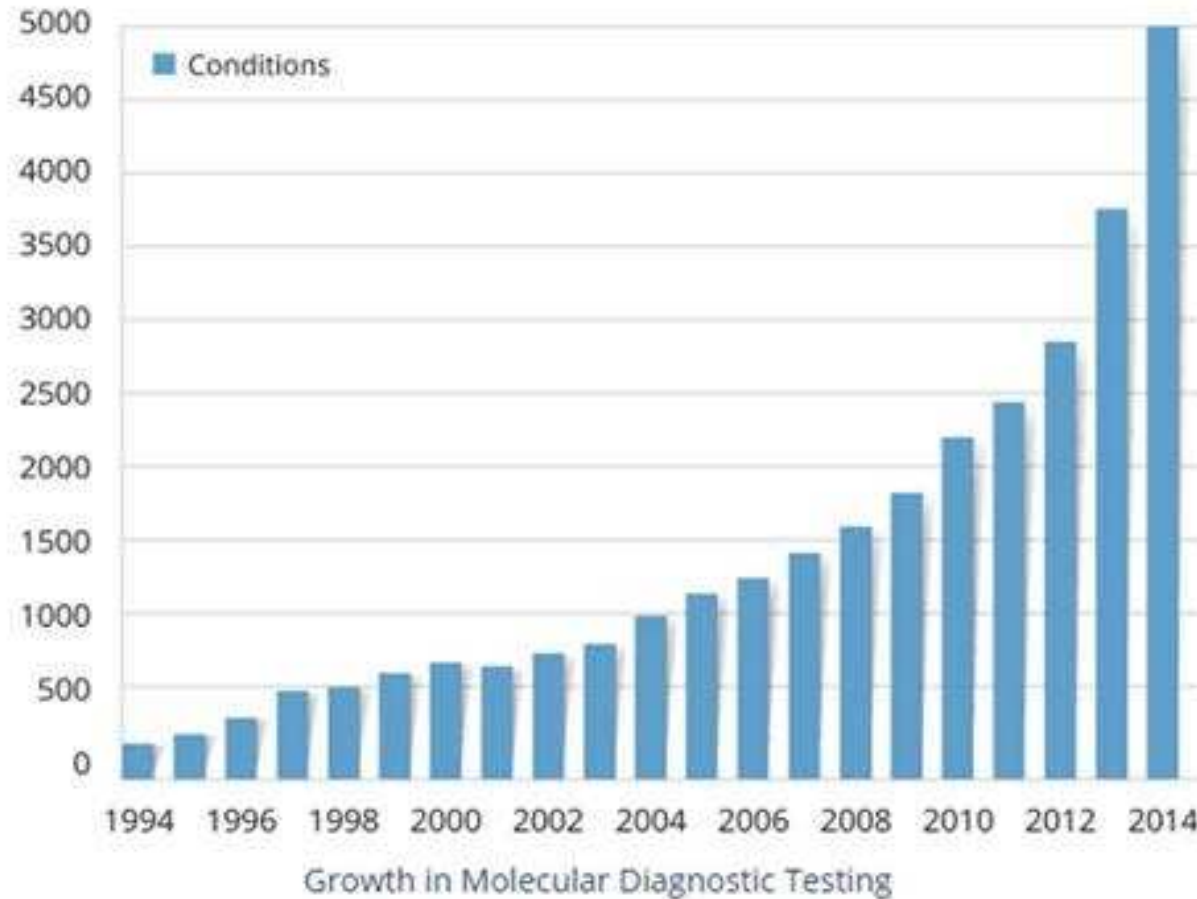


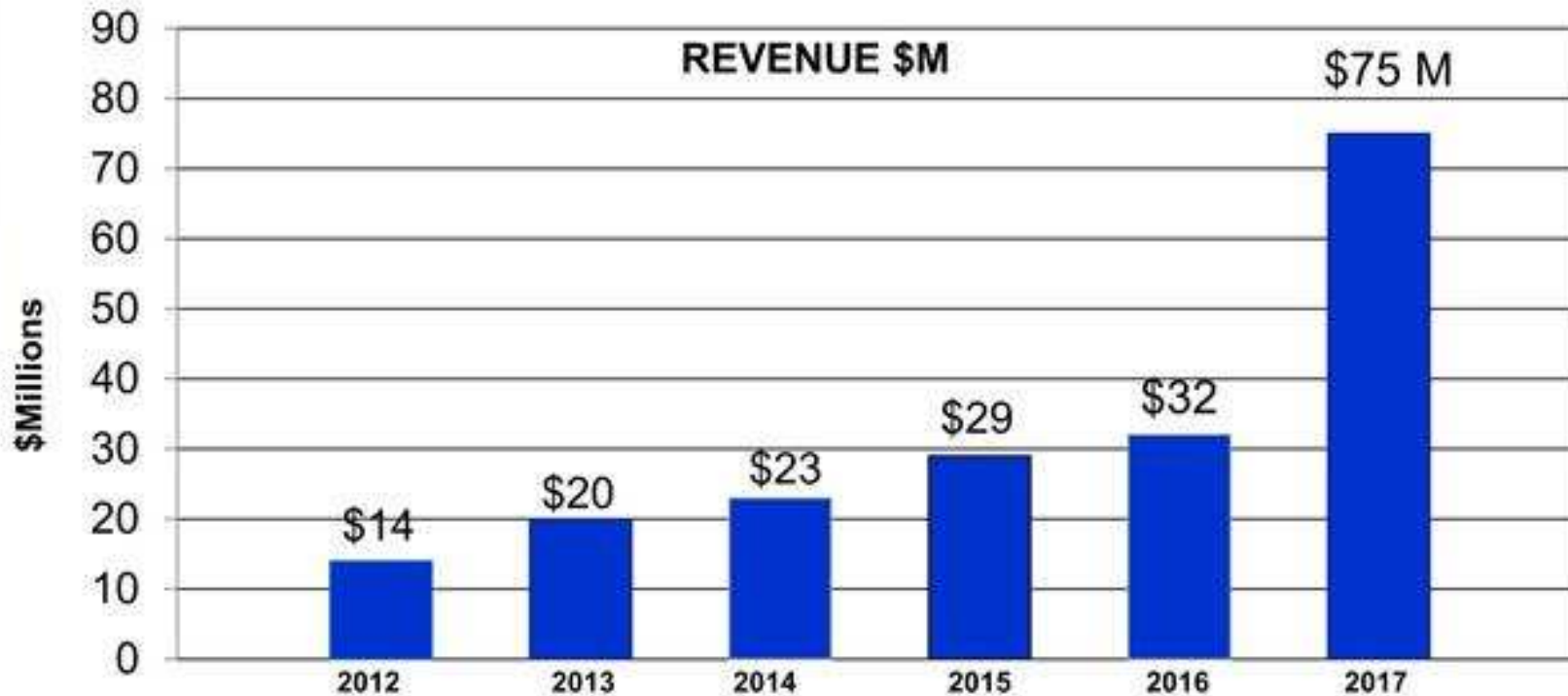
Figure 1. 1994 - 2012 data from GeneTests. In 2013, GeneTests was transitioned to the NCI's Genetic Testing Registry. 2014 data are as of November 20, 2014.



OraSure Technologies, Inc.



Molecular Revenue Growth



November 2017 – Announced \$143MM supply agreement for Oragene DX to a leading consumer genomics customer, over several years, with minimum annual purchase requirements.



Key Enabler for Global Leaders in Genomics




One sequence. Limitless learning.

Order any product you want to sequence your DNA from just a small saliva sample. Once your initial sequencing is complete, your data will be securely stored and will be available to use with products from any upcoming Helix partner, for as long as you wish.

[Learn more about how it works.](#)



See what your DNA can tell you.
Click to explore our services below.



23andMe Genotypes One Millionth Customer

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

WuXiNextCODE



Genesis Healthcare.Co



Microbiome Impact to Healthcare

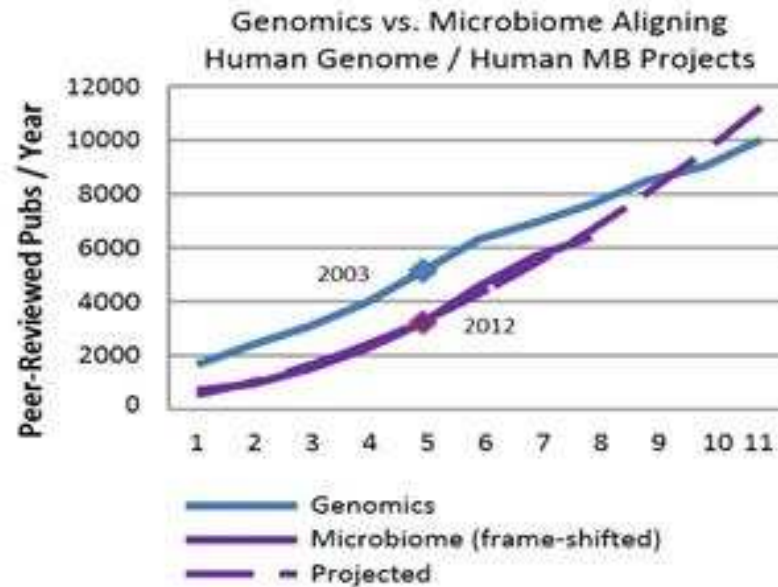


The human-associated microbiome comprises the trillions of microorganisms that live on us and in us.

- The microbiome is believed to influence many diseases and biological testing
 - 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



Leverages Population Research Infrastructure



- Overlaying Human Genome Project completion with Human Microbiome Project completion suggests 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.



Establishing a New “Gold Standard”

 OMNigene·GUT



 OMNigene·ORAL



 OMNigene·VAGINAL

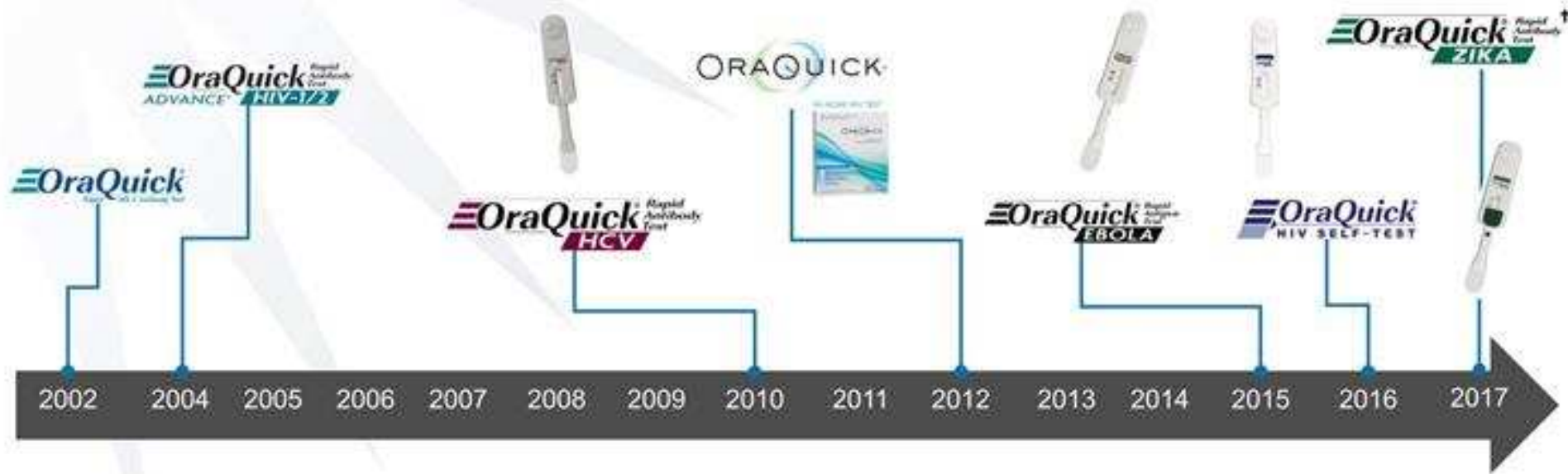


- All in one system for self-collection and stabilization of microbiome samples at ambient temperatures
- Ensures microbiota profiles accurately represent the *in vivo* state
- Possess CE-IVD mark for Gut microbiome collector
- Over 300 customers have resulted in three fold revenue growth year to date, September 2017
- Human Longevity Inc. publication proposes OMNigene® GUT as standardized collector for worldwide studies of the human microbiome*

* [A robust ambient temperature collection and stabilization strategy: Enabling worldwide functional studies of the human microbiome](#) Ericka L. Anderson, Weizhong Li, Niels Klitgord, Sarah K. Highlander, Mark Dayrit et al. Nature Publishing Group – Scientific Reports, August 25, 2016



OraQuick Platform



- Leverage existing technology to quickly respond to emerging diseases
- Rapid testing is vital to maximize linkage to care for infected patients
- Ideal solution for low resource settings

†OraQuick Zika is currently under development



HIV Self Test



Health Problem:

- 36.4 million living with HIV approximately 1/3 of the population is unaware of their status
- Majority of undiagnosed have limited or no access to health services



OraQuick
HIV SELF-TEST

Opportunity/Drivers:

- ~100M HIV rapid tests are deployed annually in Africa
- 40 countries have adopted HIV self-testing policies, 48 additional expected
- Recent **WHO** prequalification for HIV self test
- Recent **Gates Foundation** agreement for HIV self test
- UNAIDs cited self-testing as an innovation critical to achieving the 90:90:90 goals

Our Solution:

- OraSure offers the only WHO prequalified oral HIV self test



HIV Self Test Market Opportunity



- UNITAID/PSI Self Testing in Africa (STAR) program
 - Completed Phase 1 in Zimbabwe, Malawi and Zambia (750K units)
 - Executing against Phase 2 (4M units) expanded to include South Africa, Swaziland and Lesotho
- Ongoing discussions with additional countries to deploy now that product is WHO pre-qualified
- Funding organizations highly supportive (Global Fund, CIFF, PEPFAR, UNITAID, Gates Foundation)
- Gates Foundation \$20M for subsidized purchase of self-test over 4 year period
- Additional upside opportunities expected from UNITAID's call for proposals to scale-up HIV self-testing
- OraSure HIV Self Test is now eligible for procurement by Global Fund and PEPFAR grantees





Hepatitis C

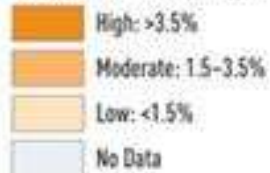


WHO leading effort to eliminate viral hepatitis by 2030

Fig. 1.20. Global epidemiology of hepatitis C virus infection



Prevalence of Hepatitis C



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



Source: CDC

Health Problem:

- 170M people infected globally, 4-5M people infected in U.S.
- 30,000 new HCV infections per year in the U.S.
- New Hepatitis C infections nearly tripled over 5 years
- The majority of HCV infections remain undiagnosed

Opportunity/Drivers:

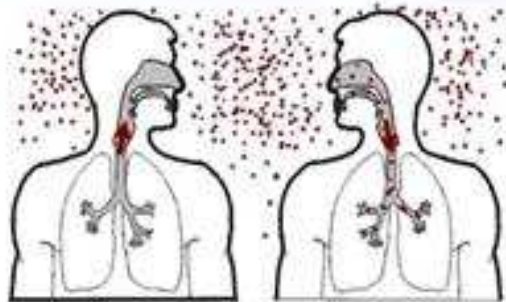
- Recognized bodies and countries contemplating HCV eradication programs
- Price for HCV therapy is reduced in developing countries

Our Solution:

- First and only FDA-approved, CLIA-waived rapid HCV test
- Only WHO prequalified rapid oral fluid HCV test
- Accurate and simple test: sensitivity and specificity comparable to lab-based immunoassays with results in 20 minutes



Tuberculosis



OMNIGENE[®] SPUTUM

Study published in the Journal of Epidemiology and Global Health. Real world results reduced culture contamination from 12% to 2% and improved TB detection by 9% *



*Maharjan et al. J Epidemiol Glob Health. 2016 Apr 27.
[doi:10.1016/j.jegh.2016.04.002](https://doi.org/10.1016/j.jegh.2016.04.002)

Source: WHO

Health Problem:

- Ongoing global crisis, kills ~5K people each day
- 10.4 M people infected and 1.8M died in 2015
- Highly infectious – spread through the air

Opportunity/Drivers:

- WHO goal to reduce TB related deaths and new cases 90% by 2035
- Need to collect, transport and process viable sputum samples in low resource settings
- ~200M samples collected each year
- Targeting WHO endorsement

Our Solution:

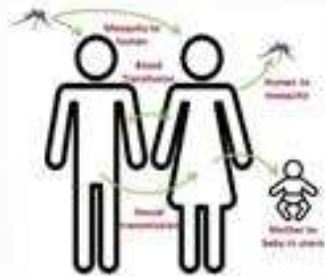
- A reagent designed to liquify and decontaminate sputum samples while maintaining MTb viability for 8 days between 39°F and 104°F
- Improves efficiency and results for the lab by eliminating use of NaOH/NALC



Zika



Easy transmission



OraQuick® Rapid Antibody Test
ZIKA

Health Problem:

- 32,724 infections in U.S. and territories
- Easy transmission, flu-like symptoms
- Congenital birth defects ~5% of pregnancies
- Guillain-Barre Syndrome: <1% of all infections

Opportunity/Drivers:

- 67 countries reporting Zika infections since 2015
- 171K confirmed cases in the Americas alone
- Awarded \$16.6M BARDA contract
- "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, Oct 2016

Our Solution:

- Rapid point of care test on OraQuick platform under development

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



Ebola



Ebola Outbreaks in West Africa (since 2014 epidemic)



OraQuick® Rapid Antigen Test
EBOLA



Health Problem:

- CDC is actively surveilling in Africa to prevent another Ebola epidemic
- Cadaver testing is critical for outbreak management
- Rapid response is required to control outbreaks

Opportunity/Drivers:

- Leverage existing OraQuick platform technology to create rapid tests to address emerging diseases
- Awarded \$10.4M BARDA contract
- Received Emergency Use Authorization ("EUA") from FDA

Our Solution:

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



Business Development Objectives

Over \$175 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 buyer



Summary

- Approved products address substantial opportunities in molecular diagnostics and infectious disease point-of-care testing
- Early stages of several revenue growth drivers
- Growing and diversified product portfolio
- Active business development program
- Strong capital structure and sustained profitability to support growth



OraQuick Rapid Antibody Test
HCV

ORAGene-Dx
For collection of Buccal Swabs



ORACollect-Dx



OraQuick Rapid Antibody Test
ADVANCE HIV-1/2

