

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): January 4, 2019

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

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16537
(Commission
File Number)

36-4370966
(I.R.S. Employer
Identification No.)

220 East First Street
Bethlehem, Pennsylvania
(Address of Principal Executive Offices)

18015-1360
(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))

Indicate by a check mark whether the registrant is an emergent growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 – Regulation FD Disclosure.

On January 4, 2019, OraSure Technologies, Inc. (the “Company”) issued a press release in which it announced the execution of definitive agreements to acquire CoreBiome, Inc. and Novosanis NV and reaffirmed its revenue guidance for the fourth quarter of 2018. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

On January 4, 2019, the Company held a webcast conference call with analysts and investors, during which Stephen S. Tang, Ph.D., the Company’s President and Chief Executive Officer, and Roberto Cuca, the Company’s Chief Financial Officer, discussed the acquisitions and revenue guidance for the fourth quarter. A copy of the prepared remarks of Dr. Tang and Mr. Cuca is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

On January 10, 2019, Dr. Tang will make a presentation at the JP Morgan Healthcare Conference in San Francisco, California. A copy of Dr. Tang’s presentation is attached as Exhibit 99.3 to this Form 8-K and is incorporated herein by reference.

The information in this Item and attached Exhibit 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. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated January 4, 2019, Announcing Two Acquisitions and Reaffirming Fourth Quarter 2018 Revenue Guidance.
99.2	Prepared Remarks of Stephen S. Tang, Ph.D. and Roberto Cuca for OraSure Technologies, Inc. Analyst/Investor Conference Call Held January 4, 2019.
99.3	OraSure Technologies, Inc. JP Morgan Healthcare Conference Presentation, dated January 10, 2019.

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: January 4, 2019

By: /s/ Jack E. Jerrett
Jack E. Jerrett

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OraSure Technologies, Inc. Announces Two Acquisitions and Reaffirms Fourth Quarter 2018 Guidance

CoreBiome leverages OraSure's leadership position in microbiome sample collection with end-to-end laboratory services for sample processing, sequencing, and bioinformatics

Novosanis' urine collection technology expands molecular collection portfolio and advances OraSure's expertise in non-invasive sampling

Bethlehem, PA – January 4, 2019 – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point of care diagnostic tests and specimen collection and stabilization devices, today announced that it has entered into definitive agreements to acquire two companies. The transactions are expected to close within the next week. OraSure also reaffirmed its fourth quarter 2018 financial guidance.

"These acquisitions clearly demonstrate our commitment to our innovation-driven growth strategy," said Dr. Stephen S. Tang, Ph.D., President and CEO of OraSure Technologies. "The acquisitions of Novosanis and CoreBiome, both innovators in their respective markets, add differentiated products and services that we expect will enhance our Molecular business, our longer-term corporate growth profile, and returns for our stockholders. Both transactions will leverage the sales and marketing resources of our wholly-owned subsidiary DNA Genetek to cultivate commercial customers, key opinion leaders and academic collaborators."

CoreBiome

CoreBiome is a privately-held, Minnesota-based early-stage microbiome services provider that accelerates discovery for customers in the pharmaceutical, agricultural, and research communities. CoreBiome's technology provides information-rich characterization of microbial diversity and function, paired with machine learning and expert analytics. CoreBiome's proprietary genomics pipeline and optimal algorithms deliver speed and scalability in the lab as well as highly precise analytics. CoreBiome was co-founded in 2016 by Dr. Dan Knights, a globally recognized expert in microbiome informatics who has developed leading methods for analyzing microbiome data, along with Dr. Daryl Gohl and Dr. Kenny Beckman, domain experts in genomics methods and clinical lab operations.

"The global microbiome market is expected to grow by double digits, from approximately \$325 million in 2017 to \$725 million or more in 2022," said Dr. Tang. "Expanding our services through the CoreBiome acquisition will allow OraSure to optimally address future microbiome research needs, capture new segments and expand our leadership position in this dynamic market."

"The microbiome is transforming how people do research in human health and agriculture. Companies are increasingly looking to understand how the complex behavior of the microbiome affects their product

development, and this requires big data," said Dr. Knights, CEO of CoreBiome. "CoreBiome's highly scalable and reproducible BoosterShot™ platform allows researchers to efficiently run high-resolution DNA sequencing on thousands of microbiome samples. This means investigators can now measure important changes often missed in under-powered studies. CoreBiome's bioinformatics platform uses machine learning and advanced data visualization to help customers leverage that big data and to make world-class microbiome expertise available on-demand."

The CoreBiome acquisition positions OraSure to become a leading, end-to-end solution provider for researchers, therapeutic and diagnostic development customers, and Direct-to-Consumer companies," said Dr. Tang. "We look forward to accelerating the adoption of CoreBiome's cutting-edge microbial genomics technology and analytics expertise into DNA Genotek's customer network. We're excited about the synergies that will come from combining DNA Genotek's proprietary sampling and stabilization technology with CoreBiome's platform across the many industries that will be impacted by the microbiome."

Novosanis

Novosanis is a privately-held, Belgian company founded as a spinoff company from the University of Antwerp, Belgium, in 2013. Novosanis is an early commercial-stage producer and distributor of urine sample collection devices targeted primarily at the liquid biopsy, Sexually Transmitted Infection (STI) screening, and urological cancer markets.

Novosanis' primary product technology is Colli-Pee, an easy-to-use device designed for the standardized collection of first-void urine in the privacy of the user's home or at a clinic. The initial commercial application is as a collection device for liquid biopsy tests in the prostate and bladder cancer markets. Additionally, product validation and clinical trials are underway with industry-leading STI test manufacturers. Colli-Pee is the only product specifically designed to collect a first-void sample and offers significant advantages to urinary testing companies, including superior test performance, ease-of-use for both collection and in the lab, and flexible customization options based on specific need.

"The Novosanis acquisition represents a clear fit in our stated 'core growth strategy' for our Molecular business – to grow our portfolio of collection products beyond oral samples by leveraging expertise in collection and stabilization tools and technologies – all of which can be used at home or in the clinic," said Dr. Tang. "The Colli-Pee urine collection device has utility in high-growth markets, including liquid biopsy and STI diagnostics where OraSure can leverage its existing intellectual property, brand, and market expertise to deliver even more value to existing, and new, Molecular customers."

Dr. Tang continued: "We believe there is a significant opportunity for an easy-to-use, differentiated product that combines our existing stabilization technology with Novosanis' first-void sample and volumetric capabilities. The Colli-Pee product is the perfect answer for this unmet market need. DNA Genotek built its business on establishing DNA from saliva as a proven and trusted sample type for molecular analysis. We believe a key enabler for similar development of the urine market will be an improved collection experience with Colli-Pee, combined with ambient temperature stabilization of the sample."

Dr. Vanessa Vankerckhoven, co-founder and CEO of Novosanis, added, "The Novosanis team is excited to become part of the OraSure family. The Colli-Pee device is complementary to OraSure's existing portfolio of non-invasive sample collection devices. The acquisition will allow us to ensure further growth and expansion of our Colli-Pee device globally."

"With our growing customer base, we've been rapidly expanding our manufacturing capacity in recent months," Koen Beyers, Novosanis co-founder and Chief Technology Officer explained. "I'm looking forward to building scale and diversity of our innovation with OraSure and DNA Genotek."

CoreBiome and Novosanis Acquisitions – Financial Considerations

The transactions are structured with an upfront payment and potential additional payments based on future performance. The Company expects that the acquisitions will together contribute from \$4 million to \$7 million in net revenues in 2019, with \$0.03 to \$0.05 per share of dilution to non-GAAP earnings excluding transaction costs and required acquisition accounting adjustments.

Fourth Quarter 2018 Guidance

The Company continues to expect net revenue to range from \$46.5 million to \$48.0 million – representing full year revenue growth of 7% over 2017 – and net income of \$0.09 to \$0.11 per share for the three months ended December 31, 2018.

Investor Conference Call

The Company will host a conference call to discuss the foregoing transactions on Friday, January 4, 2019 at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time). On the call will be Stephen S. Tang, Ph.D., President and Chief Executive Officer, and Roberto Cuca, Chief Financial Officer. The call will include prepared remarks by management and a question and answer session.

In order to listen to the conference call, dial (844) 831-3030 (domestic) or (315) 625-6887 (international) and reference Conference ID# 3783126.

About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of point-of-care diagnostic and collection devices and other technologies designed to detect or diagnose critical medical conditions. Its first-to-market, innovative products include rapid tests for the detection of antibodies to HIV and HCV on the OraQuick® platform, oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications, and oral fluid laboratory tests for detecting various drugs of abuse. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, commercial and industrial entities and consumers. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health.

Important Information

This press release contains certain forward-looking statements, including with respect to the acquisitions of CoreBiome and Novosanis, and the expected benefits thereof, and 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 the acquisitions 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; failure to realize the expected economic benefits of the 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 or that our actual integration costs may exceed our estimates; ability to market and sell products, whether through our internal, direct sales force or third parties; 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; 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 significant customer concentration in the genomics business; impact of increased reliance on U.S. government contracts; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our 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; impact of negative economic conditions; reduction or deferral of public or other 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; 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 meet financial covenants in credit agreements; ability to attract and retain qualified 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 our 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, 2017, Quarterly Reports on Form 10-Q, 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 press release and OraSure Technologies undertakes no duty to update these statements.

OraSure Technologies, Inc.
Analyst/Investor Conference Call
January 4, 2019

Prepared Remarks of Dr. Stephen S. Tang and Roberto Cuca

Please see “Important Information” at the conclusion of the following prepared remarks

Introduction – Steve Tang

Thank you Jeanne. Good morning everyone and welcome to our call.

I am delighted to share the news that OraSure has entered into definitive agreements to acquire Novosanis and CoreBiome. The transactions are expected to close within the next week.

These acquisitions are the first example of our innovation-driven growth strategy taking flight.

As I've shared in past calls, our business development efforts are focused on identifying opportunities to license technology or acquire products or companies that complement or leverage our existing business, or enhance our end-to-end service offerings.

The acquisitions of Novosanis and CoreBiome, both innovators in their respective markets, advance our innovation-driven focus by adding differentiated products and services that we expect will enhance our Molecular business, our longer-term corporate growth profile, and returns for our stockholders.

Both transactions will leverage the sales and marketing resources of our wholly-owned subsidiary DNA Genotek to cultivate commercial customers, key opinion leaders and academic collaborations.

Let me share some key highlights on the two companies.

Novosanis is a privately held, Belgium based company which was founded in 2013 by Vanessa Vankerckhoven and Koen Byers as a spin-off company out of the University of Antwerp.

Novosanis is an early commercial-stage producer and distributor of urine sample collection devices targeted primarily at the liquid biopsy, Sexually Transmitted Infection screening, and urological cancer markets.

Novosanis' primary technology is called "Colli-Pee", an easy-to-use device suited for the standardized collection of first-void urine in the privacy of the user's home or at a clinic.

Colli-Pee is the only product specifically designed to collect a first-void sample. The utility of first-void urine has been gaining acceptance as a biomarker-rich sample type for oncology and STI/HPV applications. Further, Colli-Pee has made it simple for a patient to collect a volumetric, first void-urine sample. A standard pee cup is what is being used today, but it is not volumetric and can be difficult to easily collect a first-void sample.

Colli-Pee offers significant advantages to urinary testing companies addressing an unmet need in the market for:

- superior test performance,
- improved ease-of-use for urine collection,
- features that support high throughput automation in the lab, and
- flexible customization options based on specific need.

The Colli-Pee urine collection device has utility in high-growth markets, including liquid biopsy and STI diagnostics where OraSure can leverage its existing intellectual property, brand, and market expertise to deliver even more value to existing, and new, Molecular customers.

DNA Genotek built its business on establishing DNA from saliva as a proven and trusted sample type for molecular analysis. We believe a key enabler for similar development of the urine market will be an improved collection experience with Colli-Pee, combined with ambient temperature stabilization of the sample.

We believe there is a significant opportunity for an easy-to-use, differentiated product that combines our existing stabilization technology with Novosanis' first-void sample and volumetric capabilities. The Colli-Pee product is the perfect answer for this unmet market need.

The Novosanis acquisition represents a clear fit in our stated 'core growth strategy' for our Molecular business – to grow our portfolio of collection products beyond oral samples by leveraging expertise in collection and stabilization tools and technologies – all of which can be used at home or in the clinic.

Since urine testing is a more mature market opportunity, its overall growth rate is more stable. However, submarkets like cancer biomarker screening and others served by

innovative products like Colli-Pee have the opportunity to grow at significant double-digit rates.

Moving on to CoreBiome, a privately held, Minnesota-based microbiome services provider that spun out of the University of Minnesota.

CoreBiome was co-founded by Dr. Dan Knights, a globally recognized expert in microbiome informatics who has developed leading methods for analyzing microbiome data, along with Dr. Daryl Gohl and Dr. Kenny Beckman, domain experts in genomics methods and clinical lab operations.

Their proprietary technology provides fast and information-rich characterizations of microbial diversity and function, paired with machine learning and expert analytics.

The global microbiome market is expected to grow by double digits, from approximately \$325 million in 2017 to \$725 million or more in 2022. Expanding our services through the CoreBiome acquisition will allow OraSure to optimally address future microbiome research needs, capture new segments and expand our leadership position in this dynamic market.

Today, OraSure offers limited wet lab and sequencing services. CoreBiome's offerings fill a key portfolio gap for OraSure with DNA extraction, library prep and metagenomics sequencing services.

We have said one of our primary focus-areas for business development is the enhancement of our end-to-end service offerings primarily in the microbiome area through customization, fulfillment, laboratory and analytics services. The acquisition of CoreBiome could not be a better 'fit' for this objective.

We believe CoreBiome represents a meaningful down-stream opportunity to build OraSure's microbiome capabilities towards an end-to-end solution with immediate differentiation AND to maintain a leadership position as our products and services offering evolves.

Adding CoreBiome's sample processing, shotgun sequencing, metabolomics analysis, and bioinformatics positions OraSure to become a leading, end-to-end solution provider for researchers, therapeutic and diagnostic development customers, and Direct-To-Consumer companies.

Microbiome researchers are increasingly looking to understand the functional role of the microorganisms in the microbiome. CoreBiome metagenomics services address this need.

We look forward to accelerating the adoption of CoreBiome's cutting-edge microbial genomics technology and analytics expertise into the customer network of DNA Genotek.

We're excited about the synergies that will come from combining DNA Genotek's proprietary sampling and stabilization technology with CoreBiome's platform across the many industries that will be impacted by the microbiome.

Importantly, we believe CoreBiome's technology and services offering is the ideal extension of DNA Genotek's established leadership in proprietary sampling and stabilization technology. The combination of DNA Genotek's expertise in sample collection and stabilization and Core Biome's unique approach to sample preparation, analytics and bioinformatics position us well to become a true market leader across multiple segments of the microbiome space.

Together, we believe these acquisitions will support our move to a tools, services and diagnostics model. By marrying deeper tools offerings with end-to-end services, we can support a multi-omics view of systems biology to inform health and wellness.

I'll now turn the call over to Roberto to review the financial components of the transaction.

Roberto Cuca

Both of these transactions were completed with modest initial cash outlays. There is the potential for additional payments based on future performance.

We expect that the acquisitions will together contribute from \$4 million to \$7 million in net revenues in 2019, with \$0.03 to \$0.05 per share of dilution to non-GAAP earnings excluding transaction costs and required acquisition accounting adjustments.

We are also reiterating our 4Q18 financial guidance at this time. Specifically, we continue to expect net revenue to range from \$46.5 million to \$48.0 million – representing full year revenue growth of 7% over 2017 – and net income of \$0.09 to \$0.11 per share for the three months ended December 31, 2018.

With that I'll turn the call back to Steve for concluding remarks.

Steve Tang

Thanks Roberto.

These acquisitions are the beginning of the execution of our long-term innovation-focused growth strategy, which was approved by our Board this past summer.

We think about our strategy in two parts: First, we talk about growing our Core Business through investment in our Infectious Disease, Genomics and Microbiome businesses and a prioritization of our overall portfolio.

We expect these strategies will deliver solid double-digit growth over the planning horizon.

Second, we also see the need and the opportunity to use our capabilities and resources to expand into new markets -- what we're calling "dynamic opportunities."

These opportunities are areas where we see the ability to enhance our growth profile by moving into new forms of diagnostics such as veterinary or environmental, to name just a few examples.

They may also involve new markets and technologies, such as those exemplified by Novosanis and CoreBiome.

We believe we have a compelling opportunity to leverage the powerful combination of our strong balance sheet, and our business development strategy activities to enhance our long-term growth and profitability profile.

And we expect these business development opportunities to advance our goal of being an innovation-driven company by adding **differentiated** products and services in high-end growth markets around the world – again as exemplified by these acquisitions.

In closing, we are very excited about our recent progress in the area of business development. These acquisitions represent clear 'fits' in our strategy to use business development to build upon our solid organic growth trends and enhance our longer-term growth profile.

Importantly, these acquisitions represent our initial steps in our long-term innovation-driven growth strategy. Given our commitment to R&D, innovation and an active business development program, you should expect more additions to the portfolio. We look forward to updating you on these developments as they occur in 2019 and beyond.

I'm now happy to take some questions.

* * * * *

[Q&A session]

Final Conclusion – Steve Tang

Thank you for participating on today's call and for your continued interest in OraSure. Have a good afternoon and evening.

Important Information

This document contains certain forward-looking statements, including with respect to the acquisitions of Novosanis and CoreBiome, and the expected benefits thereof, and 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 the acquisitions 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; failure to realize the expected economic benefits of the 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 or that our actual integration costs may exceed our estimates; ability to market and sell products, whether through our internal, direct sales force or third parties; 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; 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 significant customer concentration in the genomics business; impact of increased reliance on U.S. government contracts; failure of

distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our 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; impact of negative economic conditions; reduction or deferral of public or other 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; 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 meet financial covenants in credit agreements; ability to attract and retain qualified 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 our 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, 2017, Quarterly Reports on Form 10-Q, 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 call and OraSure Technologies undertakes no duty to update these statements.

OraSure Technologies

JPMorgan Health Care Conference
January 10, 2019



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.

- Industry leader in DNA/RNA sample self-collection, stabilization and preparation products and rapid point-of-care infectious disease testing.
- **Multiple growth drivers, many in early stages of uptake and market growth:**
 - Leadership position in molecular sample collection/stabilization expanding customer base and broadening utilization
 - New products and services focused on the Microbiome offer tremendous growth potential
 - Expand further in established markets
 - Strong demand for OraQuick HIV Self Test which addresses significant market opportunity
 - OraQuick HCV test being evaluated for country wide eradication programs
 - Developing and acquiring new products and programs for large global opportunities
 - Two recent exciting acquisitions highlight our active business development efforts
 - Focused on expanding offerings to provide end-to-end solution encompassing tools, diagnostics and services
- Significant ramp in manufacturing capacity for OraQuick and Oragene and improved production efficiency
- Strong cash position with no debt and sustainable profitability



Molecular business

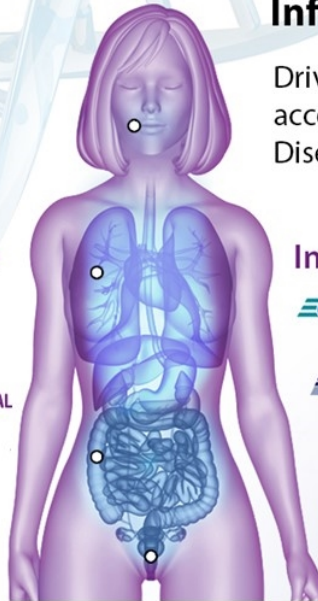
Leverage the strength of our Molecular business into new growth markets with existing and new technology

Human Genetics

- ORAgene-DNA
- ORAc collect
- ORAgene-RNA

Microbiome

- OMNigene-GUT
- OMNigene-ORAL
- OMNigene-VAGINAL



Infectious Disease business

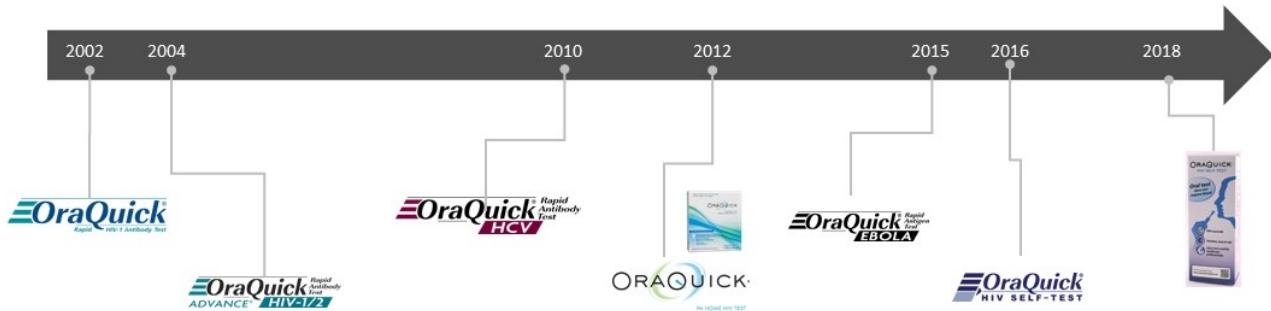
Drive unprecedented global access to our Infectious Disease solutions

Infectious Disease

- OraQuick
- OraQuick ADVANCE HIV-1/2
- OraQuick HIV-1/2
- OraQuick HIV SELF-TEST
- ORAQUICK
- OraQuick EBOLA

History of Developing Infectious Disease Solutions

- Proven and reliable lateral flow platform
- Rapid testing is vital to maximize linkage to care for infected patients
- Ideal solution for low resource settings





OraQuick
HIV SELF-TEST

Global Health Problem:

- 36.9M living with HIV
- Estimated that only 75% of people with HIV know their status
- Majority of undiagnosed have limited or no access to health services

Opportunity/Drivers:

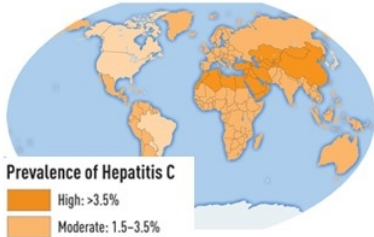
- Gates Foundation charitable support agreement for international HIV self testing breaks down cost barrier
- UNAIDS's cited self-testing as an innovation critical to achieving the 90:90:90 goals of diagnosis, therapy and viral suppression
- UNITAID/PSI Self-Testing in Africa (STAR) program
- A majority of purchases were outside of STAR initiative in Q3 2018

Our Solution:

- OraSure offers the only WHO prequalified rapid oral HIV Self Test

Source: WHO/UNITAID

Map 3.04. Global epidemiology of hepatitis C virus infection



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



OraQuick Rapid Antibody Test
HCV

Source: WHO & CDC

Global Health Problem:

- Globally, an estimated 71M people have chronic Hepatitis C infection
- Approximately 399,000 people die each year from HCV
- An estimated 3.5M people in the US have chronic HCV with an estimated 41,200 new infections in 2016
- The majority of HCV infections remain undiagnosed

Opportunity/Drivers:

- Antiviral medicines can cure more than 95% of persons with HCV
- 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

* VWB and FSWB only

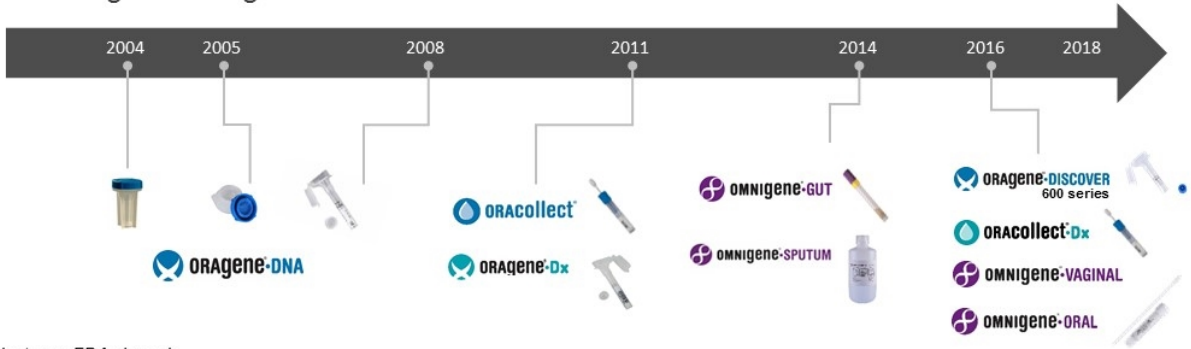
Molecular – A History of Innovation

- All-in-one, easy, reliable and non-invasive collection
- High quality DNA and RNA
- Ambient temperature stability
- Compatible with high throughput automation
- Strong IP
- Strong revenue growth

6,000+
customers

in 100+
countries

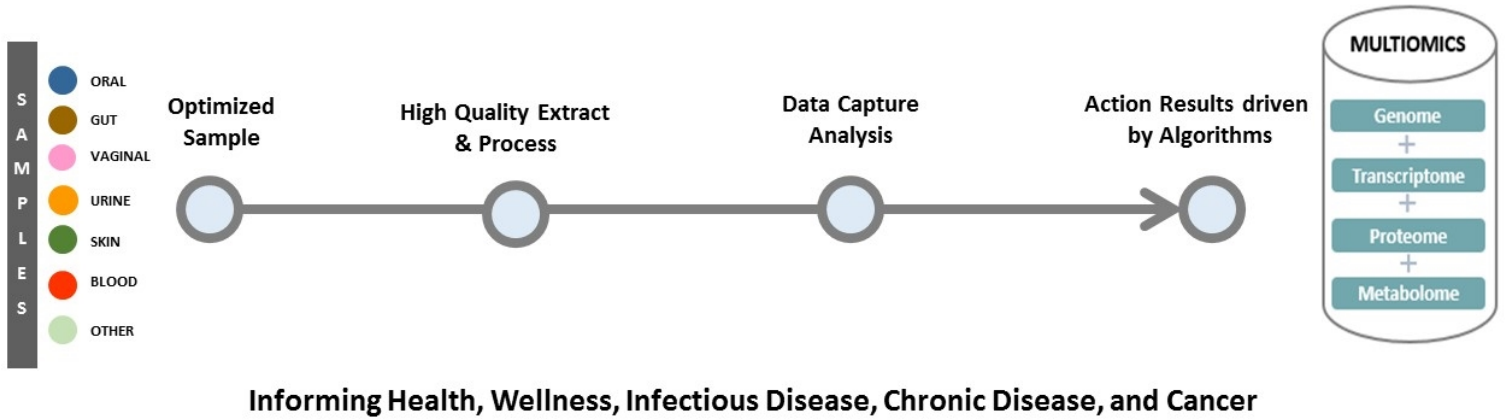
~3,000
peer-reviewed
publications



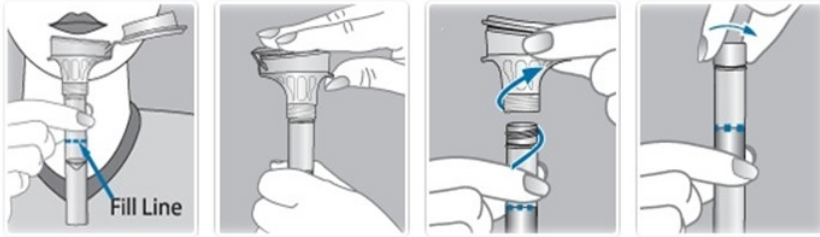
Note: DX products are FDA cleared

Building blocks for better informed health and wellness

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



Growth coming from existing customers and increased demand from emerging genetic testing offerings and large studies



- Anytime, anywhere, anyone sampling
- All-in-one, easy, reliable and non-invasive assisted and self-collection

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

 **ORAGene-Dx**

 **ORAcollection-Dx**

Key Enabler for Personal Genomics

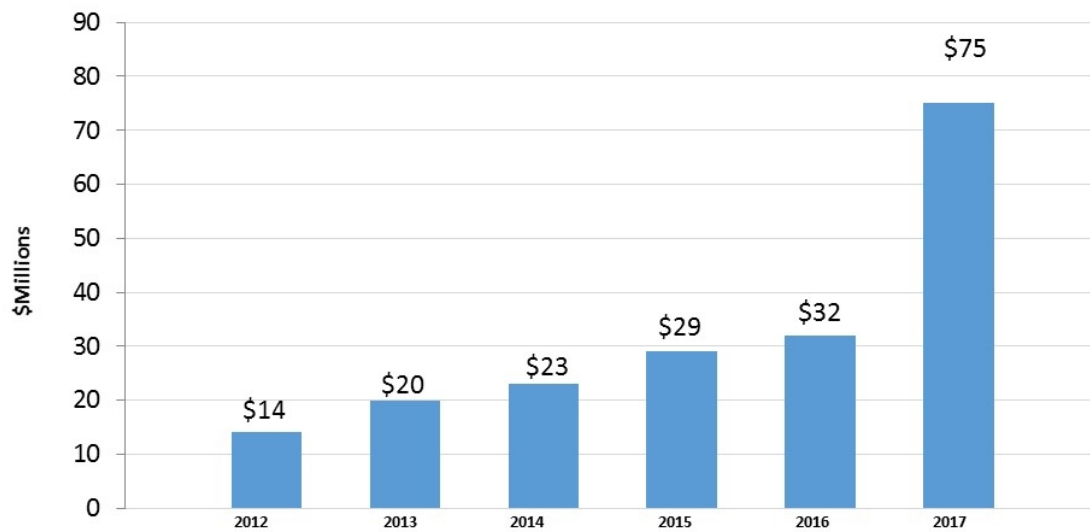


November 2017 – Announced multi-year \$143M supply agreement for Oragene•Dx to a leading consumer genomics customer, with minimum annual purchase requirements.

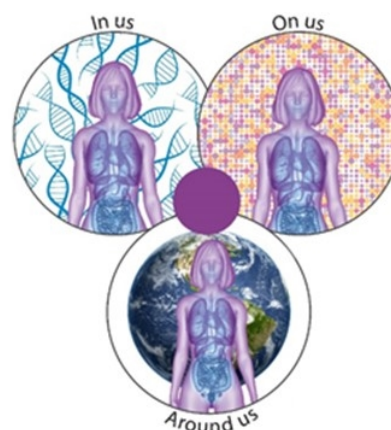
DNA Genotek “has done for DNA collection what Google did for Web searches: made it ridiculously simple and efficient.” – *TIME Magazine*

Embark’s Dog DNA Test Kit, which uses a customized version of our Performagene product, was one of Oprah’s Favorite Things 2018. “There’s nothing better than discovering your roots—and that goes for fur babies, too... Incredible!”

Molecular Revenue Growth



- 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



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

DNA genotek
MICROBIOME

Snapshot the microbiome

OMNIGENE[®]
ORAL
GUT
VAGINAL

Collection to discovery

- Self collection & ambient stabilization kits
- Customization & logistics
- Donor direct shipments
- Extraction & sequencing
- Analysis & reporting

GENO FIND Services
CLIA/CAP

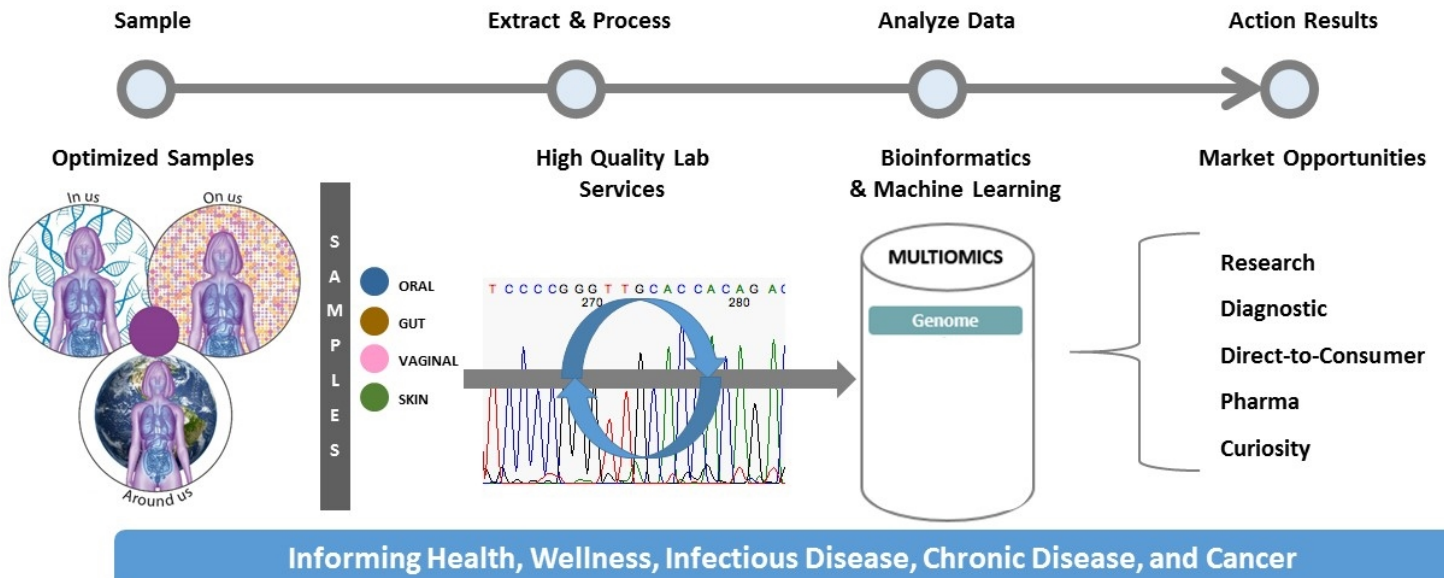
"Stabilization of biological samples is crucial for accurate analysis of microbiome data
..... **provides a robust, reproducible workflow that enables standardized global collection, storage, and analysis of stool for microbiome studies**"

 HUMAN LONGEVITY, INC.[®]

"... "The Biobank for Microbiome Research in Massachusetts (BIOM-Mass) at the Harvard T.H. Chan School of Public Health **will create a state-of-the-art facility and integrated platform** allowing the Massachusetts life science community to collect, use, and analyze microbiome-targeted biospecimens in human populations"

 HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH

From sample to solution: Tools & Services to transform optimal data into health insights



Strong cash position with no debt

- Enhance the Company's long-term growth and profitability profile
- Provide attractive returns for our stockholders going forward
- Identify opportunities to license technology or acquire products or companies that complement or leverage our existing business or enhance our end-to-end service offerings
- Advance our goal of being an innovation-driven company by adding differentiated products and services in high-end growth markets around the world



Novosanis' urine collection technology expands molecular collection portfolio and advances OraSure's expertise in non-invasive sample collection and stabilization



Strategic Rationale: Colli-Pee technology serves high-growth markets including liquid biopsy and STI diagnostics where OraSure can leverage its existing intellectual property, and brand and market expertise to deliver even more value to existing, and new, Molecular customers

- Privately held, Belgium-based; founded in 2013
- Early commercial-stage producer and distributor of urine sample collection devices
- **Colli-Pee**, the only available easy-to-use device designed for the standardized collection of first-void urine in the privacy of the user's home or at a clinic
- Offers significant competitive advantages to urinary testing companies including: superior test performance, ease-of-use for both collection and processing, flexible customization options based on specific use case requirements
- Initial commercial application is as a collection device for liquid biopsy tests in the prostate and bladder cancer markets

Powering systems biology services with CoreBiome



CoreBiome leverages OraSure's leadership position in microbiome sample collection with end-to-end laboratory services that include sample processing, sequencing, and bioinformatics



Strategic rationale:

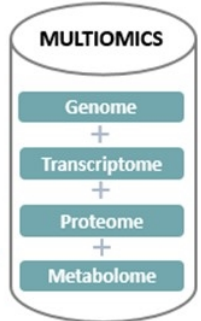
- Positions OraSure to become a leading, end-to-end solution provider for researchers, DTC companies and therapeutic and diagnostic development customers, from sample to solution
- Powerful synergy from combining DNA Genotek's proprietary sampling and stabilization technology with CoreBiome's platform
- Privately held, Minnesota-based microbiome services provider
- Co-founded in 2016 by domain experts in microbiome informatics, genomics methods and clinical lab operations
- Proprietary technology provides fast, information-rich characterizations of microbial diversity and function, paired with machine learning and expert analytics
- Early-stage commercial company with customers in pharmaceutical, agricultural, and research communities

BoosterShot™

BenchMark™

StrainView™

Core Analysis™



OraSure Technologies, Inc.

Key Takeaways

- Significant growth opportunities exist in – consumer genomics, microbiome and systems biology, eradication programs for HIV and HCV.
- We will leverage our experience in tools, services and diagnostics:
- Core saliva genomics business remains central to our overall molecular strategy, and we intend to invest and grow this key business.
- Expanding our product portfolio with new products that build on our core strengths in genomics and microbiome and to expand deeper into multi-omics and systems biology.
- Expand our core HIV and HCV franchises globally through innovative testing programs, new registrations and collaborations with our customers and other stakeholders.
- Beyond HIV and HCV, we intend to leverage our strengths and relationships with existing customers by expanding our portfolio with products synergistic with our existing products.

- Novosanis and CoreBiome acquisitions are initial results for Business Development strategy
- Innovation-focused corporate growth strategy
- Early stages of several revenue growth drivers
- Growing and diversified product portfolio
- Robust manufacturing capacity for lead products
- Strong capital structure and sustained profitability to support growth

