

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): December 19, 2024

**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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.000001 par value per share	OSUR	The Nasdaq Stock Market LLC

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 emerging 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.**

OraSure Technologies, Inc. (the “Company”) hereby furnishes the Investor Presentation that the Company will present to analysts and investors on or after the date hereof, which is attached as Exhibit 99.1 to this Current Report on Form 8-K (“Current Report”), is incorporated herein by reference and will be available on the Company’s website at [www.orasure.com](http://www.orasure.com).

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 8.01 Other Events.**

On December 19, 2024, the Company issued a press release announcing the Company’s acquisition of Sherlock Biosciences, Inc (“Sherlock”). A copy of the press release is attached as Exhibit 99.2 to this Current Report and is incorporated herein by reference.

**Forward Looking Statements**

This Current Report contains certain “forward-looking statements” within the meaning of the Federal securities laws, including with respect to products, product development and manufacturing activities, the Company’s acquisition of Sherlock, revenue growth, cash flow, increasing margins and other matters. Words such as “expects,” “estimates,” “forecasts,” “intends,” “plans,” “projects,” “could,” “may,” “should,” “will” or other similar words and expressions are intended to identify these forward-looking statements. 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: the Company’s ability to integrate Sherlock’s business and achieve the intended benefits of the acquisition on the timeline expected or at all; Sherlock’s ability to seek and obtain regulatory approval for products in development; the Company’s ability to satisfy customer demand; ability to reduce the Company’s spending rate, capitalize on manufacturing efficiencies and drive profitable growth; ability to achieve the anticipated cost savings as a result of the Company’s business restructuring, including from insourcing third party manufacturing and exiting microbiome services; ability to market and sell products, whether through the Company’s internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for the Company’s products; ability to manufacture or have manufactured 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 FDA or other regulators; the impact of the novel coronavirus (“COVID-19”) pandemic on the Company’s business, supply chain, labor force, ability to successfully develop new products, validate the expanded use of existing collector products, receive necessary regulatory approvals and authorizations and commercialize such products for COVID-19 testing, and demand for the Company’s COVID-19 testing products; 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 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 and the ability to continue to reduce costs; impact of competitors, competing products and technology changes; reduction or deferral of public 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 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 the Company’s products; impact of contracting with the U.S. government; impact of negative economic conditions; 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

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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 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; cybersecurity breaches or other attacks involving the Company's systems or those of the Company's third-party contractors and IT service providers; the impact of terrorist attacks, civil unrest, hostilities and war; and general political, business and economic conditions, including inflationary pressures and banking stability. These and other factors that could affect the Company's results are discussed more fully in the Company's filings with the Securities and Exchange Commission (the "SEC"), including the Company's registration statements, Annual Report on Form 10-K for the year ended December 31, 2023, 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. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this Current Report and the Company undertakes no duty to update these statements.

**Item 9.01 – Financial Statements and Exhibits.**

**(d) Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Investor Presentation</a>
99.2	<a href="#">Press Release, dated December 19, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**SIGNATURE**

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

**ORASURE TECHNOLOGIES, INC.**

Date: December 19, 2024

By: /s/ Carrie Eglinton Manner  
Carrie Eglinton Manner  
President and Chief Executive Officer

 OraSure Technologies, Inc.

# OraSure Technologies

ACQUISITION OF SHERLOCK BIOSCIENCES  
DECEMBER 19, 2024

 OraSure Technologies, Inc. | **DNAgenotek**  
Transforming health through actionable insight™



# Forward-Looking Statement

This presentation contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including with respect to OraSure Technologies, Inc.'s ("OraSure") acquisition of Sherlock Biosciences, Inc. ("Sherlock"), revenue growth, cash flow, increasing margins and other matters. Words such as "expects," "estimates," "forecasts," "intends," "plans," "projects," "could," "may," "should," "will" or other similar words and expressions are intended to identify these forward-looking statements. 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: OraSure's ability to integrate Sherlock's business and achieve the intended benefits of the acquisition on the timeline expected or at all, Sherlock's ability to seek and obtain regulatory approval for products in development; OraSure's ability to satisfy customer demand; ability to reduce OraSure's spending rate, capitalize on manufacturing efficiencies and drive profitable growth; ability to achieve the anticipated cost savings as a result of OraSure's business restructuring; ability to market and sell products, whether through OraSure's internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for OraSure's products; ability to manufacture or have manufactured 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 FDA or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic on OraSure's business, supply chain, labor force, ability to successfully develop new products, validate the expanded use of existing collector products, receive necessary regulatory approvals and authorizations and commercialize such products for COVID-19 testing, and demand for OraSure's COVID-19 testing products; 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 OraSure's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of OraSure to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales and the ability to continue to reduce costs; impact of competitors, competing products and technology changes; reduction or deferral of public 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 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 OraSure's products; impact of contracting with the U.S. government; impact of negative economic conditions; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of OraSure'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 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; cybersecurity breaches or other attacks involving OraSure's systems or those of OraSure's third-party contractors and IT service providers; the impact of terrorist attacks, civil unrest, hostilities and war, and general political, business and economic conditions, including inflationary pressures and banking stability. These and other factors that could affect OraSure's results are discussed more fully in OraSure's filings with the Securities and Exchange Commission (the "SEC"), including OraSure's registration statements, Annual Report on Form 10-K for the year ended December 31, 2023, 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. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this presentation and OraSure undertakes no duty to update these statements.

# Executive Summary

## Transaction Overview

- Sherlock expands OTI's portfolio with next-generation molecular diagnostics at the point-of-need (PON)
- **OTI gains ...**
  - + Scalable platform for disposable, instrument-free Molecular self-tests with strong clinical performance
  - + Addition of Sherlock CT/NG molecular self-test, if approved by the FDA, is expected to contribute to OTI's revenue beginning in 2026
- **Transaction structure:** majority of transaction consideration dependent on CT/NG FDA approvals

## Strategic Alignment

- **Innovation:** next phase of OTI's innovation strategy ... instrument-free molecular platform that delivers lab-like accuracy – sensitivity & specificity – in a rapid, disposable format
- **Talent:** strong team scientifically, technically, culturally - brings expertise & additional capabilities to OTI
- **Portfolio expansion:** adds rapid testing in areas of existing strength - sexual health, infectious disease - leverages OTI's infrastructure, strong customer relationships & commercial capabilities
- **Channel expansion:** opens opportunities to build our presence as provider of content serving growing consumer-facing channels
- **Purpose:** amplifies OTI's opportunity to improve access, quality, & affordability of healthcare

# OTI is Focused on Where the Future of Healthcare is Going...

Acquisition of Sherlock aligns with OTI's mission & vision



**Move to point-of-need (PON)  
& self-testing diagnostics**



**Growth of  
precision medicine**



**Connecting the needs of the  
user directly to healthcare**



# Powering the Shift that Connects People to Healthcare Wherever They Are

Improving access, quality, and value of healthcare with  
innovation in **effortless tests and sample management solutions**



## Diagnostics (Dx)

Actionable point-of-need & self-testing  
increases access & affordability of care

- ✓ Best-in-class portfolio of tests in infectious disease – sexual health & respiratory ... ex. HIV, HCV, Syphilis, COVID-19, Ebola, Marburg others

**More tests**  
... priority on “instrument-free”



## Sample Management Solutions (SMS)

Molecular sample collection & stabilization  
innovation drives access & discovery

- ✓ Best-in-class tools & chemistries to collect, stabilize, transport, store ...

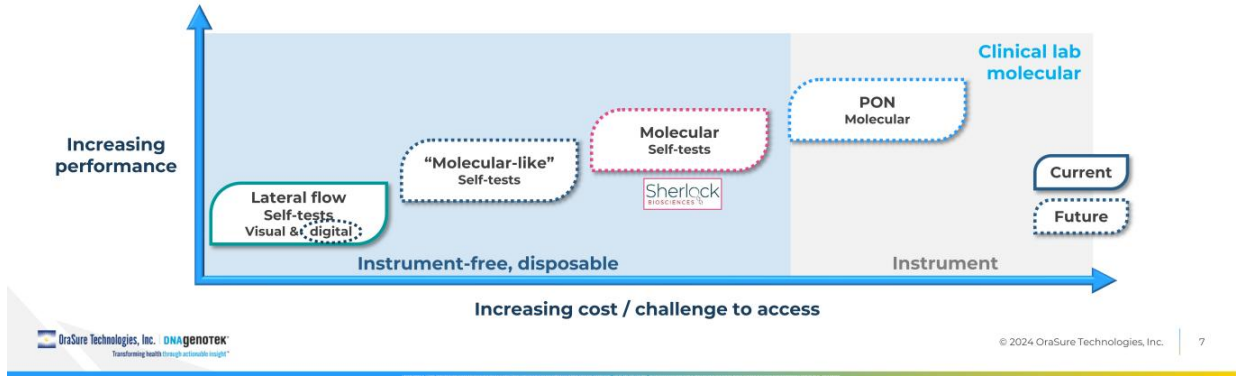
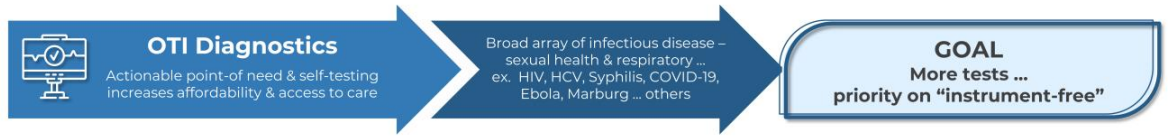
**More sample types, analytes & applications**  
... plus, value chain expansion

# Power the Industry with Infrastructure + Innovation



# OTI Portfolio – Diagnostics

Sherlock accelerates our innovation pipeline with next-gen molecular platform & new test expansion



# Sherlock Technology Platforms

Molecular testing to strengthen and broaden our diagnostic portfolio

## Sherlock Disposable Self-Test

(in clinical trial)

- Single-use, over-the-counter
- Easy to use at point-of-need
- Focused on STIs initially
- Flexibility to multiplex
- Platform for other swab-based assays



## Next-Gen Technologies

(in development)

Ambient  
Temperature  
Amplification

CRISPR  
Detection

# Sherlock Enables Entry into Large Addressable Markets while Leveraging OTI's Existing Strengths



## Attractive segments

CT/NG: \$1.5B & growing market<sup>1</sup>  
Patients desire privacy & speed  
for STI testing



## OTI strengths

Infrastructure & commercial reach  
Infectious disease portfolio breadth  
Sexual health expertise

# Revenue Growth from Sherlock Powered by NT Investments



## Growth potential

Clinical trial underway  
Anticipate submission to FDA  
by end of 2025



## Investments in innovation

Scale-up for launch  
Advance differentiated platform &  
pipeline of molecular tests

# Sherlock Enhances Key Elements for OTI's Long-Term Success

Key Elements	Sherlock Contributes
<b>Product portfolio &amp; pipeline</b>	<ul style="list-style-type: none"> <li>• CT/NG disposable Molecular self-test offers fast results, lab-like accuracy</li> <li>• Clinical trial for CT/NG test is on-going, OTI plans for FDA submission by end of 2025</li> <li>• Expanded test pipeline in development</li> </ul>
<b>Platform for the future</b>	<ul style="list-style-type: none"> <li>• Technology enables molecular performance in a rapid, low-cost, disposable format</li> <li>• Design is open to other swab-based assays, with ability to multiplex</li> <li>• Next-gen technologies in development: ambient temperature amplification, CRISPR</li> </ul>
<b>Commercial fit</b>	<ul style="list-style-type: none"> <li>• Access to Molecular Diagnostics platform in large, attractive markets</li> <li>• Addition of molecular CT/NG self-test expands OTI's portfolio of rapid diagnostics in sexual health</li> <li>• Leverages OTI's strengths, including in distribution &amp; customer relationships</li> </ul>
<b>Financials</b>	<ul style="list-style-type: none"> <li>• Expected to contribute to OTI's revenue growth following regulatory approval</li> <li>• Attractive purchase; majority of transaction consideration dependent on FDA approvals</li> </ul>
<b>Human capital &amp; culture</b>	<ul style="list-style-type: none"> <li>• Talented technical team with deep experience, expertise in research &amp; development</li> <li>• Adds new expertise &amp; capabilities in isothermal amplification technologies, fluidics, electronics &amp; CRISPR</li> </ul>







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#### OraSure Technologies Acquires Sherlock Biosciences

BETHLEHEM, PA, December 19, 2024 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. ("OTI") (NASDAQ: OSUR), a leader in point-of-need and home diagnostic tests and sample management solutions, today announced the acquisition of Sherlock Biosciences, Inc., a global health company bringing next-generation diagnostics to consumers and healthcare providers.

This acquisition expands OraSure's innovation pipeline with the addition of Sherlock's molecular diagnostics platform, which is able to provide rapid results with strong sensitivity and specificity in a disposable format that is well-suited for over-the-counter usage. Sherlock's first molecular self-test is for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG) which will expand OraSure's portfolio of rapid diagnostics for sexually transmitted infections (STIs), subject to regulatory approvals. Test results are expected to be provided in under 30 minutes by analyzing DNA and RNA from self-collected swabs using isothermal amplification. In addition, Sherlock has been developing a pipeline of other molecular tests, along with several next-generation technology platforms, including Ambient Temperature Amplification and CRISPR-based technologies that have the potential to further reduce costs and improve performance of its platforms.

Sherlock's CT/NG self-test is in clinical studies and is expected to be submitted to the FDA by the end of 2025 for review. Subject to regulatory approvals, revenue from Sherlock's CT/NG test is expected to contribute to OTI's growth beginning in 2026, benefiting from OraSure's existing infrastructure, commercial capabilities, and strong customer relationships.

OTI estimates that testing for CT/NG represents a total addressable market of more than \$1.5 billion. The vast majority of CT/NG tests in the U.S. are processed in a centralized lab, and the introduction of an affordable, rapid self-test has the potential to drive significant incremental market expansion. Additionally, public health channels play a key role in STI screening, which is an area where OraSure has a strong presence.

"The acquisition of Sherlock represents the next step in OTI's innovation strategy," said Carrie Eglinton Manner, President and CEO of OraSure. "Sherlock brings valuable capabilities with an advanced molecular platform that aims to deliver lab-like accuracy in a format that expands access to diagnostic insights through convenient, effortless tests. We are excited to welcome Sherlock's talented team to OTI and believe that Sherlock's unique capabilities will contribute significantly to the expansion of our pipeline of diagnostic tests in infectious disease, sexual health, and beyond."

**Conference Call Information**

OraSure will host a conference call to discuss the acquisition of Sherlock Biosciences at 5:00 p.m. ET on Thursday, Dec. 19, 2024. A webcast of the conference call will be available on the investor relations page of OraSure's website at <https://orasure.gcs-web.com/events-and-presentations>. Please click on the webcast link and follow the prompts for registration and access at least 10 minutes prior to the call. The webcast will be archived on OraSure's website shortly after the call has ended and will be available for approximately 90 days.

To participate in the live conference call, please follow the link below to pre-register. After registering, you will be provided with access details via email.

<https://register.vevent.com/register/B1b938f5bae2a442d9acdb83f4bdd9286d>

**About OraSure Technologies, Inc.**

OraSure Technologies, Inc. ("OraSure") transforms health through actionable insight and powers the shift that connects people to healthcare wherever they are. OraSure improves access, quality, and value of healthcare with innovation in effortless tests and sample management solutions. OraSure, together with its wholly-owned subsidiary, DNA Genotek Inc., is a leader in the development, manufacture, and distribution of rapid diagnostic tests and sample collection and stabilization devices designed to discover and detect critical medical conditions. OraSure's portfolio of products is sold globally to clinical laboratories, hospitals, physician's offices, clinics, public health and community-based organizations, research institutions, government agencies, pharmaceutical companies, and direct to consumers. For more information on OraSure Technologies, please visit [www.orasure.com](http://www.orasure.com).

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