

**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): May 29, 2020

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 5.02 – Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

New Director Appointment

On May 29, 2020, OraSure Technologies, Inc. (the “Company”) announced that Lelio Marmora has been appointed as a new member of the OraSure Technologies, Inc. Board of Directors (the “Board”), effective June 1, 2020. Mr. Marmora will serve as a Class III Director with an initial term expiring at the Company’s 2021 Annual Meeting of Stockholders. Mr. Marmora has also been appointed to serve on the Board’s Audit Committee and Nominating and Corporate Governance Committee.

Pursuant to the Company’s Non-Employee Director Compensation Policy (the “Policy”) and Stock Award Plan, Mr. Marmora was granted an initial equity award of time-vested restricted shares of the Company’s common stock having an aggregate value of \$100,000. The foregoing grant will vest two years following the grant date. Vesting will be accelerated in the event of a change in control involving the Company. Mr. Marmora will also receive fees and additional equity compensation pursuant to the Policy.

There are no arrangements or understandings between Mr. Marmora and any other person pursuant to which he was selected as a Director of the Company. Mr. Marmora does not have any familial relationship with any member of the Board or executive officer of the Company, and there are no transactions in which Mr. Marmora has an interest requiring disclosure under Item 404(a) of Regulation S-K.

A press release announcing Mr. Marmora’s appointment to the Board is attached as Exhibit 99.1 to this Report and is incorporated by reference herein.

Item 8.01 – Other Events.

On May 29, 2020, the Company announced that it has entered into a definitive agreement to purchase privately held UrSure, Inc. for cash. A press release announcing this acquisition is attached as Exhibit 99.2 to this Report and is incorporated by reference herein.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	<u>Press Release of OraSure Technologies, Inc., dated May 29, 2020, announcing the appointment of Lelio Marmora to the Company’s Board of Directors.</u>
99.2	<u>Press release of OraSure Technologies, Inc. dated May 29, 2020 announcing that the Company has entered into a definitive agreement to purchase UrSure, Inc.</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: May 29, 2020

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary



Investor Contact:
Sam Martin
Argot Partners
212-600-1902
orasure@argotpartners.com

Media Contact:
Jeanne Mell
VP Corporate Communications
484-353-1575
media@orasure.com

ORASURE TECHNOLOGIES APPOINTS LELIO MARMORA TO BOARD OF DIRECTORS

BETHLEHEM, PA, May 29, 2020 - OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point of care diagnostic tests, specimen collection devices, and microbiome laboratory and analytical services, today announced the appointment of Lelio Marmora as a member of the Company's Board of Directors effective June 1, 2020. Mr. Marmora, the former executive director of Unitaid, will serve as a Class III Director with an initial term expiring at the Company's 2021 Annual Meeting of Stockholders. He will also serve on the Audit Committee and Nominating and Corporate Governance Committee of the Board.

"Lelio's comprehensive understanding of the international health care arena, and his work with public private philanthropic partnerships will make him a valuable addition to OraSure's Board of Directors as we work to help solve the world's greatest healthcare challenges," said Stephen S. Tang, Ph.D., President and Chief Executive Officer of OraSure Technologies. "We are honored that he has agreed to serve on our Board and look forward to his impact on the Company as we continue to pursue our innovation growth strategy."

Mr. Marmora, age 53, has held substantial roles managing global health and modernization of large-scale state investments in complex political environments. He has also played senior strategic, operational and resource mobilization roles at headquarters levels in a range of international agencies. He is the former Executive Director of Unitaid in Geneva, Switzerland, from 2014 to 2020, overseeing a portfolio of \$1.5 billion in 100 countries. During his tenure, Unitaid tripled its portfolio, becoming one of the leading Global Health innovation initiatives. Prior to Unitaid, Mr. Marmora was Director for Africa and the Middle East at the Global Fund to Fight AIDS, TB and Malaria, overseeing a \$4 billion portfolio. He also served as head of the Fund's Latin America and the Caribbean Department. Earlier in his career, Mr. Marmora served in various capacities at a range of international organizations, including the World Bank, the Inter-American Development Bank and the United Nations Development Program, managing modernization of the State programs.

Mr. Marmora graduated from the Université Panthéon-Assas (Paris II) with a Master's degree in International Law and Administration of International Organizations.

About OraSure Technologies

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

conditions. OraSure's portfolio of products is sold globally to clinical laboratories, hospitals, physician's offices, clinics, public health and community-based organizations, research institutions, government agencies, pharma, commercial entities and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com.

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Company contacts:

Investors:

Samuel Martin
Argot Partners
212-600-1902
orasure@argotpartners.com

Media:

Jeanne Mell
VP Corporate Communications
484-353-1575
media@orasure.com

OraSure Technologies, Inc. Announces Purchase of UrSure, Inc.
Acquisition strengthens OraSure's leadership position in HIV field

Bethlehem, PA – May 29, 2020 – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point of care diagnostic tests and specimen collection and stabilization devices, and microbiome laboratory and analytical services, today announced that it has entered into a definitive agreement to acquire privately owned UrSure, Inc. (“UrSure”) for cash.

Based in Boston, UrSure is developing and commercializing products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV. This includes laboratory-based tests that can measure levels of the medication in a patient’s urine or blood, as well as several additional point of care products in development. These products will allow healthcare professionals to assess patient adherence and determine with accuracy if the medication has not been taken as prescribed. PrEP has been shown to be 99 percent effective at preventing HIV infection when taken daily, adding another tool to help ensure that patients stay healthy.

This transaction supports OraSure’s strategy of expanding its product offerings to include additional diagnostic products, particularly point-of-care tests that complement its current infectious disease portfolio and pipeline. OraSure has the first and only FDA-approved over-the-counter HIV rapid test which is currently being used in the federal government’s “Ending the HIV Epidemic: A Plan for America” initiative. The Company’s oral fluid self-test for HIV is the first and only WHO-prequalified oral fluid test used in developing countries to help end HIV transmissions. Importantly, adherence monitoring testing has the same call points for OraSure as HIV/HCV products in Public Health, hospitals and clinics, as well as global health segments.

“The addition of UrSure to OraSure’s portfolio complements our work with HIV diagnostics and strengthens OraSure’s position as a global leader among public-health focused diagnostic companies in the HIV field. We are now able to offer a product line that covers the spectrum from screening to treatment adherence. We are proud that we are working to end the HIV/AIDS epidemic by helping people know their HIV status, remain adherent and reduce the risk of HIV transmission.” said OraSure President and CEO, Stephen Tang, Ph.D. “This is a stellar example of how we are building on our existing expertise within the

field of infectious disease to offer our customers more value by providing access to accurate, essential information.”

Guidelines set by the Centers for Disease Control and Prevention (CDC) recommend PrEP adherence counseling but the current standard of care for adherence monitoring is self-report, which has been shown to be suboptimal at tracking objective patient adherence. In addition, treatment adherence has been identified as a significant need to ensure that goals for HIV eradication programs such as UNAIDS’ 90:90:90 and the Ending the HIV Epidemic are met. Accurate adherence monitoring is crucial because risk of HIV transmission is greater if patients do not take their PrEP or HIV treatment consistently. Testing and counseling lead to significant improvement in long-term adherence to PrEP and in attendance of follow-up visits to health care providers, ultimately reducing HIV transmission rates. Governments and payers are incentivized to ensure patients are adherent, given the high lifetime costs of a patient living with HIV. Current estimates project approximately 550,000 patients on PrEP globally by end of 2020 with more than 2 million by the end of 2024.

“UrSure was founded to develop novel diagnostics that support all patients on their HIV treatment and prevention medications. No company has more experience bringing innovative point of care tests to the public health market than OraSure, and we couldn’t be more excited to join their team.” said Giffin Daughtridge MD, MPA, UrSure, Inc.’s Co-founder and CEO.

Financial Considerations

The transaction will require an upfront cash payment of \$3 million and potential post-closing contingent consideration totaling up to an additional \$28 million. The contingent consideration consists of up to \$5 million for achievement of certain product development milestones and receipt of applicable regulatory approvals and up to \$23 million for achievement of certain revenue and funding milestones, in each case over a multi-year period. The Company intends to fund the purchase of UrSure with its existing cash balances. The transaction is subject to the satisfaction of customary closing conditions.

About OraSure Technologies

OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate, essential information. Together with its wholly-owned subsidiaries DNA Genotek, Diversigen, CoreBiome (now operating under the Diversigen brand) and Novosanis, OraSure provides its customers with end-to-end solutions that encompass tools, services and diagnostics. The OraSure family of companies is a leader in the development, manufacture, and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular services solutions designed to discover and detect critical medical conditions. OraSure’s portfolio of products is sold globally to clinical laboratories, hospitals, physician’s offices, clinics, public health and community-based organizations, research institutions, government agencies, pharma, commercial entities and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com.

About UrSure, Inc.

UrSure, Inc. was founded in 2015 by two physicians, who had started a clinic in Philadelphia and recognized that their patients were struggling to consistently take Truvada as PrEP, the medication that prevents HIV infection. In response, UrSure has developed a series of tests to measure and improve adherence to

medications for HIV prevention and treatment. To date, UrSure has received millions of dollars in NIH Small Business Innovation Research funding and commercialized the world's first test for PrEP and HIV treatment adherence, which is in use in clinics nationwide. For more information on UrSure, please visit www.ursureinc.com.

Important Information

This press release contains certain forward-looking statements, including 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 acquisitions of other companies 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; the expected economic benefits of 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 and our actual integration costs may exceed our estimates; impact of increased or different risks arising from the acquisition of companies located in foreign countries; ability to market and sell products, whether through our 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 our products; 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; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collector products and commercialize such products for COVID-19 testing; 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; ability to identify, complete, integrate and realize the full benefits of future acquisitions; 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 ("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; 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 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; 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, 2019, 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.

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