

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K/A  
(Amendment No. 1)**

(Mark One)

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

For the fiscal year ended December 31, 2019

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 001-16537

**ORASURE TECHNOLOGIES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

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

18015  
(Zip Code)

(610) 882-1820

(Registrant's Telephone Number, Including Area Code):

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

Title of Each Class  
Common Stock, \$0.000001 par value per share

Name of Each Exchange on Which Registered  
The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes  No

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes  No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging Growth Company	<input type="checkbox"/>

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.

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

State the aggregate market value of the voting and non-voting common equity held by nonaffiliates, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the Registrant's most recently completed second fiscal quarter (June 30, 2019): \$569,761,924

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of February 21, 2020: 62,002,705 shares.

**Documents Incorporated by Reference:**

Portions of the Registrant's Definitive Proxy Statement for the 2020 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report.

## Explanatory Note

The purpose of this Amendment No. 1 (this “Amendment”) to the annual report of OraSure Technologies, Inc. (the “Company”) on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission (“SEC”) on March 2, 2020 (the “Original Form 10-K”), is to amend the report of KPMG LLP (“KPMG”) on the Company’s consolidated financial statements to change a reference to the date of KPMG’s audit report on the effectiveness of the Company’s internal control over financial reporting from February 28, 2020 to March 2, 2020. Such change does not affect KPMG’s unqualified opinion on the Company’s financial statements included in the Original Form 10-K. An updated consent with the current date is filed herewith as an exhibit to this Amendment. Such consent has been corrected to include a sentence related to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases*, and to include a paragraph related to the exclusion of certain acquired companies from management’s assessment of the effectiveness of internal control and from KPMG’s audit of internal control over financial reporting.

No other changes have been made to the Original Form 10-K. This Amendment speaks as of the filing date of the Original Form 10-K, does not reflect events that may have occurred subsequent to the filing date, and does not modify or update in any way disclosures made in the Original Form 10-K, except as set forth above. This Amendment should be read in conjunction with the Original Form 10-K and the Company’s other filings made with the SEC subsequent to the filing of the Original Form 10-K.

As required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by the Company’s Chief Executive Officer and Chief Financial Officer are also filed herewith as exhibits to this Amendment.

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### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors  
OraSure Technologies, Inc.:

#### *Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheets of OraSure Technologies, Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of income, comprehensive income, stockholders’ equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company’s internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 2, 2020 expressed an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting.

#### *Change in Accounting Principle*

As discussed in Note 10 to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update No. 2016-02, *Leases*.

#### *Basis for Opinion*

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting

firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

#### *Critical Audit Matters*

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

##### *Assessment of the acquisition-date fair value of developed technology*

As discussed in Note 3 to the consolidated financial statements, the Company acquired a business in January 2019. As a result of this transaction, the Company acquired a developed technology intangible asset. The acquisition date fair value of the developed technology was \$5.0 million. The purchase price of the business combination was allocated to the assets acquired and liabilities assumed, in each case based on estimates of their respective fair values at the acquisition date. Fair values of intangible assets are estimated using valuation models prepared by the Company with the assistance of third-party specialists.

We identified the assessment of the acquisition-date fair value of the developed technology for the business acquisition as a critical audit matter. Assessing the estimated fair value of the developed technology resulted in the application of a high degree of auditor judgment. The revenue growth rates and the discount rate used to determine the fair value of the developed technology were challenging to evaluate as there was limited observable market information and minor changes to those assumptions could have a significant effect on the acquisition-date fair value of the intangible asset.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's business combinations process, including controls related to the determination of the fair value of the acquired intangible assets and the related revenue growth rates and the discount rate. We evaluated the Company's projected revenue growth rates for the developed technology by comparing the growth assumptions to historical growth rates of comparable products. We compared the acquired business' forecasted revenue growth rates to their actual historical results. In addition, we involved a valuation professional with specialized skill and knowledge, who assisted in:

- evaluating the Company's discount rate, by comparing it against a discount rate range that was independently developed using publicly available market data; and
- developing an estimate of the developed technology fair value using the Company's cash flow forecast for the developed technology and an independently developed discount rate, and compared the results of our estimate to the Company's fair value estimate.

##### *Evaluation of net realizable value adjustments to inventories for excess or obsolescence*

As discussed in Notes 2 and 5 to the consolidated financial statements, the Company has inventories with a carrying value of \$23.2 million as of December 31, 2019. Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. The majority of the inventories are subject to expiration dating, which can be extended in certain circumstances. The Company continually evaluates quantities on hand and the carrying value of inventories to determine the need for net realizable value adjustments for excess and obsolete inventories, based on prior experience as well as forecasts of product sales.

We identified the evaluation of net realizable value adjustments to inventories for excess or obsolescence as a critical audit matter. The Company's estimates regarding forecasted sales and the resulting inventory consumption and considerations related to the ability to extend inventory expiration dates result in the application of a high degree of auditor judgment.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's process for determining net realizable value adjustments for inventory excess or obsolescence. We evaluated historic write-off activity as compared to total inventories. For a selection of inventory items, we compared the Company's historic estimates of net realizable value adjustments for excess and obsolescence to the actual physical inventory disposals to evaluate the Company's ability to accurately estimate the net realizable value adjustments. We evaluated the Company's ability to forecast sales by comparing prior period sales forecasts to actual results. In addition, we selected inventory items from the underlying data used in the Company's analysis, and evaluated the Company's determination of net realizable value adjustments for those items using historic inventory consumption, the expiration date of certain on-hand inventory items and the ability to extend expiration dates.

/s/ KPMG LLP

We have served as the Company's auditor since 2002.

Philadelphia, Pennsylvania

March 2, 2020

#### **ITEM 15. Exhibits**

The following exhibits are filed as part of this Amendment.

Exhibit Number	Exhibit
23	<a href="#"><u>Consent of KPMG LLP.</u></a>
31.1	<a href="#"><u>Certification of Stephen S. Tang, Ph.D. required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.</u></a>
31.2	<a href="#"><u>Certification of Roberto Cuca required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.</u></a>
32.1	<a href="#"><u>Certification of Stephen S. Tang, Ph.D. required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
32.2	<a href="#"><u>Certification of Roberto Cuca required by Rule 13a-14(b) or Rule 15a-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 5, 2020.

ORASURE TECHNOLOGIES, INC.

By: /s/ Stephen S. Tang  
Stephen S. Tang, Ph.D.  
President and Chief Executive Officer

**Consent of Independent Registered Public Accounting Firm**

The Board of Directors  
OraSure Technologies, Inc.:

We consent to the incorporation by reference in the registration statements on Form S-3 (No. 333-228877) and Form S-8 (No. 333-220148, No. 333-118385, No. 333-102235, No. 333-50340, No. 333-48662, No. 333-138814, No. 333-151077, No. 333-176315 and No. 333-198237) of OraSure Technologies, Inc. of our reports dated March 2, 2020, with respect to the consolidated balance sheets of OraSure Technologies, Inc. as of December 31, 2019 and 2018, and the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes, and the effectiveness of internal control over financial reporting as of December 31, 2019, which reports appear in the December 31, 2019 annual report on Form 10-K of OraSure Technologies, Inc.

Our report on the consolidated financial statements refers to a change in the accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases*.

Our report dated March 2, 2020, on the effectiveness of internal control over financial reporting as of December 31, 2019, contains an explanatory paragraph that states that the Company acquired CoreBiome, Inc., Novosanis NV, and Diversigen, Inc. (collectively, the "Acquired Companies") during 2019, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2019, the Acquired Companies' internal control over financial reporting associated with 11.7% of total assets and 4.0% of total revenues included in the consolidated financial statements of the Company as of and for the year ended December 31, 2019. Our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of the Acquired Companies.

/s/ KPMG LLP

Philadelphia, Pennsylvania  
March 5, 2020

**Certification**

I, Stephen S. Tang, Ph.D., certify that:

1. I have reviewed this annual report on Form 10-K, as amended by the Amendment No. 1 (the “report”), of OraSure Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a – 15(e) and 15d –15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a – 15(f) and 15d – 15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 5, 2020

/s/ Stephen S. Tang  
Stephen S. Tang, Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

Certification

I, Roberto Cuca, certify that:

1. I have reviewed this annual report on Form 10-K, as amended by the Amendment No. 1 (the “report”), of OraSure Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a – 15(e) and 15d –15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a – 15(f) and 15d – 15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 5, 2020

/s/ Roberto Cuca  
Roberto Cuca  
Chief Financial Officer  
(Principal Financial Officer)



**CERTIFICATION PURSUANT TO  
18 U.S.C. §1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Amendment No. 1 to the Annual Report of OraSure Technologies, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 (as amended, the "Report") as filed with the Securities and Exchange Commission on the date hereof, I, Stephen S. Tang, Ph.D., President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

*/s/ Stephen S. Tang*

Stephen S. Tang, Ph.D.

President and Chief Executive Officer

March 5, 2020

**CERTIFICATION PURSUANT TO**

**18 U.S.C. §1350,**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Amendment No. 1 to the Annual Report of OraSure Technologies, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 (as amended, the "Report") as filed with the Securities and Exchange Commission on the date hereof, I, Roberto Cuca, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

*/s/Roberto Cuca*

Roberto Cuca

Chief Financial Officer

March 5, 2020