

ORASURE TECHNOLOGIES INC
Form 10-K/A
June 07, 2018
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, 2017

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

36-4370966

(I.R.S. Employer Identification No.)

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Incorporation or Organization)

220 East First Street 18015

Bethlehem, Pennsylvania (Zip Code)

(Address of Principal Executive Offices)

(Registrant's Telephone Number, Including Area Code): (610) 882 1820

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

| Title of Each Class | Name of Each Exchange on Which Registered |
|--|---|
| Common Stock, \$0.000001 par value per share | 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 and posted on its corporate Web

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site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 Accelerated filer

Non-accelerated filer Smaller reporting company

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.

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, 2017): \$1,010,050,592

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of February 23, 2018: 60,966,866 shares.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement for the 2018 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report.

Explanatory Note

The purpose of this Amendment No. 1 on Form 10-K/A (this “Amendment”) to the OraSure Technologies, Inc. (the “Company”) Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission (“SEC”) on February 28, 2018 (the “Form 10-K”), is to (i) update the opinion of KPMG LLP on internal control over financial reporting set forth in Part II, Item 9A(d) to include a previously omitted sentence (specifically, “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.”), include paragraph headers and reorder the paragraphs in accordance with the standards of the Public Company Accounting Oversight Board, and (ii) to move the Exhibit Index to Part IV, Item 15 so that it is located before the signature page.

No other changes have been made to any of the disclosures in the Form 10-K. In particular, no change has been made to KPMG LLP’s opinion that the Company and its subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. This Amendment speaks as of the original filing date of the Form 10-K, does not reflect events that may have occurred subsequent to the original filing date, and does not modify or update in any way disclosures made in the Form 10-K, except as set forth above. This Amendment should be read in conjunction with the Form 10-K and our other filings made with the SEC subsequent to the filing of the Form 10-K.

As required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, a currently dated consent from KPMG LLP and currently-dated certifications from the Company’s Chief Executive Officer and Chief Financial Officer have also been included as exhibits to this Amendment.

ITEM 9A.Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures.

The Company’s management, with the participation of the Company’s Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of December 31, 2017. Based on that evaluation, the Company’s management, including such officers, concluded that as of December 31, 2017 the Company’s disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to the Company’s management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Management's Report on Internal Control Over Financial Reporting.

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Under the supervision and with the participation of the Company's management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework, our management concluded that our internal control over financial reporting was effective 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 as of December 31, 2017.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may

deteriorate.

The effectiveness of our internal control over financial reporting as of December 31, 2017 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report, which is included below.

(c) Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(d) Report of Independent Registered Public Accounting Firm.

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

Opinion on Internal Control Over Financial Reporting

We have audited OraSure Technologies, Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2017 and 2016, 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, 2017, and the related notes (collectively, the consolidated financial statements), and our report dated February 28, 2018 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG, LLP

Philadelphia, Pennsylvania

February 28, 2018

ITEM 15. Exhibits and Consolidated Financial Statement Schedules.

(a)(1) and (a)(2). Consolidated Financial Statements and Schedules. For a list of the consolidated financial statements filed herewith, see the Index to Consolidated Financial Statements following the signature page to this Annual Report. No Schedules are included with the consolidated financial statements because the required information is inapplicable or is presented in the consolidated financial statements or related notes thereto.

(a)(3). Exhibits.

INDEX TO EXHIBITS

Exhibit
Number

Exhibit

- 3.1.1 Certificate of Incorporation of OraSure Technologies, Inc. is incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
- 3.1.2 Certificate of Amendment to Certificate of Incorporation dated May 23, 2000 is incorporated by reference to Exhibit 3.1.1 to the Company's Registration Statement on Form S-4 (No. 333-39210), filed June 14, 2000.
- 3.2 Bylaws of OraSure Technologies, Inc., as amended and restated as of February 19, 2018.**
- 10.1 Employment Agreement dated as of January 3, 2018, between OraSure Technologies, Inc. and Stephen S. Tang, Ph.D., is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 4, 2018.*
- 10.2 Employment Agreement, dated as of June 22, 2004, between OraSure Technologies, Inc. and Douglas A. Michels, is incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
- 10.3 Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Douglas A. Michels, is incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 19, 2008.*
- 10.4 Amendment No. 2 to Employment Agreement, dated as of December 15, 2010, between the Company and Douglas A. Michels, is incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
- 10.5 Amendment No. 3 to Employment Agreement, dated as of March 27, 2015, between the Company and Douglas A. Michels is incorporated by reference to Exhibit 99.1 to the Company's current Report on Form 8-K filed March 31, 2015.*
- 10.6 Retirement Agreement, dated as of January 3, 2018 between OraSure Technologies, Inc. and Douglas A. Michels, is incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 4, 2018.*
- 10.7 Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and Ronald H. Spair, is incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*
- 10.8 Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Ronald H. Spair, is incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed December 19, 2008.*
- 10.9 Amendment No. 2 to the Employment Agreement, dated as of December 15, 2010, between the Company and Ronald H. Spair, is incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
- 10.10 Amendment No. 3 to Employment Agreement, dated as of March 27, 2015, between the Company and Ronald H. Spair is incorporated by reference to Exhibit 99.2 to the Company's current Report on Form 8-K filed March 31, 2015.*
- 10.11 Retirement Agreement dated as of January 31, 2018, between OraSure Technologies, Inc. and Ronald H. Spair is incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 2, 2018.*
- 10.12 Employment Agreement, dated as of July 1, 2004, between OraSure Technologies, Inc. and Jack E. Jerrett, is incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.*

- 10.13 Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Jack E. Jerrett, is incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed December 19, 2008.*
 - 10.14 Amendment No. 2 to the Employment Agreement, dated as of December 15, 2010, between the Company and Jack E. Jerrett, is incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
 - 10.15 Amendment No. 3 to Employment Agreement, dated as of March 27, 2015, between the Company and Jack E. Jerrett is incorporated by reference to Exhibit 99.3 to the Company's current Report on Form 8-K filed March 31, 2015.*
 - 10.16 Employment Agreement, dated as of October 2, 2006, between Mark L. Kuna and OraSure Technologies, Inc., is incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed October 5, 2006.*
 - 10.17 Amendment No. 1 to Employment Agreement, dated as of December 16, 2008, between the Company and Mark L. Kuna, is incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed December 19, 2008.*
 - 10.18 Amendment No. 2 to the Employment Agreement, dated as of December 15, 2010, between the Company and Mark L. Kuna, is incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
 - 10.19 Amendment No. 3 to Employment Agreement, dated as of March 27, 2015, between the Company and Mark L. Kuna is incorporated by reference to Exhibit 99.4 to the Company's current Report on Form 8-K filed March 31, 2015.*
 - 10.20 Employment Agreement, dated as of January 3, 2011, between the Company and Anthony Zezzo II is incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K for the year ended December 31, 2010.*
 - 10.21 Terms of Employment for Michael Reed, Senior Vice President and Chief Science Officer for OraSure Technologies, Inc., is incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016.*
 - 10.22 Employment Agreement, dated as of January 7, 2008, between DNA Genotek, Inc. and Brian Smith, as amended July 25, 2011 and June 16, 2016, is incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016.*
 - 10.23 Description of Non-Employee Director Compensation Policy, as amended, is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 24, 2017.*
 - 10.24 Amended and Restated Epitope, Inc. 1991 Stock Award Plan is incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002.*
OraSure Technologies, Inc. Employee Incentive and Non-Qualified Stock Option Plan, as amended and restated
 - 10.25 effective September 29, 2000, is incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*
 - 10.26 Amended and Restated OraSure Technologies, Inc. Stock Award Plan, effective February 21, 2017, is incorporated by reference to Exhibit A to the Company's Proxy Statement, filed April 5, 2017, for the 2017 Annual Meeting of Stockholders.*
 - 10.27 Form of Restricted Share Award Agreement (Executive Officers – Employment Agreements) is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015.*
 - 10.28 Form of Restricted Unit Award Agreement (Executive Officers – Employment Agreements) is incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016.*
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- 10.29 Form of Restricted Share Grant Agreement (Non-Employee Directors) is incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
 - 10.30 Nonqualified Stock Option Award General Terms and Conditions (Executive Officers) is incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
 - 10.31 Nonqualified Stock Option Award General Terms and Conditions (Non-Employee Directors) is incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011.*
 - 10.32 Description of the OraSure Technologies, Inc. 2017 Management Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 24, 2017.*
 - 10.33 Description of the OraSure Technologies, Inc. 2017 Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed May 19, 2017*.
 - 10.34 Description of the OraSure Technologies, Inc. 2018 Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 22, 2018.*
 - 10.35 Description of Amended Long-Term Incentive Policy is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed May 14, 2015.*
 - 10.36 Description of Long-Term Incentive Policy, as amended, is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-K filed February 24, 2017.*
 - 10.37 OraSure Technologies, Inc. Deferred Compensation Plan is incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed December 21, 2011.*
 - 10.38 Adoption Agreement related to OraSure Technologies, Inc. Deferred Compensation Plan is incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed December 21, 2011.*
 - 10.39 Credit Agreement, between Wells Fargo Bank, National Association, and OraSure Technologies, Inc., is incorporated by reference to Exhibit 10 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.
 - 10.40 First Amendment to Credit Agreement, dated as of December 20, 2017, by and among OraSure Technologies, Inc., Wells Fargo Bank, National Association, and the Lending Parties thereto, is incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-k filed December 21, 2017.
 - 21 Subsidiaries of the Company are incorporated by reference to Exhibit 21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013.
 - 23 Consent of KPMG LLP.***
 - 24 Powers of Attorney.**
 - 31.1 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.***
 - 31.2 Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.***
 - 32.1 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.***
 - 32.2 Certification of Ronald H. Spair 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.***
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101.INSXBRL Instance Document**

101.SCHXBRL Taxonomy Extension Schema Document**

101.CALXBRL Taxonomy Extension Calculation Linkbase Document**

101.DEFBRL Taxonomy Extension Definition Linkbase Document**

101.LABXBRL Taxonomy Extension Label Linkbase Document**

101.PREXBRL Taxonomy Extension Presentation Linkbase document**

* Management contract or compensatory plan or arrangement.

** Previously filed with the 10-K filed on February 28, 2018.

*** Filed with this Amendment

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 June 7, 2018.

ORASURE TECHNOLOGIES, INC

By:/s/ Stephen S. Tang

Stephen S. Tang, Ph.D.

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on June 7, 2018, by the following persons on behalf of the Registrant and in the capacities indicated.

| SIGNATURE | TITLE |
|------------------------|---|
| /s/ Stephen S. Tang | President, Chief Executive Officer and Director |
| Stephen S. Tang, Ph.D. | (Principal Executive Officer) |
| /s/ Ronald H. Spair | Chief Operating Officer, Chief Financial Officer and Director |
| Ronald H. Spair | (Principal Financial Officer) |
| /s/ Mark L. Kuna | Senior Vice President, Finance and Controller |
| Mark L. Kuna | (Principal Accounting Officer) |
| *MARA ASPINALL | Director |

Mara Aspinall

*MICHAEL CELANO Director

Michael Celano

*EAMONN P. HOBBS Director

Eamonn P. Hobbs

*RONNY B. LANCASTER Director

Ronny B. Lancaster

*CHARLES W. PATRICK Director

Charles W. Patrick

*ARADHANA SARIN Director

Aradhana Sarin

*By: /s/ Jack E. Jerrett

Jack E. Jerrett

(Attorney-in-Fact)