

October 29, 2015

# **VIA EDGAR**

Mr. Martin James
Senior Assistant Chief Accountant, Office of Electronics and Machinery
U.S. Securities and Exchange Commission
Division of Corporation Finance
Mailstop 3030
Washington, D.C. 20549

Re: OraSure Technologies, Inc. (the "Company")
Form 10-K for the fiscal year ended December 31, 2014
Filed March 12, 2015
File No. 001-16537

Dear Mr. James:

This letter responds to the comments of the staff ("Staff") of the Division of Corporation Finance of the Securities and Exchange Commission (the "Commission") contained in your letter dated September 30, 2015 with respect to the above-referenced Form 10-K for the fiscal year ended December 31, 2014. Below we have reprinted these comments in bold, followed by our responses.

## Staff Comment 1:

We note that you reduce your revenues from the OraQuick® In-Home HIV test for customer allowances for cooperative advertising, discounts, rebates and chargebacks. Please describe to us the significant terms and conditions of these programs and how you account for these programs under ASC 605-50 and any other applicable authoritative literature. Also address how you determined the proper income statement classification for each program under ASC 605-50-45.

#### **Company Response:**

We began selling our OraQuick® In-Home HIV test in 2012, primarily through the three largest US retail pharmacy chains. This product is the first and only rapid HIV test available for sale directly to consumers in the over-the-counter market. We have executed sales agreements with each of our retail-trade customers which provide for trade allowances for cooperative advertising, discounts, rebates or chargebacks. Each of the sales agreements requires the Company to provide these customers with a fixed percentage trade allowance based upon the dollar-value of their individual purchases. Each customer agreement defines this allowance differently, either as a chargeback or allowance for cooperative advertising, and each customer deducts this allowance from the Company's invoice upon payment. Our initial sales agreements were for a one-year term, with annual renewal options. There is no firm commitment on behalf of the retail trade customers to provide the Company with any form of benefit in exchange for their allowance percentage, nor does the customer have any minimum purchase volume

220 East First Street, Bethlehem, PA 18015-1360 Phone: 610.882.1820 ● Fax: 610.882.2275 www.orasure.com commitment to the Company. Additionally, the Company does not receive, nor is it entitled to receive, any documentation or information pertaining to any instore advertising which the customer may elect to provide.

We have considered the guidance provided in Financial Accounting Standards Board's Accounting Standards Codification ("ASC") 605-50, Revenue Recognition, Customer Payments and Incentives, as well as the presentation guidance provided in ASC 605-50-45, Other Presentation Matters. In accordance with the general rule set forth in ASC 605-50-45-2, we have concluded that the cash consideration which the Company is giving to its retail trade customers in the form of trade allowances represents a reduction in the selling price of our product and therefore should be characterized as a reduction of revenue when recognized in the Company's income statement. We based this conclusion on the fact that the allowance is linked to a single sales transaction (multiple sales transactions are not required in order for the customer to receive the consideration) and the Company does not receive, nor will it receive, any identifiable benefit (goods or services) in exchange for the allowance given to the customer.

# Staff Comment 2:

We note that in connection with your Master Program Services and Co-Promotion Agreement with AbbVie Bahamas Ltd., you are eligible to receive up to \$75 million in exchange for exclusive rights and other services. We further note that you are recognizing the \$75 million ratably on a monthly basis over the life of the agreement. Please address the following:

- Describe the "other services" you must provide under the agreement and explain how the performance of these services impacted your revenue recognition.
- Explain to us any conditions that must be met in order to receive the full \$75 million.
- Explain to us how you determined that it is appropriate to recognize the full \$75 million over the term of the agreement.
- Tell us the payment terms for the \$75 million.

### **Company Response:**

Under the terms of the Master Program Services and Co-Promotion Agreement (the "Agreement") with AbbVie Bahamas Ltd. ("AbbVie"), the Company is required to design, develop, implement, and administer a proprietary patient care database (the "Patient Care Database"). This Patient Care Database, which is being compiled by the Company over the term of the Agreement, is used to collect information related to individuals who test positive for Hepatitis C ("HCV"), in certain US markets, with the Company's OraQuick® HCV Rapid Antibody Test (the "OraQuick® HCV Test"). The Company is responsible for selling the OraQuick® HCV Test into these markets. AbbVie does not purchase any devices from the Company, nor is it eligible to receive any royalty or payment related to units sold by the Company. Individuals who are enrolled in the Patient Care Database can choose to opt into a patient care model, in which they will receive community outreach services related to HCV education, testing, diagnosis and treatment needs directly from AbbVie or AbbVie's vendor (the "Care Model"). The Company is required to maintain the security of the Patient Care Database and the patient information contained therein, and to provide ongoing training to representatives of AbbVie on access to and use of the database. The Company is also obligated to obtain completed consent and heath care marketing authorization forms from individuals who enroll in the Patient Care Database. The Company is required to provide AbbVie or its representatives with ongoing training on the use of the Company's

OraQuick® HCV Test, and to participate in current and future co-promotion activities for certain target markets in the United States in order to effectuate enrollment into the Patient Care Database.

During the term of the Agreement, the Company is required to develop and establish the Patient Care Database on behalf of, and for the sole and exclusive benefit of, AbbVie. The Agreement specifically grants AbbVie exclusive rights with respect to the Patient Care Database, as it is created by the Company. The term of the Agreement commenced on June 10, 2014 and will continue until December 31, 2019, unless terminated sooner in accordance with its terms.

The Agreement also requires that AbbVie, among other things, utilize commercially reasonable efforts to co-promote the OraQuick® HCV Test in certain US markets and to make the Care Model available to patients in those markets. If, during the term of the Agreement, the Company decides to commercialize a future product other than the OraQuick® HCV Test for the point-of-care detection of HCV antibodies in humans, AbbVie shall have a right of first refusal to co-promote that future product in the markets covered by the Agreement ("Right of First Refusal").

In consideration for the design and development of the Patient Care Database, the exclusive rights granted to AbbVie therein, and the Right of First Refusal, AbbVie is required to pay the Company an aggregate fee of \$75 million (the "Database Establishment, Ownership and Exclusivity Fee"), subject to the terms of the Agreement. The Agreement provides that the Database Establishment, Ownership and Exclusivity Fee shall accrue and be earned ratably on a daily basis (and recorded monthly) by the Company during the period from the June 10, 2014 effective date of the Agreement through the end of the term of the Agreement on December 31, 2019. The Database Establishment, Ownership and Exclusivity Fee is non-refundable, non-creditable and not subject to setoff, except where the Agreement is terminated prior to the end of its term by the Company for convenience or by AbbVie as a result of a material breach by the Company, in which case AbbVie is entitled to receive a refund of the amount, if any, of the Database, Establishment, Ownership, and Exclusivity Fees which has been paid to the Company but which is unearned by the Company at the date of termination, as defined in the Agreement. If the Agreement is terminated prior to the end of its term in accordance with its terms (including by either party for material breach, for convenience on or after December 31, 2016, on account of the insolvency of the other party or, in certain circumstances, by AbbVie as a result of the Company's change of control), AbbVie shall no longer be obligated to make any future payments of the Database Establishment, Ownership and Exclusivity Fee and may pay less than the full Fee.

The foregoing describes certain terms of the Agreement and is qualified by reference to the entire Agreement.

We have applied the guidance provided in ASC 605, Revenue Recognition. We believe the Company's performance obligation under the Agreement is to transfer to AbbVie a series of services and rights that are substantially the same and have the same pattern of transfer over the same duration, namely the term of the Agreement ending on December 31, 2019. These services and rights consist of the development, compilation, and ongoing maintenance of the Patient Care Database for the exclusive use of AbbVie and the ongoing availability of the Right of First Refusal. We believe these services and rights represent a single-unit of accounting because they do not have value to AbbVie on a standalone basis. As such, we have allocated all of the Agreement consideration to this single unit of accounting. We have concluded that the Company satisfies its performance obligation by creating the Patient Care Database over the term of the Agreement. Given that the Company's performance obligation is ongoing and extends through December 31, 2019, and there are no other conditions to receipt of the Database Establishment, Ownership and Exclusivity Fee, including no minimum number of individuals that must be enrolled into the Patient Care Database, we believe it is appropriate to recognize the \$75 million aggregate fee ratably on a monthly basis over the life of the Agreement. Other than the Company's ongoing performance, and so long as the Agreement is not terminated early in accordance with its terms,

there are no other conditions which must be met in order for the Company to receive the full \$75 million under the terms of the Agreement.

We concluded that it is appropriate to recognize the full \$75 million over the term of the Agreement. The Company believes the \$75 million represents the fixed amount of consideration which the Company is entitled to receive in exchange for transferring the promised services and rights to AbbVie. The Agreement also provides for additional variable consideration payable upon the achievement of certain performance-based milestones based on the number of HCV positive patients enrolled in the Patient Care Database in a contract year. However, since the Company does not have any historical experience in achieving the type of performance-based milestones contained in the Agreement, the Company concluded that it is appropriate to include no variable compensation in the measurement of overall contract consideration.

Regarding the payment terms associated with the \$75 million, an initial payment of \$15 million was received from AbbVie within 30 days following the signing of the Agreement in June 2014. Pursuant to the Agreement, the remaining \$60 million is scheduled to be paid in a series of payments that result in equivalent amounts of fixed compensation being paid in each contract year. As a result, the Company initially records the cash payments received from AbbVie as deferred revenue and then recognizes the aggregate \$75 million ratably on a monthly basis as it satisfies its performance obligation over the term of the Agreement. Based upon the timing of the payments in each year, the risk of any future revenue reversal is non-existent because the aggregate cash received from AbbVie will equal or exceed any time-based revenue recognition for the Database Establishment, Ownership and Exclusivity Fee. As noted, these cash payments are non-refundable, non-creditable, and not subject to setoff except in very limited circumstances, which are within the Company's control and not likely to occur.

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In connection with the foregoing responses, the Company acknowledges that (i) the Company is responsible for the adequacy and accuracy of the disclosure in its filings; (ii) Staff comments or changes to disclosure in response to Staff comments do not foreclose the Commission from taking any action with respect to the filing; and (iii) the Company may not assert Staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please do not hesitate to contact the undersigned (610-882-1820, ext. 1477) if you have any questions or if we can provide any further information that would be helpful to the Staff.

Sincerely,

/s/ Mark L. Kuna

Mark L. Kuna Senior Vice President, Finance and Controller (Principal Accounting Officer)

cc: D. Michels, President and Chief Executive Officer

- R. Spair, Chief Operating Officer and Chief Financial Officer
- J. Jerrett, Senior Vice President, General Counsel and Secretary
- M. Celano, Chairman, Audit Committee
- J. Kalinowski, KPMG LLP