[*Confidential Treatment Requested by OraSure Technologies, Inc.]

September 29, 2009

Transmitted Via
EDGAR and Facsimile

Ms. Julie Sherman
Reviewing Accountant
Securities and Exchange Commission
Division of Corporation Finance
450 Fifth Street, N.W.
Washington, D.C. 20549

Re: OraSure Technologies, Inc. (the "Company")
Form 10-K for the Year Ended December 31, 2008
("10-K Report") SEC File No. 1-16537

Dear Ms. Sherman:

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 August 31, 2009 (the "Comment Letter") with respect to the above-referenced 10-K Report. Below we have reprinted these comments in bold, followed by our responses.

Comment 1 (Supply and Manufacturing, p.12)

Staff Comment:

It appears that upon termination of your agreement with BMX you purchased a two-year supply of HIV antigen required to manufacture the Western blot test. In your disclosure, you indicate that your current supply will be sufficient for at least the next several years. Please confirm that you will provide in future filings a more specific estimate as to when you will exhaust your reserves. Alternatively, please tell us why you believe that this information is not material. For instance, if you have made or anticipate being able to make alternative arrangements, please clearly disclose in future filings.

Company Response:

Supplementally, the Company advises the Staff that since the filing of the 10-K Report, the Company has made arrangements to purchase HIV-1 antigen from a subcontractor that had historically been used by BMX to manufacture this product for resale by BMX to the Company. The Company intends to negotiate a long-term supply contract with this party in the near future.

Consequently, we believe the remaining inventory level following termination of the BMX contract, as described in the 10-K Report, is no longer material or relevant to investors. The Company's future filings will describe the status of this alternate source of HIV-1 antigen supply.

Comment 2 (Domestic Regulations, p.17)

Staff Comment:

Refer to the penultimate paragraph of this section. With a view toward disclosure in future filings, please explain more fully the significance of the waivers you have acquired. Do the waivers apply to your laboratories or those of your customers or both? Are the waivers subject to certain restrictions? Can they expire? Please clarify.

Company Response:

We assume this comment refers to the discussion of the waiver for two of our products (i.e., the OraQuick *ADVANCE*® HIV test and Q.E.D.® rapid alcohol test) under the Clinical Laboratory Improvements Amendments of 1988 ("CLIA"), which appears at the top of page 18 of the 10-K Report. We will clarify in the Company's future filings that a CLIA waiver is issued for particular tests that meet certain requirements established by the statute and related regulations (*i.e.*, tests that employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible or pose no reasonable risk of harm to the patient if the test is performed incorrectly). A CLIA waiver does not expire. A CLIA waiver is important in that it expands the number of customers that can potentially use such a product beyond CLIA-certified laboratories to include both laboratories and non-laboratories that have not complied with the quality control, training and other requirements under CLIA.

The CLIA waiver related to our OraQuick *ADVANCE*® test has had a significant impact on the Company, and is fully discussed on page 4 of the 10-K Report. Sales of our OraQuick® test accounted for $35.3 million, or approximately 50% of our total revenues for 2008. As noted on page 4 of the 10-K Report, we received a CLIA waiver for the use of this test with oral fluid and fingerstick and venous whole blood. In the absence of a CLIA waiver, this test would be available for use by approximately 40,000 locations in the U.S. that are certified under CLIA to perform moderately complex tests. However, as a result of the receipt of a CLIA waiver, the test can also be used by approximately 140,000 additional sites in the U.S. not certified under CLIA to perform moderately complex tests. This would include non-laboratory customers such as outreach clinics, community-based organizations and physicians' offices. We believe the discussion on pages 4 and 18 of the 10-K Report adequately describes the significance of the CLIA waiver obtained for our OraQuick *ADVANCE*® HIV test.

Our Q.E.D. ® test accounted for $1.3 million, or only approximately 1.8%, of our total 2008 revenues. Although we believe the receipt of a CLIA waiver has also expanded the customer base that can potentially use this product, given the relatively small amount of revenue

generated by the Q.E.D.® product line, we do not believe further discussion of this issue is material or useful for investors.

Subject to the clarification described above, we believe there is adequate disclosure in the 10-K Report regarding the significance of the CLIA waivers.

Comment 3 (The Unavailability of Certain Products Distributed by a Third-Party, p. 26)

Staff Comment:

We note your disclosure that BMX sold the only oral fluid HIV-1 EIA screening test. In future filings, please revise to disclose more prominently that, in BMX's absence, you will be forced to conduct clinical trial and seek FDA approval for an alternative test. In addition, please expand this risk factor to discuss more fully the risk that you may not receive FDA approval.

Company Response:

[*A01] Our future filings will describe this recent change in circumstances and indicate that the previously disclosed clinical trials will not be required.

Comment 4 (Financial Statements - Note 8. Income Taxes, p. F-17)

Staff Comment:

We note that you recorded the valuation allowance of $25,978,167, which is equal to 100% of your deferred tax assets. You disclosed that "Given the uncertainty surrounding the magnitude and length of the current economic condition, [your] loss in 2008, and [your] *projection of a loss in 2009*, [you] determined that it is more likely than not [you] will not realize the benefits associated with [your] net deferred tax assets in the *immediate* future. We note approximately $17 Million out of your approximately $26 Million deferred tax assets is net operating loss carry forwards, net of tax effect. While we note your discussion about your valuation allowance in your Critical Accounting Estimates, it is still not clear to us how you determined that the entire balance of the deferred tax asset should have been reserved when approximately 88% out of your total federal net operating loss carry forwards will be expired *on and beyond 2017*. Please explain to us the basis of your analysis whereby you are projecting that it is more likely than not that you will not be able to utilize your net operating loss carry forward in 2017 and beyond. Please provide us with your analysis of available evidence, both positive and negative, that you considered in determining your need for a full valuation allowance at December 31, 2008.

Company Response:

Supplementally, we advise the Staff of the following evidence which we considered when determining the need for a full valuation allowance in relation to our net deferred tax asset balance. We have followed the guidance provided by Paragraph 17(e) of Statement of Financial Accounting Standards ("SFAS") 109, "Accounting for Income Taxes," which calls for a reduction of deferred tax assets by a valuation allowance, if "... based on the weight of available evidence, it is *more likely than not* (a likelihood of more than 50 percent) that some portion of all of the deferred tax assets will not be realized." We considered the following positive and negative evidence in reaching our conclusion that a full valuation allowance was necessary at December 31, 2008:

Positive evidence:

- The Company is a leader in the rapid oral fluid testing industry, which is a part of the growing medical diagnostics industry;
- The Company has existing contracts with domestic and international distributors and customers that we believe will generate taxable book income in future years. At December 31, 2008, we believed the future cash flows to be received from revenues generated by our long-lived assets and intangible assets (property and equipment, and patents and product rights, respectively), would exceed their book value and as such, we did not recognize any impairment loss on the value of those assets for the year ended December 31, 2008;
- The Company has several products in varying stages of development within its research and development product pipeline that could be a source of future revenues;
- As a tax planning strategy, the Company could make an election under §59(e) of the U.S. Internal Revenue Code to capitalize certain research and development expenses, within the limitations prescribed therein, thereby extending the potential expiration of certain operating loss carryforwards which would expire within the next several years; and
- Long carryforward periods are permitted under U.S. tax law for utilization of our federal and most state net operating loss carryforwards and tax credits.

Negative evidence:

- The Company has a history of pre-tax losses and an accumulated deficit of $127 million at December 31, 2008. Our Company was formed on September 29, 2000. Prior to formation, our predecessor companies also incurred significant pre-tax losses. Since our inception, our pre-tax income or (loss) for each year ended December 31, was as follows:

2000	$(12,722,187)
2001	(3,399,000)
2002	(3,342,473)
2003	(1,108,947)

2004	(559,642)
2005	9,718,898
2006	9,061,453
2007	4,293,775
2008	(8,747,968)

- In the fourth quarter of 2008, the Company completed its budgeting process, which projected a pre-tax loss of approximately [*A02] for fiscal year 2009. In fiscal 2007, the Company recorded pre-tax income of $4.3 million, and in 2008, a pre-tax loss of $8.7 million, which included $4.9 million in other income from a litigation settlement in that same fiscal year. With the budgeted pre-tax loss expected in 2009, the Company would be in a cumulative three-year pre-tax loss position of approximately [*A03] as of December 31, 2009. As indicated in Paragraph 23 of SFAS 109, forming a conclusion that a valuation allowance is *not* needed is difficult when there is a significant piece of negative evidence to overcome, such as a cumulative loss in recent years.
- The Company has not paid federal income taxes in the current or prior fiscal years, with the exception of alternative minimum taxes, and therefore, carryback of losses is not available.
- Some of the primary drivers of future revenue growth for our Company are products that are in varying stages of development and that will be subject to regulation by the U.S. Food and Drug Administration (“FDA”) or other governmental or public health agencies. The process of obtaining FDA approval is inherently uncertain and can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities, and other costly, time-consuming procedures. The approval process can by complex and lengthy. Failure to obtain or any delay in obtaining FDA approval for new products could significantly reduce our future revenues, increase our costs, and adversely affect our financial performance. As indicated, there is uncertainty surrounding the timing and cost of regulatory approvals, if obtained. As such, we cannot predict with any level of accuracy, the potential impact on future revenues or expenses associated with obtaining regulatory approval of new products.
- The uncertainty surrounding the magnitude and length of the global recession makes predicting future results from current operations more difficult than in previous years.
- At December 31, 2008, the Company did not have any significant sales backlog.
- The reversal of existing temporary differences or deferred tax liabilities is not significant on an annual basis.
- The Company is involved in patent infringement litigation, which alleges that the manufacture and sale of our primary rapid oral fluid HIV testing device infringes a patent held by another party. During fiscal 2008, sales of this product accounted for 49.6% of the Company’s $71 million in total revenues. In the event we are unable to successfully defend against the current litigation, or it is determined that a license to this patent is required and we cannot obtain such a license on reasonable terms, our ability to sell this device may be limited, which would adversely affect our results of operations, pre-tax income, cash flows, and our

overall business. As of December 31, 2008, we were unable to predict with any level of certainty the resolution of this unsettled circumstance and we expected to incur substantial legal expenses in 2009 as a result of this litigation.

- In order to remain competitive, we must regularly commit substantial resources to research and development and the commercialization of new products. The research and development process can take a significant amount of time from inception to commercial product launch. During 2008, 2007, and 2006, we incurred $20.3 million, $14.1 million, and $8.6 million, respectively, in research and development expenses. We expect to continue to incur significant costs from our ongoing research and development activities, even though future products may not be commercialized or approved by the FDA.

At December 31, 2008, we believed the negative evidence noted above far outweighed the positive evidence presented. Given the level of our pre-tax loss in 2008 and our expected pre-tax loss in 2009, we believed that we could be in a cumulative three-year pre-tax loss position even through [*A04]. Our ability to forecast future revenues and pre-tax earnings beyond 2009 is impacted by the uncertainties and unsettled circumstances described above, especially those associated with regulatory approval and clinical development expenses for our future products. We advise the Staff that this was recently proven to be true, as indicated by the June 25, 2009 Form 8-K we filed, stating that the FDA did not approve our application for approval of our rapid oral-fluid HCV test as originally submitted, but rather, is now requiring us to perform additional clinical studies in support of the test, which we believe could cost an additional [*A05]. At December 31, 2008, we did not believe that we could reliably forecast annual pre-tax earnings beyond 2009 to the level necessary to realize our deferred tax assets. As such, we did not believe that it was more likely than not that we could realize our deferred tax assets in the future, and accordingly, we recorded a full valuation allowance against our net deferred tax assets.

Comment 5 (Financial Statements - Note 12. Other Income, p. F-23)

Staff Comment:

We see that you entered into a settlement and license agreement with Schering-Plough in January 2008 to resolve your patent infringement litigation and Schering paid you $4.9 million which you recorded as other income. In future filings please reclassify this income within operating income, or tell us in detail why you believe this income is properly classified in non-operating income. Your explanation should include a discussion of why the license agreement and the underlying patent do not relate to your operating activities.

Company Response:

We recorded this settlement amount as other income in our financial statements because we believe that gains from patent litigation or lawsuit settlements are not part of the Company’s ongoing or central operations. We believe the one-time gain from this settlement is not a result of ongoing operations in the current period, but rather is an infrequent or unusual transaction. We

respectfully believe that we have properly classified the gain from this litigation settlement as non-operating income in accordance with the financial statement classification guidance provided by Paragraphs 85-86 of Statement of Financial Concepts No. 6, “Elements of Financial Statements”, and that we have also followed the disclosure guidance provided by Rule 5-03(d) “Miscellaneous Other Income” of Regulation S-X of the Securities Exchange Act of 1934.

We appreciated the opportunity to discuss this comment further with the Staff via our phone conversation on September 25, 2009. As a result of this discussion, in future filings we will reclassify this income within operating income.

Comment 6 (Exhibits)

Staff Comment:

We note your disclosure on pages 12 and 25 that you have long-term contracts with single source suppliers to provide the antigen and nitrocellulose used in your OraQuick line and that it would require significant time to replace these vendors. Given the importance of OraQuick sales to your business operations, please file these contracts as exhibits, or provide us with a detailed legal analysis explaining your basis for not filing them. Refer to Item 601(b)(10) of Regulation S-K.

Company Response:

Item 601(b)(10)(i) of Regulation S-K defines a material contract, in relevant part, as a “contract not made in the ordinary course of business which is material to the registrant . . . .” This Item further states that a contract that “ordinarily accompanies the kind of business conducted by the registrant” shall be deemed to have been made “in the ordinary course,” unless it falls within one of several categories, in which case it must be filed as a material contract unless it is immaterial in amount or significance. The only category potentially relevant here is described in clause (ii)(B) as a “contract upon which the registrant’s business is substantially dependent . . .,” including contracts “to purchase the major part of registrant’s requirement of goods . . . or raw materials.”

As indicated on pages 12 and 25 of the 10-K Report, we currently purchase the antigen and nitrocellulose used in our OraQuick® HIV test from single source suppliers. However, we believe there are alternate suppliers that can supply these products, if necessary, on commercially reasonable terms.

Supplementally, we advise the Staff that the antigen supply agreement was entered into in July 2000 and has a ten-year initial term with automatic one-year renewal terms, subject to either party’s right to terminate by giving at least 90 days notice prior to the end of the initial term or any renewal term. Under this agreement, the Company has agreed to purchase its total requirements of antigen exclusively from this vendor at a transfer price set forth in the contract. The Company is also required to pay a royalty on sales of its products incorporating the antigens during the initial ten-year period in respect of patents held by the vendor that expire beginning in 2010. During 2008, the Company purchased approximately [*A06] of antigen and paid [*A07]

in royalties under this contract. These amounts are comparable to what we paid in prior years. In the event that this vendor cannot supply any order of antigens placed under the contract, the Company is permitted to purchase the antigens from a third party free of any claims of patent infringement by the vendor.

The nitrocellulose contract was executed in January 2005 and expires at the end of 2009. Under this contract, the Company can purchase nitrocellulose at a transfer price set forth in the contract. During 2008, the Company purchased [*A08] of nitrocellulose. This is similar to purchase levels in prior years. This contract is nonexclusive, and the Company is free to purchase nitrocellulose from any other vendor it chooses.

We routinely purchase raw materials and components used to manufacture our products, such as the HIV antigen and nitrocellulose, from third party vendors. The antigen and nitrocellulose contracts are the types of supply contracts that ordinarily accompany the kind of business we conduct (i.e., the manufacture and sale of medical diagnostic products) and were clearly made in the ordinary course of business. In order to meet the filing requirement as a "material contract," each of these contracts would therefore need to be a contract upon which our business is substantially dependent or otherwise be material in amount or significance. We do not believe either contract meets this standard.

Although our OraQuick® HIV product line accounted for approximately 50% of our 2008 revenues, our business is not substantially dependent on either contract for several reasons. First, as noted above, during 2008 we purchased less than [*A09] of HIV antigen and less than [*A10] of nitrocellulose, which compares to approximately [*A11] spent that year in total for all components and raw materials used in our products. These contracts therefore did not account for a major part of our requirements for "goods . . . or raw materials." Second, as explained above, there are alternative suppliers available for both the antigen and nitrocellulose, which we believe can supply these products on commercially reasonable terms. As described in the 10-K Report, the risk facing the Company is not that alternative sources of supply cannot be found, but rather that components available from new suppliers may require additional development work and related FDA approval, both of which could cause delays in our ability to use such components in our FDA-regulated products. We believe that we have substantially mitigated this risk by the level of inventory we typically maintain for these materials. Our goal is to maintain at least a 12-month supply of both of these products, although actual inventory levels fluctuate above and below this level depending on product demand and production activity. While the timing of the FDA approval described above can be uncertain, we believe the validation and equivalency testing required for that FDA approval would be straightforward and that an alternate supplier could likely be put in place and approved before our inventory levels of either product were depleted.

Similarly, we do not believe either contract is material in amount or significance. As noted above, the amounts paid on an annual basis are not material in view of our aggregate expenditures for components and raw materials or when compared to our revenues. In view of the conservative inventory practices we follow, these contracts are otherwise not significant given our expected ability to identify an alternative source and obtain any FDA approval without disruption to our manufacturing process. Notwithstanding the foregoing, we believe the risk

discussion in the 10-K Report is appropriate given the uncertainty generally inherent in obtaining FDA approval.

For the reasons stated above, we do not believe that the long-term supply contracts for the antigen and nitrocellulose constitute material contracts as defined in Item 601(b)(10) of Regulation S-K.

Comment 7 (Exhibits)

Staff Comment:

We also note your disclosure on page 47 that you have entered a collaboration agreement with Schering-Plough to develop and promote a rapid oral fluid test for the detection of HCV antibodies. Please file this contract as an exhibit, or provide us with a detailed legal analysis explaining your basis for not filing it. Refer to Item 601(b)(10) of Regulation S-K.

Company Response:

As explained on page 47 of the 10-K Report, we previously entered into a Collaboration Agreement with Schering-Plough to develop and promote our OraQuick® rapid HCV test in the United States.[1] Pursuant to this agreement, Schering-Plough has paid us $2 million as reimbursement for certain development costs for this product and will be required to provide certain limited promotional services once this product is approved by the FDA. Development and promotional agreements are the type of contracts that ordinarily accompanies the kind of business we conduct and, for this reason, we believe the Collaboration Agreement with Schering-Plough was made in the ordinary course of business and is not a material contract required to be filed with the SEC.

Our OraQuick® HCV test is still pending before the FDA for approval and it is not certain when it will be approved. Until such approval, Schering-Plough essentially has no significant obligations under the agreement. If and when FDA approval is obtained, Schering-Plough will provide promotional support for the product but only in a defined segment of the U.S. physicians' office market. Supplementally, we hereby advise the Staff that we expect that the OraQuick® HCV test will be sold not only to physicians, but also to the large U.S. public health market and to hospitals much the same way as our OraQuick® HIV product is sold to these markets. However, until FDA approval is obtained and a commercial launch occurs, it is uncertain how material the OraQuick® HCV product will be to our business. Although the

[1] The Company has also entered into a second Collaboration Agreement with Schering-Plough for markets outside the United States, under which Schering-Plough will reimburse a portion of the Company's regulatory and development costs for international markets and provide defined promotional services. The OraQuick® HCV product has not received any international regulatory approvals and has not been commercially launched in any foreign market. In addition, Schering-Plough has not yet made any payments to the Company under this agreement. Although this agreement was not mentioned in the Staff's comments, we do not believe this second Collaboration Agreement constitutes a material contract for the reasons explained above with respect to the domestic Collaboration Agreement.

Schering-Plough collaboration will certainly assist in the commercialization of the OraQuick® HCV test, neither the success of this product nor the Company's business is substantially dependent on this contract. Moreover, in view of Schering-Plough's relatively small financial investment and the fact that the OraQuick® HCV product will not be on the market for some time, we do not believe our Collaboration Agreement is otherwise material in amount or significance.

In view of the foregoing, we do not believe the Schering-Plough Collaboration Agreement referred to on page 47 of the 10-K Report is a material contract as defined in Item 601(b)(10) of Regulation S-K.

* * * * *

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 in the filings reviewed by the Staff 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. 3279) if you have any questions or if we can provide any further information that would be helpful to the Staff.

Sincerely,

/s/ Ronald H. Spair

Ronald H. Spair
Chief Financial Officer
and Chief Operating Officer

cc: D. Michels, President and Chief Executive Officer
J. Jerrett, Senior Vice President and General Counsel
M. Kuna, Senior Vice President and Controller
A. Boerman
J. McCann
D. Morris
M. Celano, Chairman, Audit Committee
T. Koncsics, KPMG LLP
E. DeTrizio, Dechert LLP