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Orasure Technologies, Inc. F4Q08, and Full Year Earnings Call Transcript

Question-and-Answer Session

Operator

(Operator Instructions) Your first question comes from Sean Bevick of SIG.

Sean Bevick – SIG

I have a couple of questions about the false positives that were reported a few months ago at the NYC clinics. Have those false positives been leaking to any other regions? Also, you guys mentioned before that you guys monitor the false positives in your own database. Has there been any change in those false positives over the last few months?

Douglas Michels

No. You know we have a very robust sentinel site-monitoring program and the OraQuick product continues to perform exceptionally well. I think testament to that is the recent approval of our request to actually extend the dating of the OraQuick product based on enhancements that we've made to the product raw materials as well as the manufacturing process. So, no the product in the field continues to perform to its FDA approved specifications and we believe that the enhanced product is going to make that performance even more robust.

Sean Bevick – SIG

Okay and then has the FDA had any concern with oral fluid testing with regards to what happened with this NYC stuff and the HCV approval?

Douglas Michels

You know, our position with the FDA has always been one of complete transparency and the FDA has access to all of our records, they have access to all of our complaint files. I think testament to the strong performance of the OraQuick product is the fact that they've approved an extension of the products dating recently announced by us.

The hepatitis C application has been submitted. It's a complete submission and as I mentioned in my prepared remarks, the FDA has already conducted a BMO audit here, has audited one of our clinical sites and that process continues to progress. The FDA continues to be extremely supportive of our efforts and things are actually going very well.

Operator

Your next question comes from Aaron Lindberg with William Smith & Company.

Aaron Lindberg - William Smith & Company

I have a quick question on the cryo product. Do you anticipate launching additional cryosurgical products in 2009 or just the one that you mentioned earlier, the wart product, the branded wart product?

Ronald Spair

Right now our plans are to launch the wart product. As we mentioned we are launching that in Rite Aid. We expect that product to be in excess of more than 4,500 stores. We are having ongoing dialogue with other retailers. Obviously we are going to monitor how the brand performs and we will make future decisions on expansion as the year progresses.

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