

ceocfointerviews.com All rights reserved! Issue: May 5, 2014 **The Most Powerful Name in Corporate News** 



# Non-Invasive Saliva Based Technologies

Oasis Diagnostics® Corporation was founded in 2002 to address a growing need for non-invasive saliva based technologies for rapid testing, sample collection, and molecular diagnostics [DNA, RNA and proteins] in the Life Sciences area. The Company is dedicated to meeting the need for more effective screening tools, which may be applied to the early detection of diseases and medical disorders, utilizing non-invasive test specimens, particularly oral fluids (saliva).

#### Interview with *Paul D Slowey - CEO*: Conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

### CEOCFO: Dr. Slowey, would you tell us about the highlights at Oasis since we spoke last year?

**Dr. Slowey:** Major growth I would say. The last time you talked to me, we might have been four people on the inside and several people helping us on the outside. In August 2013, we received an NIH Phase II Small Business Innovation Research [SBIR] award from NCCAM, which is the National Center for Complementary and Alternative Medicine, a division of the National Institutes of Health (NIH). At that point we received funding worth about \$1.3 million dollars over two years, which immediately made us rethink our strategy and bolster the people we had in the laboratory. I think we have ten or eleven people in the laboratory in Portland Oregon and that has caused us some growing pains. As a result, we are now looking at a change in facility from a small facility to laboratory space that is probably three times as large, based on the fact that we have grown so much over the last twelve months.

# CEOCFO: Your website indicates, "Oasis Diagnostics is pioneering oral fluid diagnostics." Would you explain the concept for people who may not know the company?

Dr. Slowey: The concept is that we are dedicated to removing the pain from diagnostic testing so essentially we are trying to remove the needle or pain from a needle for all people but most importantly children and older people. Over the course of the past eleven years we have developed a series of technologies that are patented and now in use around the world that probably include about six or seven different devices. The first device we developed was for standardized saliva collection from under the tongue in a couple of minutes that can be used for general laboratory testing. We released an updated version of that product, called Versi•SAL®, that is simpler to collect, and also a new device called Super•SAL™, which collects a saliva sample from along the side of the tongue very quickly in about one to two minutes and it gives you a larger sample volume; it is more expensive but it is a unique device and it is so simple to use; it is already finding applications in humans, dogs, cats and horses and it has also been used for cervical cancer screening in Brazil as part of the national screening program there. We have developed tools that collect DNA from your saliva and give you large amounts of DNA that can be used for testing for a range of diseases by what is called PCR. There is now another tool called RNAPro•SAL<sup>™</sup> for RNA and protein collection. RNA is a smaller version of DNA and can be used as a building block for research and clinical applications and it is a useful diagnostic tool that researchers and laboratories use. We have a new device called Drug•SAL<sup>™</sup>, which has recently been renamed Accu•SAL<sup>™</sup> as it is going to be used for not only drugs but also steroid hormones, for general wellness, for infectious disease testing and others. It was originally developed for drug testing but it seems to have multiple applications. The technology that has really catapulted us forward is the VerOFy® device, which is the rapid, fully quantitative, point-of-care test platform that we are using to develop the cortisol test, which is a test for stress being developed using the NIH funds. We are also developing two other tests in parallel to that for estradiol, for in vitro fertilization in women and testosterone, for low-T in men for aging purposes and for sports medicine applications.

## CEOCFO: Regarding the stress, what are you actually measuring?

**Dr. Slowey:** We are measuring the hormone cortisol, which is a hormone that is released immediately in response to any stress that the body is subjected to. It appears very quickly in our saliva so we use our standardized saliva collection technology to harvest saliva from under the tongue in a couple of minutes. The collected sample is transferred to our VerOFy® platform, which incorporates test strips [similar to test strips that are part of commonly used pregnancy test strips] that we use to be able to quantify levels of cortisol in your saliva specimen. The amount of cortisol that is in your saliva is directly proportional to how stressed you are. In this case we have to physically quantify the levels of the biomarkers like cortisol using a small hand-held reading device. We call it LIAM<sup>™</sup>, which stands for Light Image Analysis Module. We need to read the test strips because the signal that we get is non visible to the naked eye. Therefore, we have a special camera inside our LIAM<sup>™</sup> unit that takes a picture of the test strips and from the signal that it sees on the

test strips it quantifies the amount of signal and transmits the level is sees via Blue Tooth to a smart phone or a laptop computer. There is also a read-out on a monitor on the top of the LIAM<sup>™</sup> device that tells you if your stress level is high or in the normal range and everything is ok.

#### CEOCFO: When will the test be applicable?

**Dr. Slowey:** The first application is in the research realm. The NIH funded this project because they wanted a tool that researchers can use to test people on the various conditions for stress. There is actually \$22 million spent every year by the National Institutes of Health alone just on stress research. That is the initial target but there are multiple applications mainstream when the test is more likely to be amenable to a home user. That is not going to happen this year but maybe in 2015 we may see these other applications developing. It can be used for sports medicine and older people looking at their stress levels. Cortisol is implicated in a lot of diseases and stress can be a trigger for multiple other conditions, so you should be able to watch cortisol levels go up in individuals as that particular person experiences an infectious disease, a cardiovascular event or even cancer. Also there are diseases / conditions such as Addison's disease and Cushing's Syndrome where the VerOFy® tool could be useful. There are pharmaceutical companies that would value a tool to be able to monitor stress levels in patients when they have administered their therapeutic drugs.

#### CEOCFO: How long does the cortisol stay available in saliva?

**Dr. Slowey:** We all have a normal level and it is raised in response to some sort of stress. The cortisol levels will eventually go down as the body acclimatizes to the impact of the stress. Cortisol needs to be measured at various times of the day because there is what is called a "diurnal" variation that causes variation in certain hormone levels at various times of day. Usually you would take a specimen in the morning and one in the afternoon or evening and average the two. That is what we will be doing in this case.

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#### CEOCFO: Are there competing technologies to measure?

**Dr. Slowey:** In our case, we are measuring cortisol levels in "real time" [less than 20 minutes]. There are FDA-cleared tests where you can collect the saliva specimen and send the specimen to the laboratory and the lab would then test that specimen for cortisol and give you a result. Unfortunately results are only available up to two weeks later when the stress is gone.

#### CEOCFO: What attracted you to the concept?

**Dr. Slowey:** I have been steeped in saliva technologies since 1996 and I have worked for the two premiere companies in this area. These companies have some excellent technology but we believed we could make it better. That is where this all came from; we know OraSure Technologies, Inc., the market leader very well. OraSure has about \$100 million dollars in sales and excellent ideas. They are focused on one or two main areas. Our goal is to make sure that people are getting available non-invasive technologies that can be used to diagnose diseases at low cost. Taking it one step further, instead of being able to tell you that you do or do not have a disease, we actually want to be able to tell you how much of a biomarker level that you have. Hopefully in the case of Alzheimer's and Parkinson's that we are now beginning to work on, we will be able to tell you what stage of the disease you are in, for instance if you are in the mild stage, moderate or the advanced stage of the disease.

#### CEOCFO: How do you stay focused?

**Dr. Slowey:** I tend to get a little diffuse from time to time; it is like being a "kid in the candy store" at times, where there are so many things that we could be doing but you cannot possibly do them all as a small company that is still self-funded right now. We do not have investors yet and we are still funding ourselves through the revenues of the products that we sell. We are at the point where we cannot take on too many more projects and remain viable, so that alone helps keep me focused.

#### **CEOCFO:** Are you looking for investment?

**Dr. Slowey:** We have been out for investment twice and we failed in both cases. We got very close a couple of times. However, the investment in time is a heck of a lot of work and it would detract from the corporate strategy right now. If I invested time looking for a cash influx, company sales could be impacted so I spend my valuable time looking after the sales portion of the company, because that is what drives everything else,

#### CEOCFO: Who is buying your products today?

**Dr. Slowey:** Every product is slightly different so the customer base is different. The VerOFy® device for cortisol is simple and it is going to be researchers in the beginning and then sports medicine and therapeutic companies. Other customers include laboratories, pharma companies, CROs, researchers and other companies [B2B].

#### CEOCFO: Has the medical community paid more attention to saliva based tests and do you see any change?

**Dr. Slowey:** I do actually see a significant change. For example in the past I have written a couple of book chapters at the request of other people. Both were published in 2013, so they are very recent. I was asked to write a third one in August 2013 and I was supposed to have it done by November and I have still not completed it yet! The main reason is in order to write a new book chapter you have to do a lot of research that taps into everything that has been going on in the saliva world since you wrote your last book chapter. The problem I am having is that there is so much new work being done that I am struggling to get this thing finished. By the time I am finished it is already going to be a little bit of out of date, because there will have be even more research published in that area by then. However, this is a good thing. Another example; I am a co-organizer of the first saliva symposium here in the US on an annual basis. There have been two such saliva symposiums before. One was in 1999 and the other was in 2006 and they have not had one since. I typically attend such meetings in Europe every two years. There will be one in the Netherlands on May 14<sup>th</sup> and I will be there. My co-investigator and I decided it was high time we had a similar event here in the US, but we are making it an annual event and that is going to take place in October in Boston and as I mentioned I am a co-organizer. We are trying to get as many of the luminaries in the saliva area to this conference as we can and it should be a good event.

#### CEOCFO: Why pay attention to Oasis Diagnostics?

**Dr. Slowey:** I think people are starting to pay attention to us already. I hope they pay attention to us for what we do to try to help people by providing safe and effective solutions for disease diagnosis. The members of the community are supportive of what we do and when they see what we do they get excited. This week for instance we were nominated for a local award; it is from the Vancouver Business Journal located in Vancouver Washington. Vancouver Business Journal has an annual award and we were nominated for "Innovator of the Year" and there is a ceremony next week. I will be in England at the time so I will be sending a couple of my people to represent the Company at this important event. We are also the recipient of a Frost and Sullivan Award, for "Best Product Line Strategy 2014." We also like to work with local organizations and I think the community likes the fact that we are affiliated with a marketing program at the local university [Washington State University]. They are doing an assessment of our products and how they fit into the market place. The people involved are general marketing students so they are not healthcare related specifically. I have met with them several times and the excitement that you get when you talk to these young people is important to me. They would actually like to present their Project including our products at a local meeting called PubTalk that happens in Vancouver every two months. This is where local dignitaries get together and companies present their products to potential investors.



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