

Oasis Diagnostics® Corporation is bringing to market Six Different Tools that address a growing need for Non-Invasive Saliva Based Medical Testing for DNA, RNA, Drugs of Abuse, Human Growth Hormone, Tuberculosis and Testosterone and a Point-of-Care Test Platform for Stress Detecting Cortisol

**Healthcare
Saliva Based Technology**

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Dr. Paul D. Slowey
CEO

BIO:

Paul D Slowey PhD, CEO, Oasis Diagnostics® Corporation. Managing Member, Bamburgh Marrsh LLC, Vancouver WA 98686 USA. Dr. Slowey is a founding member and 100% owner in Oasis Diagnostics® Corporation and its subsidiary Company, Bamburgh Marrsh LLC, each pioneers in the area of oral fluid diagnostics and testing. His background is in Organic Chemistry; after being

awarded his Doctorate from the University of Newcastle-upon-Tyne (UK), he spent several years as a Post Doctoral Fellow in Canada then 5 years in the pharmaceutical industry with Sterling Drug [UK]. He has over 27 years experience in the clinical diagnostic and pharmaceutical industries combined. Over the years he has held positions as Director of International Sales and Chief Operating Officer (COO) and Vice President of Sales and Marketing for companies that were the original pioneers in the development of saliva diagnostic rapid tests for infectious disease, and oral fluid collection devices. He has extensive experience in structuring strategic alliances and license agreements with both start-up and Fortune 500 companies. Dr Slowey has 12 publications in peer-reviewed journals, ten (10) issued patents, twelve (12) filed patent applications and he has made a number of oral presentations at key scientific symposia on a variety of subjects including HIV diagnosis, nucleic acid testing, the status of oral fluid testing, the Japanese Healthcare Business and Thyrotropin Receptor Antibody Assays for the Diagnosis of Graves' Disease.

About

Oasis Diagnostics® Corporation: Oasis Diagnostics® Corporation was founded in 2002 to address a growing need for non-invasive saliva based technology for rapid testing, sample collection, and molecular diagnostics [DNA, RNA and proteins]. The Company is dedicated to meeting the need for more effective screening tools, which may be applied to the early de-

tection of diseases and medical disorders, utilizing non-invasive test specimens, particularly oral fluids (saliva), in simple fashion.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine**

CEOCFO: Dr. Slowey, would you tell us about Oasis Diagnostics® and your vision?

Dr. Slowey: As a company, we started in 2002 to develop a series of oral-based diagnostic tools that would replace painful blood draws, and ever since the beginning, that has been our guiding principle. Basically, listening to what our customers tell us that they are looking for in terms of non-invasive sample collection, or diagnostic testing that uses saliva as a specimen instead of blood. Over the course of our ten-year history, we have developed a total of five different technologies with a couple of additional devices in the pipeline, and we are continually seen to be innovating as our customers dictate. That is really the way that it has evolved, it was never really meant to happen this way, but that is the way it has evolved over the years from 2002 onwards.

CEOCFO: What are some of the basic challenges in using saliva as opposed to blood, and what have you figured out that others have not?

Dr. Slowey: The biggest thing, I believe, is educating the market and customers in general on the use of saliva as a testing option. I have been involved in oral [salivary] diagnostics since 1996, and at that time, there

were companies that had very, very good saliva testing tools, but the market was not really quite ready for them at that particular point in time. Mainly because all traditional testing was done on blood, and not very much was done on saliva. Saliva has its own challenges in the specimen itself; like any other specimen, it has many impurities in it. Part of our technology or at least our trade secrets if you like, is in figuring out how to remove all of the interferants and potential contaminants in the saliva that will allow you to have a pure sample that will give you the results that you want in any downstream test or assay.

CEOCFO: What are some of the common tests that you have available today?

Dr. Slowey: We have five different tools. Some of them are for collection of things like DNA, which is a substrate for molecular diagnostic [or nucleic acid, NAT] testing. Others are for things like RNA [also for nucleic acid testing], which I believe to be the “new frontier” in diagnostics if you like. Many companies are developing drugs that are targeted for RNA, rather than DNA, so that is a big growth area. We also have a point-of-care test platform in which we are developing a salivary stress test, detecting the hormone cortisol. We also have other projects in the pipeline to develop tests for celiac disease, and other things such as human growth hormone, tuberculosis, testosterone, and various others, but these are not commercially available at this time. We do have two tools that are purely collection devices; one is called Versi•SAL®, and another Super•SAL® that each collect saliva in standardized fashion. The collected sample may then be sent to a laboratory where it may be used for applications including drugs of abuse testing, or hormones for general wellness, oncology, infectious diseases, you name it. Anything that can be done on blood can also be done typically using saliva.

CEOCFO: What is the competitive landscape? Are many companies working with saliva testing these days?

Dr. Slowey: Yes, there are some and perhaps you would call the market leader Orasure Technologies. They are a one hundred million dollar revenue company, and the company that recently got an over-the-counter test approved for HIV diagnosis using saliva specimens. Now you can go into your pharmacy, and buy a test that will allow you to self-test for the HIV virus from your own saliva. They have rather pioneered the trail, if you like. We do not look at ourselves as competitive to Orasure in that we have tools that compete with OraSure devices, but in terms of the applications that we are developing, we are working on different applications and targeting different diseases or conditions. As an example, we are not developing a test for HIV. Instead, we are developing tests for stress, potentially tuberculosis, and various other diseases, but do not see ourselves as competitive to be honest.

CEOCFO: How do you decide what you should or what you are developing tests for?

Dr. Slowey: Much of it comes from the customers again. I will give you a typical example: Celiac disease is a disease associated with gluten intolerance; many children and adults have undiagnosed celiac disease in this country, and there are tests available, but most of them are blood-based tests. A couple of them are what you would call point-of-care, where you can actually get the results immediately, but none of them are saliva based where you can actually test a child in non-invasive fashion, and determine whether they are gluten intolerant, and then obviously change their diet if they find that they are suffering from the condition. Recently a company approached us and said, “Look, we would like to develop a particular test for gluten intolerance using one of your tools.” The tool is called VerOFy®. We put our heads together and came up with the project, timing, costing and other factors and then collectively we are working together to obtain the necessary funding to move forward and develop and commercialize the product.

CEOCFO: You make it sound so simple! Do most people that buy your tests also buy the equipment from you? Do you sell a lot of your equipment to people who may not be using your tests?

Dr. Slowey: Actually, we do not sell equipment per se. Our diagnostic tools are mostly disposable. Some of them look like a razor, some of them just look like a little device that fits under your tongue, so they are very small, but once you have used them you dispose of them. Having said that some of the collection tools, for instance, are used as the front-end sampling device to collect saliva samples that can then be used on large-scale instruments that some of the larger companies like Life Technologies or Illumina, and others provide, but we as a Company do not provide any large-scale instrumentation.

CEOCFO: On the collection tools, are there differences? Is it just sort of a commodity that you are producing, or is there a reason to use the Oasis products?

Dr. Slowey: It all started because there were tools on the market, but in my opinion, they were not totally meeting customer expectations. In my original vision I saw that there were some gaps in the system, whereby our tools could fit a market need that the customers were looking for but not able to get with the currently available devices at that time. As an example, when you are collecting saliva samples from subjects, in certain instances you have to collect two samples from the same patient at the same time, in other words, there is a need to split the sample as you collect it. One of our patented features is the ability to split the sample into two or more equal fractions at the time of collection. Another feature is the issue of sample sufficiency. When you are collecting saliva specimens, sometimes it can take a long time, so you have to have a mechanism in the device, called a “Sample Volume Indicator” that indicates when the subject has collected enough saliva. In our case, it takes about two minutes maximum to collect the saliva specimen. At that time, a unique sample volume indication feature changes

color from blue to colorless indicating that enough sample has been collected for downstream processing in the laboratory. These are the types of things that set us apart from our competitors.

CEO CFO: You mentioned developing a saliva test for stress. What are you actually measuring there?

Dr. Slowey: The biomarker that is most routinely used for stress detection is cortisol. Cortisol is a steroid hormone that is released into the bloodstream and saliva, and responds to various stressors. Anytime that you get involved in a stressful situation your cortisol levels increase. As it happens salivary cortisol is a much better indicator than blood-based cortisol in terms of being able to measure it routinely in subjects that are undergoing stressful situations; there are a number of reasons for this, but one of them is that the needle itself is a stress that will automatically send your cortisol levels higher than normal. Our device basically differentiates itself from the rest of the market in that it is a point-of-care device, rather than a laboratory test. What we are doing is actually detecting salivary levels of cortisol with a small device that you stick in your mouth for approximately two minutes. After two minutes, it comes out of your mouth, you leave it for a few more minutes, and you get a series of lines that are detectable on the device; not by the human eye, because we are actually quantifying the levels of cortisol in the saliva. In order to do this, we use what is called a fluorescence-based system that actually allows you to quantify the levels of cortisol in saliva. We then utilize a special device that detects the fluorescence signal. This could be one of a number of systems, but this includes a smart phone, a webcam, and even an iTouch. Within that device, there is an algorithm built into it that will convert the signal that the camera sees into a number, which tells you whether your level of stress is high, low or medium. It is a very quantitative measure. This was all

funded through a government grant from the National Institute of Health's NCCAM division, which stands for the National Center for Complimentary and Alternative Medicine. They actually provided the funding for Phase 1 of that project, we are just about complete with Phase 1, and we filed a Phase 2 application in August 2012. We have a number of collaborative partners waiting to hear if we are going to receive second phase funds and we hope to find out if we have been successful very soon.

CEO CFO: Have you been working on an Alzheimer's test?

Dr. Slowey: We have a license to a technology for Alzheimer's disease ["AD"] detection. It is a very interest-

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ing technology from two Danish researchers, Dr Balwant Rai and Dr Jasdeep Kaur. The situation is: that within saliva there are a number of biomarkers that are detectable in the saliva that either go up or down depending on whether you have specific clinical symptoms of Alzheimer's disease; and also in Parkinson's disease. In developing a test, what we have to do is something similar to what I mentioned for the cortisol test, in that we have to be able to quantify each of a series of different biomarkers in saliva. Some of them actually go up when they are expressed in Alzheimer's patients, and others go down. We have to be able to monitor these increases and decreases in the saliva, once again using a small instrument, which might be a smart phone or some other portable, hand-

held instrument. At this point in time, we are looking for partners to help us develop this technology, because we do not necessarily have the funding in place at this point in time, but we certainly do have the internal expertise and technology platform necessary to develop an Alzheimer's test. That test would be a clinic-based test rather than a laboratory-based test. In our proposed test, you will be able to receive test results in 15-20 minutes.

CEO CFO: It seems this has almost limitless opportunities; how to you decide what to address first?

Dr. Slowey: That usually gets chosen by the customers. We have several projects ongoing, but at any given time, someone else can come along and say, "We would like you to develop a test for us based on your platform. Can we develop this particular test?" I will give you an example: The National Football League Players Association for instance, they had an interest in human growth hormone, which is obviously abused in many athletes. At this point in time, the only test that is available is a test that uses blood, and there was a Sports Illustrated article that said, "The professional footballers would prefer a urine-

based test, or something that is not invasive, maybe saliva." Unfortunately, the human growth hormone does not appear in urine, so saliva is the only option. We actually talked to the National Football League Players Association who are represented through an attorney firm, and they were extremely interested in the development of such a test, and more or less agreed to purchase the product once it was developed. Unfortunately, like us, they did not have the funds in place to be able to say, "Yes, here is the money to go ahead and develop it." We put together a team of experts, including the person who developed the blood-based test for human growth hormone, and also personnel from the World Anti-Doping Agency that actually controls testing for human growth hormone. We had every-

thing in place, but never got the funding to carry on. Like I said, the possibilities are limitless, and it goes from the realms of infectious disease testing, to biomarker development, to collecting RNA, DNA or proteins for various applications; stress tests, testosterone tests, you name it, there are lots of possibilities out there.

CEO CFO: Why do you think the medical community does not get the concept that saliva is the better way to go than sticking someone with a needle?

Dr. Slowey: It seems obvious to everybody, but a lot of it is historical. If you go back through the published literature, there are many scientific articles out there. If you want to show that your test in saliva is as good of a test in blood, what you have to do is to show a correlation between the results that you get with blood versus the results that you get with saliva. You have to realize, historically speaking, many of the papers that were published early on showed poor correlation results between one marker in saliva versus the same marker in blood, and it all goes back to the sample collection piece of it. There is a saying in the business, "bad sample in, bad sample out." It is never usually the test itself that does not work; it is usually the sample that you use to actually perform the test. This statement is a broad statement that applies to laboratory tests, point-of-care tests, in fact any tests that are done routinely, and it does not just apply to saliva specimens, this equally applies to blood, urine, hair and any other bodily samples used for testing purposes. If you get a poor sample to start with, then you are never going to get a good result at the end of the day. What has happened in the past is much of the technologies that were used to collect saliva were not providing an optimum specimen to get the right result at the end of the day. Maybe it is our trade secrets, maybe it is part of our patented portfolio, but we do believe that we have overcome

this particular problem and can provide very good samples to use for downstream processing, so that the chances of getting good results are significantly improved.

CEO CFO: What do you see a year down the road?

Dr. Slowey: We are launching a very new tool for RNA and protein collection right now, which, as I mentioned earlier, is probably targeting a new frontier in diagnostics. That will probably become a flagship product for us, and drive the business in a completely different direction, because it is likely to attract the attention of many big pharmaceutical companies out there who are currently developing RNA-based therapeutics. We will continue to innovate, and develop new tools as the market dictates. We have two new devices that were directly the result of customer requests that we received and these should be ready for market in the next few months. We have functional devices, but occasionally a customer will come along and say, "We like your device, but we need it to do this particular function for our customers. Rather than collect a specimen here and then send it to a laboratory, we would like the patient to collect it at home. Can you modify your device accordingly?" We usually answer positively, as long as there is an agreement to move forward in a collaborative manner, and also if there is agreement to purchase the product in the future. Based upon this type of agreement we will make the necessary changes and bring a new configuration to market. My sincere hope is that we will continue to innovate, and produce tools that the market is looking for right now, that can be used to improve global health.

CEO CFO: What surprised you most as the company developed?

Dr. Slowey: That we actually got as far as we are without any outside funding, because we have never re-

ceived any external funding to this point. It has all been self-financed so far. There have been some very difficult times; the last 4-5 years have not been easy, but the last twelve months have actually been a lot easier than the previous four years. When we first started the Company, the intent was to develop one or two products. It is now very surprising to me looking back that we have the growing portfolio of products that we have right now, but we are very glad that we have got to this point to be honest.

CEO CFO: Why should Oasis Diagnostics® stand out to investors and people in the business and medical communities?

Dr. Slowey: The breadth of the tools that we have, and the functionality of our products. We collaborate with many groups, and we try not to toot our own horn; we would rather people on the outside tell us what our strengths and our weaknesses are. If you look through our list of collaborative partners, which includes people like Dr. David Wong, UCLA [the former Head of the Human Saliva Proteome Project], who is in my opinion the godfather of saliva, and who was recently asked to speak to the heads of Congress on the status of salivary diagnostics in general, and a very, very nice person to boot, we are extremely fortunate. In addition, we have people like *Chamindie Punyadeera* at the University of Queensland, Australia, and Dr. Charles Streckfus in Texas and many others as collaborators. We really do have many really well respected individuals in the field, who are not only well versed in salivary diagnostics, but also undoubtedly key opinion leaders in the area. When thought leaders with the credibility they have are telling you that you are on the right track, this is really the motivating factor that keeps us moving forward in a positive direction.