CEO CFO

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With a New Line of Diagnostic Tools and Services Business to Augment their IVD Business, SQI Diagnostics Inc. has Created a Great Deal of Demand by Significant Customers - Representing Increased Volumes of Business Going into 2013

Healthcare
Diagnostics
(SQD-TSXV)

Andrew Morris, M.Sc., MBA
Chief Financial Officer

BIO:
Andrew joined the SQI Diagnostics team in 2004 as its CFO with the key deliverables of growing and enhancing the Company's financial position and corporate strategy. Andrew adds a well-rounded experience set gained in leadership roles in the areas of medical research, capital markets and corporate finance.

Prior to joining SQI, Andrew led the Corporate Finance Life Sciences group at Ernst & Young, advising private and public companies on a variety of business strategy and financial matters including private equity offerings, mergers and acquisitions, and strategic alliances.

Prior to that, Andrew gained considerable transaction experience while working in senior corporate development and finance roles in high growth and start-up companies. He also gained valuable capital markets and equity research experience at Scotia Capital, while covering companies in the Healthcare and Biotechnology sector.

Andrew's background also includes eight years conducting research in the area of human performance enhancement at the Defense and Civil Institute of Environmental Medicine.

Andrew holds an Honours Bachelor of Science from the University of Western Ontario, a Master's of Science from the Faculty of Medicine at the University of Toronto, and a Master's of Business Administration degree from the Rotman School of Management at the University of Toronto.

Company Profile:
SQI Diagnostics is a life sciences company that develops and commercializes proprietary technologies and custom products for advanced microarray diagnostics. Our goal is to become a leader in the development and commercialization of microarray and multiplexed diagnostics by offering our customers a comprehensive "turnkey" solution that increases the efficiency and ease of diagnostic testing and test development.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Morris, would you tell us about SQI Diagnostics?
Mr. Morris: SQI Diagnostics is a technology company focused on diagnostic technologies, and multiplexing technologies in the healthcare space. We are a fully integrated life sciences, diagnostics, and products company. We are focused primarily on multiplexed diagnostics in what would broadly be defined as the immunology space. We have two principle lines of business, the first is a fully integrated in vitro diagnostic business where we have cleared and approved products, cleared in FDA, licensed by Health Canada, and CE-Marked products. These are multiplexed products to aid in the diagnosis of a variety of autoimmune diseases. We also have a fully integrated, fully automated, scanner and analyzer, which is a robotic system to process the multiplex tests. The second principle line of business that we are engaged in is the Diagnostic Tools and Services business, which you can fundamentally think of as Custom plexing, or OEM business. In this, we use our multiplexing technology and apply it to other companies' or other laboratories' content and provide to them multiplexed diagnostic kits and our systems to run those kits on.

CEOCFO: What is it that SQI can offer that other companies in the same space may not provide?

Mr. Morris: In multiplexing, that is kind of the broad application of the technology, there are two fundamental types of multiplexing. One is focused on DNA testing or molecular testing and one that is focused on other kinds of tests. We are on the other side. We fundamentally look for proteins and antibodies in the blood. There has not been a fully automated and multiplexed application for the detection, measurement, and analysis of proteins and antibodies. That is what we do. We multiplex in the protein and antibody space. If you want to think about it on a disease basis, we have fully automated systems and products to aid in the diagnosis autoimmune diseases such as rheumatoid arthritis and celiac disease. We also have a pipeline of products for other diseases such as vasculitis and lupus in our development pipeline. When you are looking at the one thing that we do, what we really believe is that the market is looking for solutions that are multiplexed, but also fully automated because there are other kinds of multiplexing applications out there which are not fully automated and that aren't applied to the protein antibody space.

CEOCFO: In the protein space, is the fully automated system cheaper, more accurate, or both?

Mr. Morris: It is a general statement about a lot of different performance aspects of a particular assay, so when you get your test approved, the benchmark is that your performance is at least equivalent to the predicate assays that are currently in the market or better. On some of the performance metrics we are the same as, and on some of them we are better. We are definitely faster and cheaper from an overall cost of delivery perspective for the customer because of the multiplexing and automation - In our key markets, it is hard to make overreaching statements that apply to everything, but a large predominance of all the testing that is done on what we would call a manual or semi automated basis. There is not a single system in our markets, that we are aware of, that is completely load and go, where you can put in a consumable from a kit, the reagents in separate bottles, press a button, walk away, come back, and get a multiplexed results. That is what our systems do.

CEOCFO: Are your potential customers aware of SQI and your capabilities, or is it still getting the word out?

Mr. Morris: We are still at an early stage in commercialization of our technology. One of the things that we have to do, which is the core focus of the business on the in vitro diagnostic side or the approved and regulated testing side of the business, is to create more tests that are approved. This opens our market to more customers. Whereas we have a couple of tests approved in Canada, United States, and Europe, we are continually working on increasing the number of tests that we have that are approved or cleared or CE-marked, depending on the jurisdiction you are in. That itself creates awareness. We have a great partnering program with what we believe are the thought leaders in the various disease areas that we are developing tests, and co-publishing with them creates awareness, but we have a limited sales focus right now because of our limited menu. Growing both our menu and sales presence are two things we are in the process of doing right now.

CEOCFO: How do you decide what you would like to work on in terms of test development?

Mr. Morris: Ideally, like everyone else, we do it on a return on investment of a particular assay, test, or customer. We have two lines of business. On the in vitro diagnostic side, we first looked at the autoimmune disease market because it had some key elements that we though appealed to the use of our technology: multiple antibodies used for diagnosis, automation and current payer models for reimbursement. There are multiple things that a clinician will look for in the blood, and multiple proteins and antibodies to help him or her make an informed diagnosis. If you take the top ten autoimmune diseases, you have an average of about eight different plexes, or eight different things that a clinician would look for in the blood, the lowest being vasculitis, in which there are currently about three antibodies. We also believe the number of markers will grow a bit in the near future, up to lupus where we have a twelve plus panel in late-stage development where there are twelve different things that clinicians look for to make a diagnosis. Autoimmune disease is good because of multiple biomarkers. These are esoteric kinds of tests, which are technically a bit harder to do than blood sugar or diabetes type test or routine chemistry; being harder to do means there is more available margin. Largely in the autoimmune disease testing market, the testing volume is aggregated either at reference labs or centers of excellence. That lends itself to the appeal of the automation of the technology just the requirement for a higher volume on testing.

CEOCFO: What about the customplex side?

Mr. Morris: It developed a bit naturally over the years with our multiplexing technology being successful from a technical perspective, and being able to determine and measure concentrations of various proteins and antibodies. We have been approached by other diagnostic companies or research labs asking if we can take their content or biomarkers that they had an interest in and multiplex them on their behalf. Earlier in our growth cycle, we focused on our content in the autoimmune disease market, but as we progressed and got a bit more mature, we saw an opportunity to take other companies' content and apply our mulptiplexing technology. We started marketing that as a product in the early calendar year 2012, and we reached out through some of our technology partners. Then we did some direct selling where we focused on customers who it appeared had tried to multiplex some of their protein antibody content and maybe had not been as successful as they wanted to be. We discussed our technology with them. Those customers are either large reference labs who do some of their own content development work and test development work or contract research organizations who do a lot of product development on behalf of their customers, the drug development companies, for screening or

measuring large volumes of patient samples during the various phases of clinical trials. For us that would be more specifically in the area of immunogenicity testing. The third segment would be diagnostic companies who have protein antibody content or tests that are currently all singleplex tests that they want to multiplex.

CEOCFO: Would you tell us about the agreement with Integrated Science in Australia, and is that a typical agreement for distribution?

Mr. Morris: It is our first one. Integrated Science reached out to us. They had seen our approvals in Canada. They are one of the largest distributors of immunological testing products in Australia. Integrated Science had seen our Health Canada approvals for multiplexed celiac and rheumatoid arthritis assays. There is a reciprocal agreement between the health protection branch equivalent in Australia and Canada to not accept outright, but to make the review process for approvals of diagnostic products much easier between the two countries. If it is approved in Canada, then it is a relatively easy process to get that same technical file approved in Australia for distribution and marketing, so we believe that Integrated Sciences saw an opportunity to be the first to bring our multiplex autoimmune disease testing application into Australia. They did their due diligence on our system, thought that it was pretty appealing, and that they could make good headway selling that in Australia.

CEOCFO: Would you tell us about the market opportunity for your industry?

Mr. Morris: If you talk to people in our industry, the end-users or our target customers. You will hear two things when you mention the word multiplexing. I am specifically talking about proteins and antibodies because multiplexing has been around for quite a while in the DNA space, and we believe from a technical perspective, that is a much easier challenge to overcome. What industry-people might tell you is that a lot of people come to them talking about multiplexing but nobody really has pudding proven technology. We believe that the market is very eager to obtain working and approved multiplexing technologies for their business. We believe there is a very good market opportunity. There is also a very large nascent opportunity in companies who have tried to multiplex protein and antibody detection and measurement, and have not been successful, and there are lots of interesting bits of information to support that hypothesis. There are companies in the US or Europe who provide print for hire services for the proteins and antibodies on a variety of substrates on a contract basis. These are companies that came out of spotting DNA, so they saw there was an opportunity to try this for proteins and antibodies. You will not find approved protein and antibodies on micro arrays, which is the technology that we use in our approved products. The conclusion that we drew with obviously talking to target customers is there is a big need, there is this nascent demand for multiplexing protein and antibody diagnostics. The lack of success in achieving approved tests is the key hurdle to adoption of the technology. We believe there is, to an extent, the notion in the market, that we could not do it, then it is hard to believe that anyone else can. Over the last couple of months, we have had a number of, fairly significant OEM opportunities that have come through SQI to conduct due diligence to qualify our ability to multiplex protein/antibody-based test, and several to the point of giving us challenged blood panels that they have provided to see how this blood would perform on our system. These were done on cleared or approved tests, so we would expect them to work well, and they did not surprise anyone in terms of the results. These things have all come through positively. We believe that we created a demand for our customplex business, and we believe there is a lot of demand for our pipeline of regulated tests, so with the growing menu, that demand becomes more commercially feasible. We are at the turning point what of we believe in terms of having a menu on the IVD side that will support our customers and our company's growth. On the OEM and customplex side, we have just started getting through the diligence process with a number of customers, but it has all been very responsive and positive that the demand seems to be real, and that there is a big benefit driven to our customers from SQI's multiplexing technologies. The benefits are effectively the cessation of the requirement to use labor in running these tests, and to get many more results for each unit and test effort that you put in. If you use a lupus example, depending on the lab you are, you use approximately twenty-four kits of lupus ELISA kits to get the same number of "billable" result as you would from one of our kits on an equal number of patients samples basis. Each one of those ELISA kits could take three to four hours of labor to run in the lab, and our system would run those equivalent 24 kits on one of our microarray kits in approximately three and a half hours with approximately twenty minutes of labor input.

New investors are able to invest at a time where we have initiated a new line of business to augment our IVD business with the Diagnostic Tools and Services business, and, where we believe we have created quite a bit of demand and a robust sales funnel. We believe these are significant customers who we believe represent significant potential volumes of business to be won in the next twelve months. - Andrew Morris, M.Sc., MBA

CEOCFO: So it is a significant difference!

Mr. Morris: It is a significant difference. When you talk to labs nobody really pushes back on the analysis of the labour savings. And, in this analysis we are only counting the hands-on time when we are comparing to the ELISA testing, and there is a lot of idle time consumed in an ELISA process, waiting for things to incubate and to be run through one of the processes. With our system, it is a pure load and go system. You load the kits, walk away, and you come back three and a half hours later; all

the data has been analyzed, and all the results are available.

CEOCFO: What is the financial picture like at SQI Diagnostics today?
Mr. Morris: We did announce two tranches of a private placement recently, so we have improved our balance sheet quite a bit. From a cash/burn timeframe perspective, things are also much better than they were a couple of months ago, and we believe that with the sales funnel, we particularly have in our diagnostic tools and services business that we can significantly extend that runway based on customer appetite for our DX tools, services, and IVD products.

CEOCFO: Why should investors pay attention to SQI Diagnostics today?
Mr. Morris: With SQI, the value to the potential investor is a mirror image of the value that we drive to our target and existing customers in which we save them a lot of money. That drives earnings per share to their bottom line. SQI's economics are similarly affected in that almost each dollar that we drive to our customer's bottom line, we drives a gross margin dollar to our top line. We believe that our shares are trading prettycheaply right now, compared to the fifty-two week trading history. New investors are able to invest at a time where we have initiated a new line of business to augment our IVD business with the Diagnostic Tools and Services business, and, where we believe we have created quite a bit of demand and a robust sales funnel. We believe these are significant customers who we believe represent significant potential volumes of business to be won in the next twelve months.

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