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In conversation with Christopher Moreau

March 2, 2010 by [leonardzehr](#) · [Leave a Comment](#)



As CEO of Miraculins (TSX-V:MOM), Christopher Moreau represents a new breed of biotech executive. No PhD in chemistry for him. Rather his background is in financial services, business development and operations management. But 13 or 14 years ago, Mr. Moreau learned quickly the workings of medical science when his father was diagnosed with Non-Hodgkin's Lymphoma. As he recalls, he took a two-year sabbatical from work, immersed himself in understanding the illness and treatment options, and became comfortable talking to physicians and translating that disease information for the family. In fact, he was so convincing and knew so much about what he was talking about that one clinician mistook him for a medical doctor when he tried to have his father enrolled in a clinical trial at Stanford University. Recruited to Miraculins in March 2006 to be VP for business development by co-founder Dr. Albert Friesen, Mr. Moreau became a quick learner again, absorbing the company's technology like a sponge before moving into the executive suite in February 2007. In this exclusive interview with BioTuesday.ca, Mr. Moreau discusses Miraculins' new business strategy, the outlook for its diagnostics and immunoassays, and its breakthrough partnership with Inverness Medical Innovations (NYSE:IMA).

Let's begin with a brief historical sketch of Miraculins.

It was founded eight years ago and was originally using mass spectrometry to look for protein biomarkers in the area of prostate cancer that would prove to be an improvement over the PSA test. It initially found five protein markers and had pretty good clinical results that sent the stock price up to a high of around \$2.20 in 2005 on the potential of that giant market. Confirmatory studies of the five biomarkers reduced the panel to two biomarkers that, at the end of the day, performed similarly to PSA in screening, so we realized that we were not going to replace PSA testing. The markers continue to show promise in more select utilities but further testing is required.

That was about the time I joined Miraculins as VP of business development. It was a tough time to get investors excited about biomarker discovery. And I wasn't comfortable with the risk of relying only on mass spectrometry and basic discovery. About a year after I joined the company, the President stepped down and the board promoted me to President and CEO. And the first thing I did was begin to seek ways to improve the company's business model.

What are the elements of the new model?

In June 2008, we announced a shift in our business model that moved us further down the diagnostic assay development and commercialization pathway. Our business plan now focuses on in-licensing or acquiring and developing diagnostic opportunities that have completed early-stage research and address unmet clinical needs. The bottom line is we have moved away from basic research and discovery to focus on diagnostic development and commercialization.

How did the new business model evolve?

I had pitched Abbott Labs on our prostate technology, which had advanced from those early days, but Abbott decided it was too early for them. About a month or two later, I received a call from Dr. Stephen Frost, who I had met at Abbott, and whose job was to evaluate oncology assays that Abbott might license or acquire. He had just left Abbott after a 15-year career and was now working as a consultant. I hired him to review some of our additional data and he liked the work we had done. We began to discuss an idea that he had, which was to set up a division that specialized in acquiring and advancing early technology.

Diagnostics is traditionally broken down into four elements: imaging, genetic testing, medical device/algorithm and immunoassays/biomarkers, the latter of which is Dr. Frost's background and where Miraculins had hung its hat. So that's how it evolved.

How is the new strategy working?

We signed our first deal in October 2008, licensing rights to 35 protein biomarkers from Toronto's Mount Sinai Hospital in maternal health and, specifically, for a disease of pregnancy called preeclampsia. It has an incidence rate of 5% to 7%, and there is no diagnostic test for the disease. The company that can develop an effective diagnostic will be looking at potentially screening all pregnant women. So the market is significant.



Preeclampsia is believed to be caused by some sort of low oxygen condition that occurs at the time of conception. Arteries that provide blood flow to the placenta do not form properly, which can cause a cascade of events and cause heart attack, stroke and organ failure in the mother. It's serious enough that when a case is confirmed, the only known cure is delivery of the child and removal of the placenta.

So the Holy Grail is finding a marker that's diagnostic at the end of the first trimester or the beginning of the second trimester. After a few months of acquiring this technology from Mount Sinai, we had confidentiality agreements in place with most of the world's biggest diagnostic firms, who literally came knocking on our door.

What should investors know about your relationship with Inverness?

They were excited enough about the preeclampsia technology to step up to the table and fully support our R&D. To have fully advanced those 35 biomarkers would have cost us between \$7 million and \$8 million and would've taken us years. To have a big partner like Inverness support all those costs, and drive it through on a much more timely basis, is a very significant deal for Miraculins. It would have been difficult for us to go out and raise \$7 million with a market cap of only \$2 million at the time. So our deal is a validation of our business model, our capability to acquire something, build value and partner it out. And it reduces dramatically the risk of this program.

Inverness also wanted to put a sublicense agreement into place. It allows them to execute a sublicense on any of those markers at any time. And that's going to be really significant event for Miraculins because it will be a

signal that they have done all the work they need to do on one of those markers or a panel. And they're now ready to advance it to commercialization. Under our agreement, once Inverness triggers a sublicense, it covers all the costs to take it through to first sales.

What's the market opportunity?

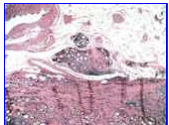
This market has been projected in the billion-dollar range in annual sales worldwide. We've already received an exclusive option fee from Inverness, so we've left the realm of pre-revenue and will have revenue this year. Full regulatory approval and first revenue from commercial sales are potentially two-to-three years away. While we're restricted from discussing terms of the deal, whenever Inverness exercises its option to license any of the biomarkers, Miraculins will receive additional fees, developmental and commercial milestone payments and royalties on sales.

You haven't given everything away to Inverness though.

We retained rights in two separate areas. First, we retained rights to sell non-automated ELISA kits, which is an "enzyme-linked immunosorbent assay" test. Basically, ELISAs combine the specificity of antibodies with the sensitivity of simple enzyme assays along with an additional process that causes a colour change. This allows for sales of "research use only" (RUO) kits, which are not competitive with Inverness at all. In fact, we have plans this year to release a ROU kit for one of the lead markers in this group of 35. It's a protein called endoglin that has been widely studied and is a diagnostic for preeclampsia in the second trimester. It's not a perfect marker by itself, but it can be used to designate risk in patients. In our view, it's a lot better than blood pressure and protein in the urine which are really just symptoms of the condition. So, we have been working all along on the potential of launching "analyte specific reagent" (ASR) sales in the U.S. based on endoglin, where we would sell clinical grade reagents to reference laboratories and they would develop and sell internal tests based on the reagent with less FDA regulation. We are in discussions with some large clinical reference laboratories in the U.S.

Since much of the preeclampsia work is being conducted in-house at Inverness, we've freed up a lot of our laboratory focus. And we are now looking to in-license one or two additional technologies and continue on with our new business model.

What's the clinical status of your prostate technology?



After we found out that our biomarkers were behaving similarly to PSA, we did another study and found that our test can distinguish between high-grade and low-grade prostate cancer. Specifically, our test is effective in determining whether or not you have high-grade prostate cancer. Why that's important is that once prostate cancer is confirmed using biopsy, 20% of men tend to be high-grade and 80% low-grade. High-grade prostate cancers are the most aggressive and need aggressive treatment. But if you have low-grade prostate cancer, there is a treatment approach called "active surveillance" or "watchful waiting", where you can watch the disease and don't necessarily have to be aggressive in treating it.

Our test could also be used to help determine when low-grade prostate cancer is changing into high-grade. And that could be an alternative to putting men through biopsies. That's been our focus. We want to continue doing additional studies, but for that test, I'm now looking for a major partner. And we are in discussions with a couple of large diagnostics companies.

We would also like to launch a RUO kit in the near term, which would give research scientists interested in this area an opportunity to start using our test, doing research and publishing data, as a way to develop awareness in our biomarker. It's a good strategy, especially if you want to develop some interest from partners. We've invested seven-to-eight years in this and now it's time to get a big partner to step up and work on it with us.

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Christopher J. Moreau

Title:

President & CEO, Miraculins Inc.

Born:

November 16, 1964.

Education:

Attended University of Manitoba, Bachelor of Arts Program 1982 – 1984

Career Highlights:

Vice President Operations for Short Court International, VP Sales for IMI Winnipeg, President of Advansis Capital Corporation, Winnipeg

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