

Interview: Michael Cloutier, President, InterMune, Canada



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Michael Cloutier, President of InterMune, elaborates on the challenges of navigating the Canadian healthcare system as a small pharmaceutical company, and highlights some methods by which Canada can provide a stable environment for Canadian companies to grow.

You have had an extensive and varied career, with positions in the Canadian Diabetes Association, Critical Outcome Technologies, AstraZeneca, Pharmacia, and Searle. What have you been able to bring from all these experiences to your current position as head of InterMune Canada?

Being able to bring leadership from a very broad perspective is advantageous as it allows me to accelerate the tremendous work that has already been accomplished in InterMune Canada. Most importantly, I have to ensure that Canadians living with IBF are going to be best served with InterMune's new technology, the first and only product available for mild to moderate IBF in Canada. I have to leverage all of my experiences in a way that helps guide InterMune Canada to be as effective as possible. As a smaller organization, InterMune can move more quickly than slow-paced, bureaucratic large companies. The downside of course is that the entire focus of this organization is really on one product in one area, and therefore does not have the flexibility or latitude to move within two or three different therapeutic areas with different products.

Nevertheless, InterMune has a remarkable opportunity for people with IPF who previously had no viable solution. I hope to continue bringing leadership to a great group of people that were already

succeeding.

Given Canada's capital access issues, would flow-through shares be useful for a company like InterMune and should the government be providing more of such incentives?

Flow-through shares would be extremely useful for Canadian based start-ups. InterMune Canada does not really need local capital as it is funded internationally. However, the company does need tax incentives for investment in areas in which the company actively partners. InterMune needs to partner with public payers to ensure that its technology is delivered to those who most need it and can least afford it. Canadians are fundamentally conservative, and I think many Canadian investors have historically not seen a rich return on investment in biotechnology; Therefore they are reticent, given the volatility of the market today. There is money to be invested in Canada, but it is not necessarily going to biotech because of investors' unfamiliarity and consequent hesitance in the biotechnology space.

What does Canada need to do to ensure that the gap between research and commercialization is filled?

Canada needs to support products that are commercialized, and people will see the benefits through the economics of investing and realizing reward. Equally important is the perception of Canadian innovation turning into viable solutions for people living with medical conditions and diseases. When investors start to move away from investments that are perhaps less socially acceptable or politically correct, then the industry may have an opportunity to demonstrate enhancing the quality of life for people while garnering economic value. The government can support the discovery of molecules and utilization of innovation by expediting review times, shortening the time for regulatory processes, supporting clinical programs with tax incentives, and then ultimately for smaller companies, to implement solutions like flow-through tax credits, which have literally made other industries viable for investors.

In turn, what do you think is going to be necessary to keep those companies here in Canada as opposed to being sold off to some other multinational?

There may not necessarily be a way to keep companies Canadian. However, the purchase of small companies by larger organizations is not necessarily detrimental, if they can drive greater viability from the asset and ultimately help more people. I think Canada should be concerned about the unemployment and process of reemployment that this system brings, especially since unemployment rates for highly trained professionals are so high today. Companies like InterMune

must be upfront about the volatility of their business to new employees given the buyout potential of many companies. Having one platform or product in a smaller organization can be a great success or a great risk, depending on the situation.

It seems as if Canadian entrepreneurs enjoy the process of building and selling a company and then starting over again.

Many look at the Canadian generic industry's strength as a result of government policy and early stage investment, and perhaps we could apply an equally supportive view towards the upstarting biotech innovation industry in this country. The general public will not believe that the government should help large multinational organizations become more profitable. Some people will always believe that big pharma is bad pharma, but I do believe that there is an opportunity in this country to convince the general public that upstart pharma or biotechnology companies, who create jobs for young scientists and value for patients, are viable in terms of either continuing with their mandate or becoming part of an entrepreneurial exercise. Successful serial entrepreneurs in the scientific community who re-invest their own money for new ventures are healthy for the industry. The government must focus on this kind of activity, especially since so many start-ups struggle to recover from debt.

What is Canada's advantage?

I think people have a very strong respect and opinion of the pharmaceutical business in Canada within the industry. I think that many other parts of the world see Canada as a sophisticated marketplace where there is still much to be learned. We have some of the world's leading experts in any therapeutic class, as well as some of the best patient advocacy and support organizations worldwide that are seen as being leaders. Canada has tremendous business executives and employees. This country is a great place to observe and we have the advantage of being out ahead of the biggest market of the world, and that increase in attention has been good in terms of supporting local Canadian needs. The Canadian population is winning as a result of that.

How has the Canadian market reacted to InterMune's promotion of Esbriet, the only approved medicine for idiopathic pulmonary fibrosis?

Currently, a substantial number of Canadians are on the product, indicating the market reacted positively. Because the product is only reimbursed in the private system, there is presently a limited market size. It is difficult to capture the full extent of a marketplace without public reimbursement, because historically healthcare professionals have not thought broadly about a therapy until it is publically reimbursed. InterMune is a good corporate partner and citizen in terms

of public education about the existence of IPF, its available solutions, and whether those solutions are appropriate for individual patients. InterMune is a good partner to healthcare professionals by assisting with the delivery of care, though education and support for interstitial lung disease clinics. InterMune is also a very good partner to the government in terms of finding solutions to bring Esbriet to those who need it in an economically appropriate way. The government needs to spend its money carefully and InterMune can help to negotiate solutions for this medication across Canada using the best scientific evidence available.

Esbriet was approved in Canada and the EU before it was in the US. This is unusual in that specialty drugs are often very hard to get into the Canadian market. Why is Esbriet taking longer to get into the US, where the product is still in Phase III clinical trials?

Molecules have historically been available in Canada before the US. In the case of Esbriet, the FDA did not believe that Esbriet's data submission was sufficient enough for approval, whereas the regulatory authorities of Canada deemed Esbriet to be acceptable as well as those of Europe and Japan. It is simply a matter of different decisions about data being made in different marketplaces.

What is the strategic importance of InterMune Canada to the organization's operations?

InterMune's results will speak very positively to the viability of its product in the US and in other markets. The company is performing exceptionally well in terms of exposure to healthcare professionals, value demonstration, and subsequent prescriptions. Despite a very limited market due to lack of public reimbursement, InterMune has started strongly in the private and cash-paying marketplace. We are excited at the prospects of being able to expand to the total market and providing even more patients with Esbriet. I think our global headquarters have perceived the way that InterMune Canada is commercializing, marketing, and promoting Esbriet as being a strong model.

Can InterMune serve as a model for other, similar companies?

The method by which InterMune is marketing and commercializing this product can serve as a role model. InterMune is using a specialist distribution process through a small network of pharmacies that deliver the product directly to patients. The partnering of healthcare professionals with nurses in a third party organization that helps patients with solid experience in the product is a great learning model for companies worldwide. I think InterMune has a great model for partnering and creating exceptional value for people affected by IPF.

What is your strategic vision for the affiliate?

In the short term, we have been able to partner effectively with government to obtain public funding for Esbriet. We have also advanced the employment of good scientists, clinicians and researchers, developing opportunities for the Canadian scientific community. InterMune has also participated in global programs around its pipeline development, both in terms of ongoing work in fibrosis and pirfenidone. In the next five years, InterMune Canada will be a larger organization, employing more people, supporting more Canadian scientists, clinicians and researchers, and providing value to a far greater number of Canadian patients with IPF and perhaps other therapeutic areas.

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