

# Interview: Dr. Philippe Douville, President and CEO, Milestone Pharmaceuticals, Canada

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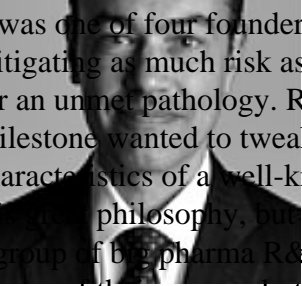
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*Dr. Douville talks investment, the company's role in R&D in Canada and their plans for some of their future products.*

**You founded Milestone Pharmaceuticals in 2005, having founded Galileo Genomics and Allosteric Pharma. What were the main objectives in founding Milestone?**



I was one of four founders of Milestone. The idea was to start a new company based on the concept of mitigating as much risk as possible by using clinically validated mechanisms of action that could be adapted for an unmet pathology. Rather than bringing in novel but untested university science like many companies do, Milestone wanted to tweak existing mechanisms and use focused medicinal chemistry to change the characteristics of a well-known molecular class and adapt it to an unmet need. At its outset, the company had this philosophy, but no molecules or ideas. In order to raise money, we formed a "drug hunters" club, a group of big pharma R&D executives who had decades of experience and who had great ideas during the course of their careers but were never able to fully develop and explore them within a big pharma setting. We held a one-day workshop where each executive presented an idea based on a clinically validated mechanism of action followed by a general discussion and rating of each project. The winning idea was to create a short acting, calcium channel antagonist to treat transient-cardiovascular diseases, such as arrhythmias and stable angina. This was the idea of ex-GSK Jeff Leighton, who was Vice President of Global Pharmacology and chairman of GSK's cardiovascular programs.

**Many biotech companies in Canada are built to be sold, which does not contribute to economic development in the country. How might a restructuring of the biotech organization help to ensure that these companies here maximize economic output?**

This really depends on the investors that back a particular company. There are huge barriers to entry involved with entering this industry because of the money needed to develop drugs, so as a small company you must attract VCs. Many VCs are not interested in building another pharmaceutical company, but would rather develop a good project or idea and then sell it in order to ensure a return on investment to themselves and their own investors during a predetermined time horizon. By contrast, other investors prefer their companies to develop their molecules all the way through to market entry. Milestone follows the first business model. Although it would be nice to build a Canadian pharmaceutical company that would not be sold, my focus is on our shareholders. We will develop our lead molecule, MSP 2017, through early phase clinical trials and patient proof-of-concept and then find a pharmaceutical or specialty pharmaceutical partner to either acquire the company or continue developing the molecule through a licensing agreement. Thus, the change in partnership creates value for us. Eventually, the molecule itself will be developed and sold in major global markets including Canada.

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**Access to capital is the big issue for biotech companies in Quebec, and venture capitalism is not always the most reliable source of funding. What is your assessment of this? What advice might you have for a biotech company looking for VC funds?**

The world has changed. Before 2008 it was possible to raise less than \$5 million with a discovery idea or compound, and then raise more money to finish preclinical studies and enter clinical trials. Since 2008, financing is an even greater risk than it was previously and you need to raise enough (\$15-20 million) to be able to get to a meaningful inflection point, i.e. Phase II trials to attract a partner or raise another round of financing. If the partnering environment is not favorable, you want to be sure that your investor syndicate is willing to continue development and invest in a Phase III trial. Therefore, my advice to an entrepreneur is to bootstrap as much as possible in the beginning to build up a compelling "story" before going to see investors. You need to build up a technical package, understand market and reimbursement issues, the regulatory environment, the competitor landscape as well as how to develop your molecule all the way to approval, regardless of whether you will go on to do a phase III or partner out the asset, as well as a myriad of other things. You must then raise enough to complete Phase II trials. You have to demonstrate to VCs that you are serious and understand the industry and the entire development path of your molecule. In other words, you really have to do your homework because VCs are even more savvy in this post-2008 world. Many VC funds have disappeared, and while there is more money per project, there are fewer projects being funded because the hurdle is much higher now.

If you are new to the biotech game, don't hesitate to get advice from experienced biotech entrepreneurs and CEOs to improve your chances of successfully raising money from investors.

**To what extent does Milestone Pharmaceuticals play a central role in the Canadian R&D sector?**

Milestone is under the radar right now. The company will emerge when it starts clinical trials later this year. I do not want to sell Milestone too soon. I want to ensure that when I start corporate development activities that we have human data. Timing is everything and my objective is to develop Milestone in the best way possible to maximize value for Milestone's shareholders regardless of its geographical location.

**Milestone has raised \$17 million in venture capital since 2006. How is this investment allocated throughout the structure of the company?**

The fact that Milestone is a semi-virtual company allows it to efficiently allocate capital. It doesn't make sense for a one-product company such as ours to build up specialized teams of scientists for a few months and then dismantle the team a short time later. Rather, Milestone is taking full advantage of a great CRO infrastructure. This gives us the freedom to go anywhere in the world to tap into this expertise. It allows the company to efficiently allocate our precious acquired VC capital.

**How has this investment translated itself into terms of revenue generation for the company?**

At the moment, there is no revenue until Milestone is acquired or the project is licensed out. When the partner develops and brings the product online, there will be developmental milestones payments, and royalties as a percentage of sales and so forth.

**MSP 2017 is a novel and potent short-acting calcium channel antagonist in preclinical development for the treatment of PSVT that works at home in the unmonitored setting. What is the potential of this drug when it becomes commercialized?**

MSP 2017 will fill an unmet need for patients who have certain forms of moderately severe arrhythmia and experience acute episodes of paroxysmal supraventricular tachycardia (PSVT) every so often. These unpleasant episodes can be likened to a bad migraine or an attack of stable angina. MSP 2017 is being developed as an intranasal spray that would terminate the arrhythmia episode within a few minutes. This would eliminate the need to visit the emergency room and IV administered adenosine. Many patients are treated with

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ablation, which is an invasive cardiac procedure. This is frightening to many patients, and a nasal spray would be a much better option for many to manage their episodes. While some countries have higher rates of ablation than others, there is a need for this in the G7 industrialized countries and other parts of the world. Ablation rates in the BRIC countries, for example, are lower than the G7 countries. The potential for MSP-2017 in these countries could be very attractive, and this will be explored in more depth with additional market research. We believe that the global market potential for MSP-2017 is over a billion dollars per year.

**What is your short term plan for future expansion?**

Our short-term plan is to continue to evolve the company as it prepares to go through clinical trials. This means working with new CROs and with new clinical advisors to ensure further development.

**Are you looking to create more partnerships?**

Not at the moment, but that will start once clinical trials begin later this year. This will be a one to two year process. I plan to bring in business development expertise to aid finding a partner for Milestone. This will start at the end of 2013, coinciding with the start of our clinical trials.

**What is your strategic vision for Milestone Pharmaceuticals as a flagship Canadian biotech company in the next four to five years? What would like to have personally achieved in that time as well?**

Very simply put, my vision is to successfully complete our clinical trials followed by a successful partnership.

**What will be your final message about Milestone?**

Milestone has a unique product that fills an unmet need based on a clinically validated mechanism of action. We have attempted to mitigate as much risk as possible. It is a great and innovative project.

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