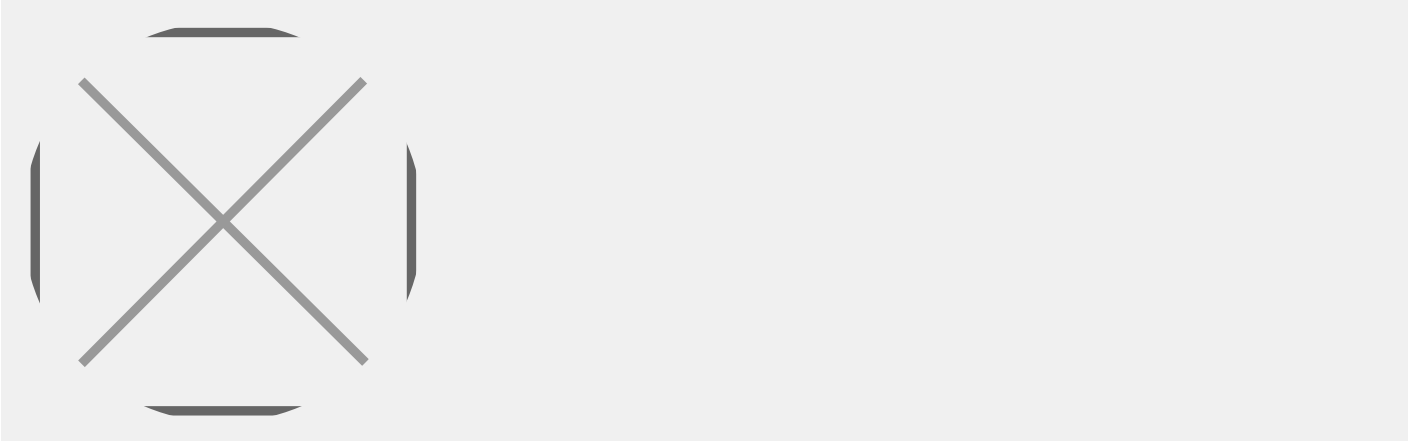
Interview: Roberto Bellini, President & CEO, Bellus Health, Canada



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The CEO of Bellus Health outlines his strategy since 2010 to change the focus of the company from Alzheimer's to a niche disease, AA amyloidosis, as well as the strategic shift towards becoming a semi-virtual model company. He also considers the importance of creating global links to capital as a biotech company, and the challenges of partnering to commercialize products as a company focused on drug discovery.

Prior to joining Bellus Health, you were responsible for the investment and operational activities of Picchio Pharma. What were you able to bring from that experience upon joining Bellus Health?

Picchio Pharma was the family-holding company that was created to invest in biotechnology after the sale of Shire Pharmaceuticals in 2001. Therefore, Picchio is the Bellini family office vehicle to invest in the biotech space. My primary mandates there were deployment of capital and portfolio management. Picchio has made a number of investments in the space, one of which is Bellus. The other important investments are Virochem Pharma, which was purchased by Vertex Pharmaceuticals in 2009, and Klox Technologies, a medical device company focused on dermatology. I brought my experience in accessing capital to my operational position at Bellus. Finding capital to move projects forward is a key part of the business, and when I first joined Bellus, at the level of vice-president for business development, my first mandate was to find capital for one of the company's projects.

What were your initial objectives upon becoming CEO in 2010?

When I first joined, Bellus was more diversified and had a large structure with over 50 employees. The company was undertaking large studies in Alzheimer's disease using a full-scale team. With the support of shareholders and the board of directors, we changed the strategy and focus of the company. We decided to focus on a more targeted niche indication, such as amyloidosis, which is the company's current focus. The drug is called Kiacta for AA amyloidosis, which is a rare disease that affects the kidneys. Bellus already had good Phase II/III data and we had a plan to develop and fund the program into a confirmatory phase III study.

The second aspect of the strategic plan was to change the way that Bellus does business by transforming the company from a full-scale model to a semi-virtual model. The idea was to keep the design and strategic thinking in-house, but to outsource the operative aspects of drug development. Bellus put a partnership in place with an American private equity group called Auven Therapeutics to finance the phase III confirmatory study of Kiacta. This group gave Bellus a $10 million upfront payment, and made a commitment of $50 million for the phase III study of Kiacta. After speaking to the FDA, the design for the Kiacta phase III study was done in-house and the actual execution is being done by a CRO. This overall strategy allowed Bellus Health to reduce its size to ten employees. The burn rate has been reduced considerably as well, from $2 million per month to less than $300,000 per month.

What can biotech companies do to promote themselves in Canada or internationally in order to obtain the capital and attention that they need?

For many years, biotech companies have been too reliant on local sources to access capital. Canadian and particularly Quebec biotech companies were principally relying on the existing government-initiated funding structures. When that local capital disappeared, the local industry suffered greatly.

Biotech is a global business, not a local one. Our natural clients are not local companies but large pharmaceutical and biotech companies with multinational commercial networks. Therefore fundraising and access to capital should also be global. You can never be too reliant on one source of capital. One can have local links but must always also look to create global links to access capital.

Vivimind is a patent-protected product on the market. What implications does that have in terms of Canadian intellectual property laws?

Drug developers like Bellus Health work to create drugs for a global market. When we assess projects to develop, we look at the market potential primarily in the three large pharma markets: US, Europe and Japan. I still however believe that having strong local regulations is fundamental to support the local biotech industry. I am a proponent of strengthening intellectual property in Canada, and even putting legislation in place that supports the biotech industry. A key focus for us is the legislation for development of drugs for rare diseases like Kiacta. The US, Europe, Japan, and Australia all have regulations in place to provide benefits for the development of these kinds of drugs. Canada does not have this legislation in place; hopefully this will change soon.

However, Canada offers many opportunities for biotech companies. There are great universities that propel great science forward, as well as a strong infrastructure, and incredibly talented and experienced individuals who know how to develop these products. Canada has the capability to develop world-class products. I think Canada is on par with the best in the world.

Bellus Health's primary pharmaceutical candidate, Kiacta, is in phase III clinical trials. What is this compound's latest development?

Kiacta is Bellus' most advanced and important product, which is currently in the last stage of testing, phase III. It is for a rare disease, AA amyloidosis, which affects the kidneys of 30,000 to 50,000 patients in United States, Europe and Japan. AA amyloidosis patients' kidney functions deteriorate quite rapidly from diagnosis and within 10 years, most are on dialysis or dead. Kiacta binds the amyloid inhibiting it from forming toxic fibrils and plaques that clog the kidneys. Bellus' phase II/III study demonstrated a 42 percent risk reduction in kidney damage for patients on Kiacta. The potential market size is approximately half a billion dollars per year in peak sales.

Bellus has agreements with the FDA and EMEA to run a confirmatory phase III study, which is currently on-going. If this study generates similar results to the first study, Kiacta will receive approval.

Given the huge potential of kidney disease products, what opportunities do collaborations hold?

Kidney disease is an area of high-end unmet medical need. Dialysis costs can go up to $100,000 per year in the US. If you can develop a drug that can delay dialysis, you are saving the healthcare system a lot of money. You will have access to strong pricing because you are providing a solution to an unmet medical need. Eventually, Bellus will collaborate or sell its Kiacta program to a large pharmaceutical company for the commercialization of the product. Bellus does not have its own commercial aspirations.

Vivimind is a patent-protected memory protection program that is derived from naturally occurring amino acids found in seaweed. What was the potential that you saw in this product?

Vivimind was first developed as a pharmaceutical for Alzheimer's disease. It ran a large phase III clinical study that demonstrated some benefits for patients, but not the level required to garner approval from the FDA. Bellus received countless letters from patients that had been on the product that wanted to continue taking it. As Vivimind was a natural product, we decided to repurpose it as a nutraceutical rather than a pharmaceutical. The company then started to put distributor agreements in place to begin selling Vivimind.

You mentioned that Bellus Health enjoys different strategic partnerships for its products with companies around the world. What is the selection process behind choosing these companies?

Finding the right partner for your asset is extremely important. It is not one size fits all. People sometimes think that giving a product to a big pharmaceutical company solves everything; however, it may not be the right solution for that particular product. In the case of Vivimind, the product is a nutraceutical so we therefore sought out companies with sales forces that had nutraceutical expertise.

You have to find motivated partners that want to make your product their highest priority. This is nearly impossible to find in big pharmaceutical companies where your product is competing with the pharma company's large internal pipeline. When Bellus Health was looking for a partner to put Kiacta into phase III, the company received several proposals from big pharmaceutical companies. Kiacta is a niche indication for about $500 million, and while this is a very good market size it is not blockbuster status. Therefore we felt that the product would not be prioritized with a big pharmaceutical company. Rather than compromising as a second or third priority product with a big pharmaceutical company, Bellus partnered with Auven Therapeutics, a global private equity fund. This company has a very senior team that brought the expertise of big pharma as well as deep financial resources to develop the asset. Most importantly, Auven Therapeutics put a high priority on the development of Kiacta.

What are your short- to medium-term goals for Bellus Health?

Drug development companies in Canada are often using the build-to-sell model today, and we are no different. The goal is to build Bellus and develop its product pipeline to the point of a sale within three to four years. The cycle of building, selling, and then building again is becoming more and

more prominent in Canada.

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