Interview: Jeffrey Bacha, CEO, DelMar Pharmaceuticals Inc., Canada

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The CEO of DelMar Pharmaceuticals discusses British Columbia's competitive strengths in the biotechnology space, and demonstrates how his company's therapy for glioblastoma will change the way in which a number of cancer treatments are administered.

What is British Columbia's competitive edge in the biotech space?

Experience and brainpower are primary factors in BC. The British Columbian Cancer Agency, University of BC and Simon Fraser University have established a strong research and intellectual property base from which the industry can build. BC has been at the forefront for many years in the growth of the life sciences industry in Canada. A broad talent base of management and research talent was attracted here, and that experience, leveraged across the quality research being done at our academic institutions creates a good climate for germinating and growing companies leading to a strong history of success.

Does Vancouver's proximity to San Francisco help?

It is true that there has been more cross-pollination up and down the West coast, for example between Vancouver and San Francisco, than from West to East across Canada. Having said that, I believe the original driver of the focus and opportunities afforded to startups built in BC was access to capital. That access has changed somewhat, but there is a very strong entrepreneurial spirit here leading to continued funding of startups.

Does the province of BC provide unique sources of access to capital?

There are some very strong tax incentive programs in BC, certainly for individual investors putting money into a private BC-based company. The VC community in Vancouver, while historically strong, has struggled in the last few years, which has created many challenges in attracting larger follow-on investments.

What have you brought from your various experiences with biotech and applied to DelMar?

Having the opportunity to be associated with a number of very good teams, and seeing how teams can come together toward tackling a scientific market or capital-raising has been beneficial as we built DelMar. Most of our team has come together with different experiences but having worked together in the past, which we have leveraged toward success.

Could you highlight a couple of key milestone achievements since joining?

DelMar was founded as a private BC company in 2010, and is thus a relatively young organization. Since then, we have put together a great team with experience covering about 20 oncology approvals. We filed an investigational new drug (IND) for our lead product candidate, VAL-083, within a year of founding the company. We have modernized the manufacturing for VAL-083 as an older compound and a first-in-class chemotherapy. We have advanced VAL-083 into clinical trials in refractory glioblastoma, filed new patents and brought the company to the public markets in the United States.

DelMar's flagship product, VAL-083, targets a number of cancers. Could you describe this in a bit more detail?

VAL-083 is an "old school" cytotoxic. It binds to DNA, in rapidly dividing cells, interrupts that process leading to apoptosis, or cell death, in the cancer. VAL-083 was heavily studied at the National Cancer Institute (NCI) in the United States during the "original" war on cancer in the late 1970s and early 1980s. DelMar's team has experience in mining historical data to identify promising cancer therapeutics that hadn't been fully appreciated in that era. We were intrigued by the evidence of activity in different tumor types in NCI-sponsored clinical trials. Interestingly, VAL-083 crosses the blood brain barrier, and thus a number of those trials and a focus focused on brain tumors. There was clear evidence of activity in glioblastoma from those trials. Also, the way VAL-083 works against cancer appeared to be different from current therapies used to treat GBM such as Temodar®. These data from the literature provided stepping stones for us to build a plan to

validate the activity of the drug and refractory GBM, where there is a huge unmet medical need. Based on modernizing the original science behind VAL-083, we have created a new patent position and built a pathway to not only move toward commercialization in the refractory disease but to also to study the drug in newly diagnosed patients. Given the presence of certain biomarkers, we will be able to identify the patients who are unlikely to respond to the current standard of care and potentially offer an efficacious alternative with VAL-083.

DelMar works in partnership with Guangxi Wuzhou Pharmaceuticals for accelerating clinical trials. What are the origins of this partnership?

DelMar's focused strategy has been built around data from the NCI. When we took the drug back into clinical trials, we had to find a quality contract manufacturer to provide the drug for us. This drug is a cytotoxic, and typically at an early stage these drugs are often made in Eastern Europe or Asia. Our team had previous experience sourcing drug products in the clinical trial stage from China, so it was logical for us to look there for a manufacturing partner. We learned that Guangxi Wuzhou Pharmaceuticals was not only a good quality manufacturer, but also held an approval for leukemia and lung cancer in China. We initially established a clinical supply relationship. Over time, we developed new data and an understanding of how CML and cell lung cancer are treated in China, and we realized that VAL-083 drug could be repositioned to be more beneficial to patients and to have greater sales potential. Our strong partnership with Guangxi Wuzhou Pharmaceuticals has created a global supply opportunity and the chance to benefit patients and to grow sales where the drug is already approved. Our next step is to establish a marketing partnership with an organization that has an existing oncology sales force on the ground in China.

Are there advantages to doing clinical trials in China where the population is much bigger?

Currently, all of DelMar's clinical trials are done in the US in the refractory GBM population. That being said, there are very high quality clinical research centers in China, and the sheer number of available patients means enrollment may be easier. It is always important to ensure that the data quality is not only supportive of the results you seek, but can be leveraged worldwide. We have a strong group of clinicians established as an advisory board in China who will work with us and Guangxi Wuzhou Pharmaceuticals to generate new post-market clinical data under the context of the current label. We believe this work will show physicians how VAL083 should be used in the context of modern care and will result in meaningful patient benefit and strong sales growth.

How do you protect IP in Canada?

Our strategy to protect our intellectual property in Canada is the same as in the rest of the world. We have been granted orphan drug protection in gliomas in the US and Europe, which gives us advantages in terms of accelerated development opportunities and market exclusivity following approval of seven years in the US and ten years in Europe. Beyond that, we have filed a number of new patents. There has been a strong history of success in establishing new patents including new chemical composition claims by other companies who have developed and commercialized older pharmaceutical assets. So far our first US patent has issued and we will continue to seek issuance of new claims worldwide. We expect to have a very strong patent portfolio in addition to our orphan drug protection.

VAL-083 has not been approved for any indications outside of China. What is the potential for that to change?

DelMar's focus has been in glioblastoma, the most common and aggressive form of brain cancer. Our business model looks at "proven" cancer therapies in terms of the safety profile, mechanism-of-action and historical efficacy. VAL-083 meets these criteria. Based on these data, we seek to determine where in the mechanism has the biggest impact for patients who need it in the context of modern care. Glioblastoma and refractory glioblastoma are obvious diseases on which to focus. Currently, the median survival without care is only 4.5 months from diagnosis. Even with today's best standard of care, survival is less than two years. Unfortunately, most patients do not respond to current therapies. Based on VAL-083's mechanism it is not subject to the same resistance mechanisms of today's standard of care in GBM. This led us to the path to move to GBM. The pathway toward approval in a refractory cancer like GBM tends to be a Phase II registration-directed trial rather than a large Phase III study, which means the drug can be streamlined and put on the market more quickly than many other treatments. We hope to advance VAL-083 into a registration-directed trial for GBM in the United States during 2014.

What is the commercial value of this drug in the coming years?

GBM affects 15,000 patients in the US. The incidence of the disease, about four out of every 100,000 people is similar worldwide. It is a relatively small patient population; however, the current frontline therapy sells $1 billion annually today. Thus there is clear market and commercial potential. The World Health Organization estimates there will be a million cases a year of lung cancer in China by 2025, of which 90 percent will be non-small cell lung cancer. Significant challenges exist in the treatment of NSCLC in China and world-wide. The NCI's research supports on the activity of VAL-083 in China along-side of the label in China, and we believe that there is a commercial opportunity for VAL-083 in a number of cancer indications.

What would you like to have achieved in the next few years?

We would like to see this drug on the market to treat glioblastoma patients. We would also like to see the patients benefit from VAL-083's experience in China on a global basis. Most companies with our business model tend to be acquired before commercialization, but no matter what happens we believe there is a market with great potential value for DelMar's products.

What is DelMar's defining characteristic in the Canadian biotech space?

At one point, there were seven profitable biotech companies on the planet, three of which were in Vancouver. This, as well as the success and potential of the industry, is not always recognized. Similarly, DelMar has an international focus. Headquartered in Vancouver, DelMar was founded as a Canadian company with an experienced clinical team in California. We are developing a drug leveraging historical data from the US and China along-side of new data from Canada, the US and China. We are excited about the opportunity to build from there.

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