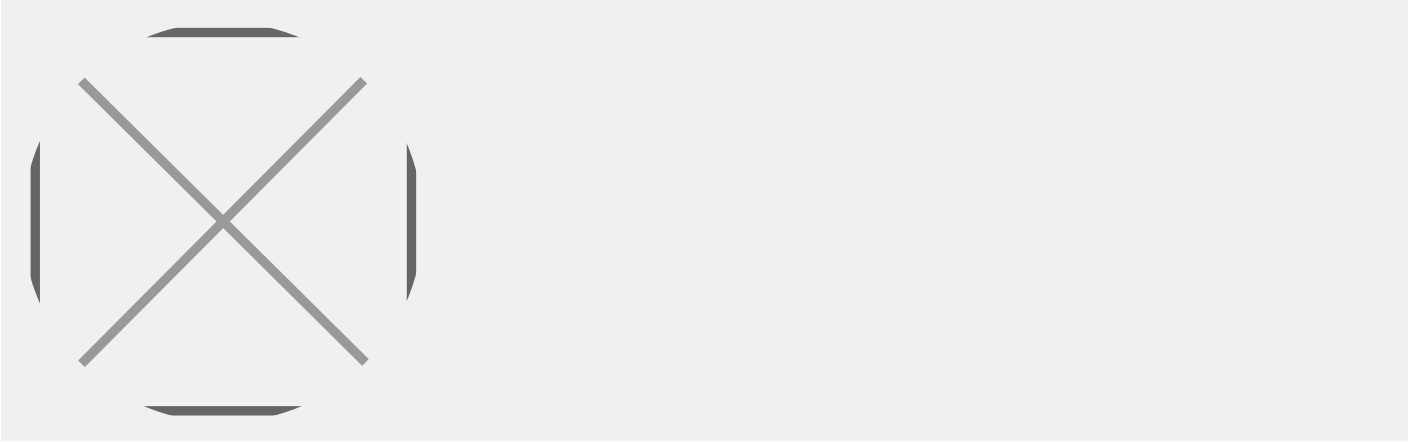
Interview: Tony Cruz, Chairman and CEO, Transition Therapeutics, Canada



05.11.2013

Tags: R&D, Transition Therapeutics, Biotech

Tony Cruz of Transition Therapeutics discusses the challenges of biotech companies in Canada and his company's unique business model that has adapted to the changing needs of big pharma through risk mitigation.

You founded Transition Therapeutics in 1998. What was the reasoning behind founding a biotech company focused on CNS and cardiovascular back then?

It was an excellent time to start companies. There were resources, Venture Capitals, lots of technologies and interest in those technologies. At that time I was also head of the Canadian Arthritis Network, which moved technologies in arthritis from universities to development and industry. The idea was to start three companies at that time to demonstrate that movement of technology, and Transition was one of them based on a technology from the University of Toronto. The name "Transition" was derived from the need to transform platforms many times over until you succeed.

Was the environment for bridging the gap between science and industry better in that time?

It was actually more difficult back then from the academic perspective. At that time, many universities did not like the idea of their scientists starting their own companies and changing the direction of science towards R&D as opposed to pure research. However, there was enough

financing, resources and interest from investors that it was easier to attract financing to take risk. Today there is little to no money for risk. Major institutions that invest in these areas now want clinical data before investing. Even big pharmaceutical companies are having difficulties funding that area.

Will that change in the future in the Canadian context?

I do not see the incentive for change. I see discussion about putting money into venture capital, or lump sums of money given to certain groups to invest in the area, but this is not enough. You need a culture of investment and incentives for everyday investors with large amounts of capital to put money into areas they think are the next winner, and the associated risk must be shared. To do that you need more product, which currently does not exist to attract the $5 to $10 million it would require in order to take the company to the next level.

How do you convince heads of biotech companies to take that risk to target the big disease indications, when small disease indications and me-too products will not attract strong ROIs?

It is a balance. People actually want me-too products with a slight improvement, because they are less risky, which is why they want clinical data. The problem is incentivizing a payer to reimburse products that show relatively small added benefit compared to existing products. Early-stage products need to identify their market position and advantages very early on in order to obtain funding or partnerships; otherwise, payers will not pay and the product will not go to market.

What will it take to build a pharma Bombardier independently in Canada?

It will take more biotech companies to foster an industry, and a culture of investment to attract foreign investors to drive growth. Unfortunately it is becoming more difficult for a company to take any product all the way to market. Biotech companies are being acquired more quickly as big pharma seeks to add products to their sales and development portfolios. As these companies have positive clinical results, the companies are being acquired or their products are licensed by big pharma. Today, many companies use royalties to mitigate risk for investors. This is becoming more and more important; royalties are being sold to raise capital for companies that want to broaden their pipeline.

How was Transition’s partnership with Elan created for its leading Alzheimer’s candidate?

Transition took on a product developed from the University of Toronto. We decided to partner early in the development cycle because Alzheimer's is an expensive and risky area in which to develop a product. We therefore out-licensed to Elan as a partner because of their knowledge in this area with a similar molecule, and because they had a great following in the investment community for that program. By licensing our molecule, it put Transition in the limelight. Transition offered an oral molecule that interacted with amyloid as a target and showed fewer adverse events.

What is the commercial potential of this product?

This depends on efficacy. There is currently nothing for agitation and aggression that works well for Alzheimer's patients. This drug would be an add-on to existing therapies. About 60 to 70 percent of patients with mild, moderate or severe Alzheimer's have behavioral changes, all of whom could use a therapy like this. There are very few products developed for that indication, so the market opportunity is very good. Additionally, Transition's drug has a good adverse event profile to suit this patient population.

Transition also licensed in a series of preclinical compounds from Lilly in the diabetes space. Where in the clinical stage process is this project?

Lilly exercised their option to take that technology internally, which provided a $7 million milestone and a commitment from Lilly to move the technology into Phase II, to which Transition is contributing $14 million. This should allow the technology to move into a large Phase II efficacy trial based on clinical data seen in obese diabetic subjects. We believe this program will control glucose levels similar to incretin therapies like Victoza or Byetta, and will help with weight loss.

Could you talk about your recent deal with Lilly for osteoarthritis?

Transition had access to some of Lilly's compounds available for development that they did not take forward. We have looked at a number of technologies in recent years with them, and we decided that their osteoarthritis compound had a real market and development opportunity. We used the prototype agreement from our TT-401 molecule and applied it to this agreement as a mirror image.

In a sense, this defined the company. Transition reviews lead compounds developed by big pharma with its broader approach of compiling supportive data across all functional areas of development. The data from these well-characterized drug candidates is evaluated and Transition in-licenses candidates to advance through Phase I and Proof of Concept (POC) clinical studies for large Phase II trials. Transition's pharma partner retains an exclusive option to assume all rights to the drug

candidate following review of data from pre-defined studies. Transition takes on a defined development risk and receives a return on its investment and futures, such as royalties for risk or milestone payments.

What are the advantages for Transition with this kind of approach?

Transition can maintain a small infrastructure in the earlier stages of development. We can outsource preclinical and clinical data to CROs, but we control development as a whole. Our costs are also predictable, which allows us to mitigate risk to take compounds into Phase I. This model is applicable to multiple indications, which diversifies risk. You also get enough resources back that it pays for your ongoing operational costs and with enough futures, you can be very successful with a reasonably sized indication.

Big pharmaceutical companies need to broaden their pipeline, which is becoming their biggest expense. Transition's model is an easy way to mitigate their risk by outsourcing the broadening of their pipeline. They can now make better decisions having POC data available on additional drug candidates to reduce risk in prioritizing programs for later stage development.

What makes Transition Therapeutics the partner of choice for big pharma?

It is often our products. We meet big pharma's criteria when we out-license a drug by insuring data is compiled to meet the needs of each functional development discipline. Big pharma brings many people in to do due-diligence each with a functional experience. You must ensure that your data provides all those people with sufficient criteria that allows them to make a decision for licensing. Many companies have a difficult time in doing that. In terms of us licensing from Pharma with an option to take a drug candidate back, it is the same criteria. We have good relationships with our partners, because they can rely on Transition's work in order to make decisions. Their goals and our goals are aligned.

What would you like to achieve in the next five years?

Transition's model of advancing molecules to proof of concept and then partnering with big pharma has proven to be very cost-effective. The idea is to in-license additional molecules and to continuously advance them to a de-risked licensing stage for big pharma. Our most advanced molecules will provide enough resources, via milestone revenue, to expand the pipeline in order to advance more molecules simultaneously. Transition's goal is to have a pipeline with multiple programs focused on late stage development and approval. Because our low infrastructure costs, those revenues will go back to our investors, or be invested in other products. Biotech companies

can be very dilutive, and so Transition’s constant focus is to maximize investment of investors’ capital for long-term ROIs.

You have to develop a business model for the times. I believe that right now, risk mitigation is one of those opportunities. Transition is meeting the opportunity to address a key need of industry, which is to mitigate risk from the lead molecule to human proof of concept stage. We can fund and perform the activities that provide that risk mitigation, and now we look for success as these drug candidates advance toward approval.

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