Interview: David Malta and Daniela Couto, Co-Founders, Cell2B, Portugal

30.07.2014

Tags:

Cell2B, biotech, start-up, entrepreneurship

David Malta and Daniela Couto, Co-founders of Cell2B, discuss the companyâ??s origins and plans to achieve market authorization, and what makes the fledgling company the partner of choice.

What do you see as Portugalâ??s capacity for the local life sciences industry to grow?

DM: Portugal is one of the best-positioned countries to grow for life sciences today because it has one of the best human resources pools from which to extract. Portugal has one of the highest per capita PhD levels in life sciences in Europe, and the government has been investing noticeably in life sciences, driving companies to innovate and move forward.

DC: In terms of GDP, Portugal also has received a large amount of EU and ERC grants over the last five years. The numbers indicate that there is a growing critical mass in the life science sector within the Portuguese community.

We see the emergence of biotech hubs worldwide; is there something that Portugal has that distinguishes the country?

DM: Portugal could be a hub for biotech with high standards of quality and lower investments to develop products. Translating basic science into commercial products therefore might be slightly easier here. There is also great proximity between companies, research centers and even the government in terms of committing to move Portugal forward in life sciences. INFARMED and health authorities in general are easy to access. There has also been a lot of public money coming into biotech and life sciences in general that can help catalyze by matching private investments working as non-dilutive funding.

DC: Portugal also has an historical connection between Africa, South America and Asia that as a fairly small country can be very well explored. Being between Europe and the US also creates a good connection. Instead of looking at Portugal as an entry platform to Europe, you can actually look at Portugal as an exit to rapidly growing emerging markets.

How do you see the potential of the public venture capital market to help life science companies in Portugal grow?

DM: There is still a lack of capacity inside the venture community of Portugal to properly evaluate and fund life sciences projects, mainly in terms of moving from seed funding to Series A funding. However, this is an issue across Europe. In parallel, there is a lot of grant money available in Portugal. This has been significantly geared towards R&D and life science companies, which have been well positioned to capture that money, more so even than venture capital funds. There has still been a significant level of investment in biotech companies that was typically matched with government grants. Together they could catalyze the emergence of a new generation of companies in Portugal, which are yet to grow.

As a cell-based therapy company, does Cell2B offer a good model for finding a niche?

DC: I hope we can become a good role model in the future. Today, Cell2B is a very early-stage company. We have strong investment through PhDs and research centers in the cell-based therapy space with contract manufacturing organizations that have attracted many clients worldwide for clinical trial stages.

Twenty percent of companies in P-BIO are related to cell therapy and regenerative medicine, which is significant. So critical mass is starting to form in this area.

Cell2B develops therapies for immune and inflammatory diseases. How did this idea come about?

Cell2B was borne out of collaboration between an oncology hospital and the stem cell lab at the Technical University of Lisbon. We started by treating patients with acute graft-versus-host disease (GVHD), which is the rejection after bone marrow transplant. Historically, patients have been treated based on hospital exemptions, and results have consistently been positive. We have a pool of six treated patients, all of whom survived with no recurrence of the background disease itself. That provided a strong incentive to create Cell2B, since the survival rate of GVHD is usually between five and 30 percent. In 2011 we incorporated Cell2B with the intention of continuing to treat patients through clinical trials. In 2012 Cell2B closed the first series of investment with Portuguese, Spanish and American business angel investors through seed funding. Now we are raising Series A funding for clinical trials. We have orphan designation in Europe for GVHD and we have positive feedback from the EMA to start clinical trials, which we will do in 2014. Additionally, according to our hypotheses, the underlying mechanism action also has the potential to treat other immune and inflammatory diseases. The first Phase I/II and safety studies will take place in four countries and as we move on to later stages we will move to more countries beyond Europe. In terms of collaborating with the industry, Cell2B is certainly open, and this will happen sooner or later in the development cycle. We are raising series A to move forward, and during clinical development we will see what happens.

Will you look to move onto bigger investors as the company grows?

DC: Ideally, for Series A we will attract larger investors and remain with them through the process of clinical development and early market stages.

What makes Cell2B the partner of choice among all the cell-based therapy companies in Portugal?

DM: Cell2B is the most developed company, and the only one ready to start clinical trials with a clearly defined lead product and with positive feedback from EMA to move forward. Cell2B is at the

forefront of an emerging cluster because of our development cycle.

What is the market potential of your technology if it becomes commercialized?

DC: The immune area is very large. We are now running animal studies for other diseases to prove that there is a potential to treat diseases such as RA, IBD, or Crohnâ??s disease, all of which have large markets. Looking at GVHD alone, the market is $2.9 billion in just Europe and the US. With the current standard of care, mortality rates are quite high for the most severe cases of acute GVHD resistant to first line treatment, as I mentioned. They are not effective for patients. This makes GVHD a very appealing market, even as an orphan disease.

Cell2B won the 50 hot Portuguese startup and Iberian-American Entrepreneurship Award. What can other companies learn from Cell2Bâ??s successes?

Other companies can learn from the way we formed the company, which is unique. From day one, we brought a team of 11 employees with different skills to the table. That helped to drive the entrepreneurial spirit of Cell2B and to attract more visibility. Awards and recognition are great, but the most important thing is to get to the product with a market. We are still far away from that ultimate objective; at that point we will have a better story to tell regarding role modeling. But certainly the skill sets and investor pool are important differentiators. We pursued the path of business angel investors as opposed to traditional government-backed seed funds, which provided us more in skill sets from the investor perspective.

DC: Cell2Bâ??s business angel investors include individuals and two organizations. We have a large spectrum of experts, from immunologists to bank investors and venture capitalists. It is a very large spectrum of people who are willing to support the company throughout its lifetime.

Innovation versus entrepreneurship is a common issue worldwide; as a fairly entrepreneurial country, does Portugal have a competitive edge in that regard?

DM: As a country we are not perfectionists, so we do not necessarily want to have the best product in the world, but rather something that works and meets the criteria to move forward. Globally that should be a bigger advantage for Portugal than what it is currently. There is something in the Portuguese DNA to move forward, but we do not necessarily need to invest in the best product in the world, but rather focus on having a good product that works.

What advice might you give to a young entrepreneur looking to make a career in Portugal in biotech?

DC: Take your time to know how to market your science. US-based scientists learn this from scratch, and Portuguese innovators could learn from the American example.

DM: You also need to think about what you are doing and put together a good plan to proceed. The willingness to do things in Portugal might hurt establishing a good plan to begin with; while you take time to learn how to pitch, put together a good plan too.

What are your ambitions for Cell2B in the next five years?

DM: We want to have completed the first development cycle for GVHD treatment, and being at or close to market approval for this treatment.

DC: Cell2Bâ??s positioning is to tackle an unmet clinical need that today has no clear benefit. We can bring much more value by partnering with a company that has been doing it for a longer time.

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