Luca Benatti â?? CEO & Board Member, EryDel

> The major factor that separates the US from Europe is the cultural approach to investment. US investors do not judge entrepreneurs for past failed companies or ideas, whereas their European counterparts sometimes do

17.02.2022

Tags:

Italy, EryDel, Biotech, Europe, European Biotech

Serial bioentrepreneur Luca Benatti introduces EryDel, an Italian firm based on the concept of using a patientâ??s red blood cells to deliver drugs. Benatti also weighs in on the strengths and weaknesses of the Italian environment for biotech start-ups and his ambitious roadmap for EryDelâ??s future growth.

Can you begin by introducing your entrepreneurial journey up to this point?

My background is in molecular biology and genetics. Following time abroad in Oxford, I joined the pharmaceutical industry in Italy and spent over ten years in research and development (R&D) positions, predominantly in neuroscience.

In 1998, I launched a biotech start-up, Newron Pharmaceuticals, in Italy with some colleagues, creating a business plan, liaising with venture capitalists, and raising money to progress the company. This process taught us a lot and in 2006 we took the company public in Switzerland â?? a very enthusiastic market for biotech â?? in what was one of the three largest biotech IPOs in the world at the time. The company progressed to the approval stage for its Parkinsonâ??s disease product, which has made it to market and is being commercialised in Europe and the US. The success of this entire process demonstrated our knowledge and competence in the neuroscience

space.

In 2012, after several years in position as CEO, I wanted to try something new. I developed an interest in some early technology that had been developed at a university in the small Italian town of Urbino and, sensing its value, joined what was then a very small start-up â?? EryDel. We raised substantial money from venture capital, and the business recently completed a Phase III clinical trial for ataxia telangiectasia; a rare neurological condition with no available therapy.

Additionally, I am on the board of Intercept Pharmaceuticals, a US-based company listed on the NASDAQ, specialising in liver disease. Moreover, I am member of the strategic advisory board at Zambon and founder of Italian Angels for Biotech, an association aimed at growing early-stage start-ups in the Italian biotech and life science sector.

What are the most important lessons you have learnt as an bio-entrepreneur?

There is a lot to learn. I have made many mistakes, but these mistakes are crucial for success as they have allowed me to approach issues differently the next time I am faced with them. This applies in different instances from scientific, to regulatory, or commercial matters. Having gone through the biotech development process multiple times and having made mistakes allows me to better advise new ventures and steer them in the right direction.

How would you characterise the experience of being a bioentrepreneur in Italy, which may look like a less mature ecosystem than other locations?

There is commonality between the Italian environment and other European markets, however, Italy is less developed than other countries in the region such as the UK, Germany, and France.

The major factor that separates the US from Europe is the cultural approach to investment. US investors do not judge entrepreneurs for past failed companies or ideas, whereas their European counterparts sometimes do. All business plans are considered independently and the market is bullish, with a lot of trust and money.

Companies in the US have the capability to raise more money in their venture rounds. As a result, these companies have greater flexibility and the opportunity to change their business plans without needing to raise additional funds every time.

The environment in Europe is more restrictive and selective. Specifically, there is a tendency to distrust entrepreneurs that have failed in the past. This does not take into account the complexity and high-risk nature of the sector with few projects reaching the market. Consequently, this perception from the financial market offers European companies in the industry less capital than those in the US market.

Therefore, there is a dramatic effect on European businesses transitioning into US companies in the long run as they move to list on the NASDAQ due to the trust in the business, the number of investors, and the large amount of capital.

How strong are Italyâ??s scientific fundamentals and in which regards could the overall ecosystem be improved?

The Lombardy region and the Milan area are home to top research centres such as the San Raffaele Hospital and the European Institute of Oncology. These institutions are able to successfully compete with other key research hubs such as Cambridge or the Max Planck Institutes for European grants. Additionally, the quality of the publications and research in Italy stands out compared to many other European countries.

The gap affecting Italy is the reduced capability to transform science into business. The fragmented transfer office system is not helping scientists access the resources needed to shape their business plans and attract investors.

Additionally, the lack of early access to capital reduces the capability to transform these businesses. This is one of the reasons along with other entrepreneurs I founded the Italian Angels for Biotech; there was a significant need to both increase Italian start-upsâ?? access to angel funding and share experience with them so that they could grow to a sufficient size to attract venture capital.

Likewise, there is limited access to experienced managers and entrepreneurs in Europe, which reduces the potential of these start-ups to grow. Although managers from Big Pharma companies possess an attitude and mentality to be excellent managers in structured organizations, they are frequently less effective in early-stage companies.

Can you outline the science behind the technology that EryDel is developing and what you hope its applications might be?

EryDelâ??s technology consists of a specialized system (Red Cell Loader), a sterile single use kit (the EryKit) and process solutions based on the concept of using a patientâ??s red blood cells to deliver drugs. What makes this product unique is its ability to be used at the point of care. Our proprietary machine first takes a small sample of blood from the patient and automatically processes it. After 90 minutes, it produces the final bag containing the patientâ??s red blood cells and the drug or biological to be delivered to the patient. The patient is then infused with the solution and the treatment takes effect.

There are three foreseeable applications for this technology. The first product we have developed is the slow-release formulation for ataxia telangiectasia, which is currently in Phase III. The pro-drug is encapsulated into the red blood cells and, once infused into the patients, the active drug is gradually being released into circulation over a four-week period. Phase III has demonstrated that this product is safer and reduces the side effects in patients while retaining its effectiveness in slowing disease progression.

The second line of products is aimed at shielding enzyme therapeutics from the immune system. This is for therapies that substitute the missing enzyme for other rare disease conditions with non-functional enzymes in patients with a serious disease. Currently, these enzymes are available as therapeutics, however, their use can cause an immune response and severe anaphylactic shock when injected into the patient. EryDel has demonstrated that these enzymes can be encapsulated into the red blood cells with the same procedure and machine. The enzyme is carried through the body by the red blood cells that work as bioreactors, and when the substrate of the enzyme moves into the red blood cell, it is cleaved to reduce the toxicity caused by its high blood concentration. Consequently, the enzyme is not directly exposed to the immune system and should not cause an immune response by the patient.

The third area of usage for the device is at the research level. The technology is being used for red blood cells to produce microvesicles, small vesicles produced by the red blood cells, which are a

vehicle for gene therapy. Therefore, EryDel proposes using the same technology again to reduce immunogenicity and overcome one of the major problems of available gene therapy approaches.

How important are partnerships for EryDel currently?

A partnership is not one of the companyâ??s priorities. Once EryDel receives approval for the treatment of ataxia telangiectasia, which currently does not have an available therapy, the business will build its commercial infrastructure. This commercialisation of the product will begin in the United States, where we hope to be able to access additional capital. As a result, EryDel believes it will become profitable in the next few years and it will use the profits to build out European Markets and additional pipeline products.

Is there enough data to make the value proposition understandable for investors and buyers of the product?

EryDelâ??s Phase III data shows meaningful results and a clear benefit on delaying disease progression and loss of ambulation in patients.

With regard to the enzyme-related product, the delivery system is solving the safety issues related to these treatments and potentially providing more patients access to these treatments.

How challenging is it to build a company based on a delivery system compared to a product?

It is a different business and one that is highly complex. The FDA defines EryDelâ??s product as a combination product due to the three components: The medical device or machine, the red blood cells of the patients that are required to deliver the therapeutics, and the active compound, which is either a small molecule, a protein therapeutic or genetic material.

Therefore, all three components must meet the criteria and specifications of the FDA to get approval. This creates complex regulatory issues and the need for specific marketing structures. However, EryDel is bullish on the opportunity that this product represents, and that of the other products in its pipeline.

How well funded is EryDel to reach the next milestones in its development and how do you foresee your approach to funding developing?

Eventually, the company will need to list and gain access to the public market. There is the potential to conduct an IPO in 2022, however, there is no rush and the company has long-term investors to support it for more time if needed. Nevertheless, joining the public market will be fundamental to accessing the capital required to transform the company from an R&D platform to a fully integrated commercial business.

Today, if the company wants to do a successful IPO and stay in a market that allows it to raise additional capital and create value for shareholders, the only option is the NASDAQ.

What is your take on the current financial environment for biotech?

In the last few years, there have been high levels of excitement for early programs and IPOs for companies that previously would not have been able to be supported at that stage of development.

Currently, there is a readjustment to the market and this year, the companies that are listing are less risky, more mature, and with more advanced programs. This will raise the attractiveness of a company like EryDel compared to those working on discovery programs in risky and relatively unexplored areas like gene therapy.

How do you plan to grow the EryDel team?

EryDelâ??s short term goal is to open a US office and begin building a US based team. This is to prepare for building the commercial infrastructure in the United States as well as to position the company to list on the NASDAQ.

Additionally, there is a larger pool of experienced entrepreneurs and managers in the US than in Europe.

What is your final message to PharmaBoardroomâ??s international audience?

EryDel has proven that it is possible to build a successful business from European science. Having started out at a small university in Italy, our technology is now close to reaching the market and our future looks bright.

See more interviews