Peter Bauer – Managing Director, Bioinova, Czech Republic



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Bioinova's CEO and managing director MUDr Peter Bauer PhD introduces the biotech company's shift from a university spin-off to a privately held entity. Whilst describing the powerful properties of stem cells for autologous and allogeneic transplantation, which they base their Research and Development on, Bauer evaluates the commitment that comes with Advanced Therapy Medicinal Products (ATMPs) in terms of time and costs, and shares some of his most ambitious goals as well as views on the importance of enthusiasm when it comes to leading and motivating a team.

Can you give us an overview of how Bioinova's activity has evolved since you joined as Managing Director in 2016?

When I accepted this position, the company was still a spin-off of the Institute of Experimental Medicine, and shortly after I joined, new investors came in and the company became a completely private entity. We basically started over again, almost from scratch. People were used to the connection between Bioinova and the institute; to the typical spin-off dynamic, where some things that were discovered at the institute were attempted to be transferred to clinical trials by the company.

When the ownership-related association with the Institute of Experimental Medicine ended, we discontinued the production of the contemporary products and three clinical trials for which

Bioinova had been the sponsor and started to develop our own medicinal products based on stem cells.

Today, approximately 70-80 percent of our time and energy is dedicated to Research and Development, while 20-30 percent goes into Good Manufacturing Practice (GMP) manufacturing processes and quality control. Of course, there are still many mutual-interest collaborations going on with the institution: we constantly help each other.

What are the ingredients of Bioinova's service offering?

In the last three years, we were able to develop two ATMPs based on stem cells. We launched a clinical trial earlier this year in orthopaedics and are launching the second phase for the respective trial. Moreover, we are preparing a Phase I/IIa trial in ophthalmology.

BiCureSol is our branded solution that allows manufacturers to store and transport their stem cells-based ATMPs intact (fresh) for 72 hours at low temperatures. The cells maintain their characteristics and viability providing sufficient time for quality control – to make sure what exactly is given to the patient. Such tests include sterility, phenotype evaluation, revealing potential impurities in the product, etc.

While the use of frozen mesenchymal stem cells for regenerative medicine and tissue engineering has not been approved yet in the Czech Republic, such preservation methods would bring us a step closer to broader accessibility of stem cells in clinical practice. We are trying to put it to market as a ready-to-use solution that manufacturers can buy to transport and preserve cells at low temperatures.

We are also moving into the field of diagnostics, where we developed a rapid test that is now under optimization with contract manufacturers, and into DNA testing. Since I obtained my PhD degree in molecular genetics, among others, this is a scientific field I am passionate about. We would like to commercialize this solution faster. It is a part of our business model to generate funds within the company for R&D and of course to help our investors.

Furthermore, we also double up as a clinical research organization (CRO) and a contract manufacturing organization (CMO), and can offer contract manufacturing to our collaborators in the country or from abroad, in addition to transferring candidate medicinal products to GMP-compliant ATMPs.

Your main field, Advanced Therapy Medicinal Products (ATMPs), requires a lot of commitment. What is your investors' approach in this regard?

Commercialization is a very long process in ATMPs. After successfully going through clinical trials Phases I, II and III, you can attempt to register it for market access.

Not only do ATMPs require a long-term commitment, but they are also expensive. Data from 2018 shows that there were ten or more ATMPs, although not necessarily stem-cell-based ones, registered for Market Authorisation Holder (MAH) within the European Medicines Agency (EMA), six of which have been retracted from registration due to lack of sales because of their high costs.

Bioinova and similar companies are not the right places for investors who expect fast turnover. It is important to have smart investors, willing to take a higher risk, who value factors such as know-how and Intellectual Property, and who are relatively patient regarding their investment return.

What are some of the most urgent unmet medical needs that biotechs like Bioinova are targeting in the Czech Republic?

We started working in orthopaedics and will go into ophthalmology and a couple of other fields next. The ultimate goals are to target disorders untreatable with available conventional interventions, to treat genetic diseases, to achieve cell replacements where needed, etc.

Although we have our own vision on which diseases to target, we listen a lot to the clinical specialists, as some drugs on the market are not really able to help patients, and the specialists are the ones who know what kind of treatments are needed.

The main illnesses in the Czech Republic are obviously civilization diseases such as cardio- and cerebro-vascular diseases, diabetes, age-related disorders, neurodegenerations that include dementia (e.g. Alzheimer's Disease) and cancer. We wish we could reliably produce stem cells that affect these kinds of civilization diseases, as there is a need for it. It would be great, too, to efficiently treat rare diseases such as Amyotrophic Lateral Sclerosis (ALS), but we need to make sure we aim at the right pathogenic target, in other words, that we are replacing what needs to be replaced.

Often, the question is whether to tackle the cause of the disease or to treat some of its consequences. Ideally, the stem cells would replace the dying cells. We really want to understand

what those cells are doing and try to manipulate them for successful treatment. When working with stem cells, whose basic characterization is their ability to differentiate into various cell types, if you manage to show them the way and to replace the damaged tissue or at least to partially ameliorate the damage, we then can talk about *per se* regenerative medicine or tissue engineering.

What are Bioinova's most exciting projects or initiatives?

We would like to increase our capacity and to grow the team as well as to expand internationally through organic growth.

Moreover, as we are also a service provider, private companies and academic institutions from abroad often approach us. The challenge is market access. It would be helpful if some regulations between the European Union countries were more unified. At the moment there are certain differences that prevent their more efficient spreading across borders.

I have a goal for when we have managed to register some ATMPs. This may not be a business-minded plan, but, if we succeed, I would like to have covered the production with some margin and discount, at least partly, the research and development investments in order to make those medicinal products much more affordable to the population. This would align with Bioinova's mission to bring to market innovative, affordable, and effective treatments.

How would you evaluate the government's efforts to foster innovation in the Czech Republic?

In the field of Artificial Intelligence (AI), the Czech Republic has, to my knowledge, the highest number of scientists per capita in the world. The country has highly competent people; there is mental potential. However, what is missing is the funding. Many scientists leave the country to pursue their dreams. It is enriching to experience science in different environments; to get to know different ways of thinking. The problem is that many scientists do not come back. Fortunately, the government recently started to address this issue by increasing the funding of R&D in academia and in several industries. The investment is planned to increase by 0.1 percent per year until 2035, when it should reach 2.5 percent of GDP. The scientific environment in the Czech Republic should become more attractive in the upcoming years.

At Bioinova, we try to attract talent from abroad as well. In fact, we have had applications from all over the world, including Spain, Turkey, Mexico, Italy, Poland, Hungary and the United States, among others.

Could you tell us about your philosophy when it comes to leadership and company culture?

A leader of a company should set an example; never try to gain respect by raising one's voice. Those who surround me tend to say that I am naïve and trust everyone. Maybe I am, but I expect people to be good. Even though some might not show it too much, there is usually a positive side to everyone's attitude.

Also, enthusiasm is crucial. Of course, there is financial motivation, but more importantly, there should be motivation for a team to come to a job that they enjoy and that helps people. It is key, in my opinion, that they see the difference they make in the lives of patients. I want my team to be aware of the influence that they have and therefore we always share clinical data with them, among other initiatives. Although the responsibility of the team members seems to start and end at certain points in the laboratory, I want them to see the consequences of their hard work, outside of the laboratory and outside of our company.

When we recruit people, we pay a lot of attention to the candidate's personality. If they lack experience in a particular area, we are happy to teach them.

Considering the size of Bioinova's team — ten people — it is impressive what we have achieved. Our people are our treasure, and I make sure to let them know.

What advice would you give young biotech companies that are looking to make an impact in the lives of patients?

Firstly, I would advise them to listen to the needs of clinical specialists. It would be exceptionally rewarding to heal a patient with a very rare metabolic disorder for instance. However, such disorder may only occur to one in a billion people. These kind of diagnoses, often requiring very specific or individualized approaches are, in my opinion, rather great opportunities or challenges for academic institutions. It may sound harsh, but I would encourage biotech companies to aim for areas where more patients can be helped or rescued. It is vital to find a balance between personal

interest and public interest.

Finally, they should not be scared of obstacles they encounter. Here, the fact that we are small does not stop us from trying to make a big impact. Even a small clown can put on a big show.

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