

Ladislav DroÅ¾ák CEO, APIGENEX, Czech Republic



In [Novo Nordisk's] own words: "APIGENEX is our VIP CRO in chemistry and pharmacology"

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Ladislav DroÅ¾ák, CEO of APIGENEX, reveals the company's strategy to survive after a leadership change and a reshuffling of the small-molecule science operations at their main client, Novo Nordisk. DroÅ¾ák also discusses APIGENEX's future goals of investing in robotics and automation. APIGENEX's services include chemistry, experimental pharmacology, clinical pharmacology, registration and pharmacovigilance to offer not only MNCs, but also local industry and academia, the opportunity to have their idea become a reality.

You joined APIGENEX as a research scientist in 2007 and became CEO in 2009. How did you climb the corporate ladder in such a short period of time?

My whole life I had the ambition to work in a scientific company focused on high technology research in organic chemistry. Soon after I joined RE&D VUFB (now APIGENEX), I started to collaborate with the then management in order to put the company on a better track. In doing this, I presented my ideas and vision on how to drive the growth of the company in the future. In 2009, due to certain personal problems of the then director, I was presented with an offer to acquire the company, which I considered and finally accepted.

What hurdles did the company face once you took over as CEO?

The company was in a challenging situation. First, we had to relocate our offices and laboratories because our rental lease agreement had ended, and the property owner wanted to redevelop the site. In 2010, after a long search, we finally succeeded in finding a new location a few hundred meters from the previous premises and which was really suitable for our vision of building up modern organic chemistry laboratories and accredited animal facilities for our experimental pharmacology department. In terms of the hurdles we had to face, the challenging part of it was finding financing needed to undertake a complete overhaul of a brownfield area of approximately 4500 square meters, as well as to be able to finance new technologies and equipment, which was no small task.

Second, in 2007, Novo Nordisk stopped small-molecule drug research – this was a disaster for APIGENEX as Novo Nordisk’s requests accounted for nearly all the lab’s activity. Thankfully, six months later, the Danish company approached us again, which led to the signing of a renewed agreement for small-molecule projects and crucially we expanded the agreement with projects based on peptide synthesis. This year marks our 25th anniversary for our continuous collaboration with Novo Nordisk. In their own words: “APIGENEX is our VIP CRO in chemistry and pharmacology” • they picked us above all the other CROs in Asia and Europe and I am very proud of that.

APIGENEX has a long-standing collaboration with Novo Nordisk. How did this relationship start and how has it evolved over the years?

I would say the relationship has been mutually beneficial for both parties. It is based on a long-term collaboration drawing on Novo Nordisk’s trust in our abilities and our capacity for staying open to the needs of a big multinational corporation. A particularly strong aspect of our collaboration is our reliability, confidentiality and trustworthiness. APIGENEX We have proven to come up with good and innovative solutions and we are always open to hearing the needs of our clients.

Historically, as one example out of many, we collaborated with them in an interesting project studying the effects of peroxisome proliferator-activated delta receptors (PPARs δ) on metabolic syndromes. Novo Nordisk gave us the freedom to operate, and we met their goals. By starting off our relationship on the right foot, Novo Nordisk now sees us as a strategic partner.

As a scientist by training, how have you adapted to the challenge of leading a company?

One day you are a scientist and the next, following a small revolution in the company, you become CEO. Suddenly, I had to implement many changes in a short period of time. It was a high-risk situation. Novo Nordisk could have stepped out of our partnership at any time because of the company’s new situation or the lack of trust in a new CEO. To resolve the situation, I presented myself to Novo Nordisk and explained the new course and the strategic direction of APIGENEX. Fortunately, as a scientist I had an attractive vision for our company, which Novo Nordisk found very interesting.

Everything was a puzzle and I just had to solve it.

APIGENEX originated from the Research Institute for Pharmacy and Biochemistry in the 1950s which was involved in the development of many small-molecule drugs. Since then,

biologics have changed the rules of the pharmaceutical industry, and are one of the fastest-growing classes of therapeutic compounds, outpacing the growth of small-molecule drugs. How have you adapted the company to this revolution?

A small company needs to listen and adapt to the needs and strategies of bigger companies. A clear example of this situation is when Novo Nordisk closed its small molecule drug research department. APIGENEX was initially focused on the development of small molecules by solid-phase synthesis. In response to Novo Nordisk's action, we were forced to venture into new areas in order to keep our clients.

At that time, PolyPeptide Laboratories closed its affiliate in the Czech Republic and relocated to India. Lucky for us, knowledgeable specialists and chemists were suddenly made available. We took the opportunity to hire them, and together, we built a completely new department dedicated to peptide synthesis. We transitioned from solid-phase synthesis of small molecules to peptides. Today, we are leaders in peptide synthesis in the region of Central Europe. The department grew from making ten peptides in 2008 to over 100 the next year and eventually thousands per year and we continue to grow.

I do not know of similar companies in Hungary or Poland who have the strength that we have, and I would like to believe we are a leader in this area. The starting point for our new journey was the construction of a GMP facility from scratch – we can now produce peptides in compliance with GMP standards for veterinary and human markets.

Over time we have been able to make very complex and custom-made peptides for both commercial and academic clients on a global scale.

APIGENEX provides products and services based on four main pillars: organic chemistry, peptides, experimental pharmacology, and GMP. Which services are the most in-demand by the pharmaceutical industry?

The needs of our clients vary greatly. Some clients approach us with a single product that they want more information on – specifically regarding the relationship between the chemical structure of a molecule and its biological activity. For this type of request, we prepare combinatorial libraries (small molecules and peptidomimetics). Our robotic synthesizer allows for the efficient parallel synthesis of hundreds of such compounds. From these libraries, they can find better lead compounds upon assay testing, especially when it comes to defining the relationship between toxicity and physiological activity of the compound. At the same time, we are able to test these molecules in our animal facility dedicated to both pharmacokinetics and pharmacodynamic studies. The facility houses 45,000 mice, 21,600 rats, as well as 750 hamsters and 240 Guinea pigs. It is also certified for genetically modified organisms (GMO).

An example of our other capabilities is that we can transform successful candidates from the above-mentioned activities into further stages of pre-clinical R&D, including the optimization of synthetic processes and analytical work, going as far as the preparation of clinical batches for human clinical trials I – III and even the production of the actual active pharmaceutical ingredient (API). This is also reflected in the name of our company, which is a combination of two words, API and –genesis–, APIGENEX.

Since 2013, APIGENEX has been collaborating on a project entitled "Development of new-generation anti-cancer immunotherapeutics". What progress has been made on this front?

For this project, we are collaborating with the IOCB and the Institute of Microbiology of the Academy of Sciences. They developed a revolutionary type of immunostimulant based on lipophilic normuramyl-glycopeptide. It strongly activates the human immune system without unpleasant side effects such as fever, shivers and nausea among others.

We acquired the rights for this compound and are currently developing its application in our labs, and we have come to a close realization of the outputs. This development research is very different from the services we offer to our clients. This is not in the area of diabetes, metabolic syndrome or others – it is immunology. Needless to say, we have a very clear dividing line between our internal research and our services as a CRO company.

What do you think is lacking for the Czech Republic to become a life sciences hub with a thriving biotech ecosystem, like the one in San Francisco Bay?

In the Czech Republic, we see many universities, with excellent and innovative scientists, working in this area. There is great potential for discovering new solutions and therapies in the area of life sciences. Nonetheless, in California, they have a stronger entrepreneurial foundation, where hundreds or even thousands of small companies are looking to revolutionize the industry.

Lately, we see many innovative spin-offs originating in universities or institutions globally. I would be happy to see more companies in the Czech Republic fighting to do the same, whether they are focused on chemistry, biology or technology. It is a good opportunity to network and promote cutting-edge science and technology.

Here at APIGENEX, we collaborate with scientific institutions and start-ups who come up with their ground-breaking ideas and, thanks to our expertise and experience, we often help move these ideas forward.

Some ideas have the potential to transform into for example a new drug or disease marker. We help them take their discoveries to the next level. As an example I can give an early-stage anti-cancer compound which was originally developed by the Institute of Molecular Genetics and which we developed and prepared in scale-up for phase I clinical trials in our labs and GMP facility under cGMP conditions.

In general, MNCs do operate differently. Bigger companies have clear goals and are very specific about what they want while small biotech companies look for a broad spectrum of services in chemistry, analytics and production as small companies have a narrow focus on a limited number of activities and as a result they need to outsource some others.

I encourage more brave scientists to begin an entrepreneurial journey.

What are your priorities going forward to grow the business and position APIGENEX as a partner of choice to the pharma and biopharma industry?

Our goal is to maintain our leading position in terms of the services we provide. In this industry, we see that automation and artificial intelligence are increasingly more important. For this reason, we would like to invest in technology that will allow us to skyrocket production. I am not talking about

doubling or tripling production; I am talking about multiplying it by thousands! And this is strongly connected to investing in technologies and robotic equipment which can ensure the right quality and exponential quantity of production. Overall, this technology will give us a head start over our competitors and the flexibility to respond to our clients' needs.

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