

Interview with Gabor Somlyai, Managing Director, HYD LLC.

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You founded HYD almost 20 years ago, in 1992. Can you first explain to our readers why you made the switch from doing research at the Hungarian Institute of Oncology to setting up your own company?

I already knew when I was a teenager that I wanted to work on research in the area of oncology. However, when I graduated as a biologist in 1982, I could not find a job in this field. Therefore, I continued my recombinant DNA work in another area of research. This was at a Plant Protection Institute of the Hungarian Academy of Science, where my job was to investigate the genetic background of certain bacteria that caused diseases in certain plants. In 1988, I obtained my PhD, went for half a year to Georg-August University of Gottingen in Germany and subsequently to the University of Missouri, Columbia in the US. The day I returned from the USA, I gave my notice to my former employer as I wanted to test my ideas in cancer research.

I was glad to turn to a field of research in which I was much more interested, and found a job at the National Institute of Oncology as a senior research fellow. When I arrived there, I came with the idea to investigate the role of deuterium in living organisms. I first started preparing deuterium-depleted water at home, and brought it to the Institute to make the first experiments on the correlation between lower deuterium content of water and cell proliferation in cell cultures. The first experiment already proved that with lowering the D-concentration of the media, we could inhibit cell growth. In the next experiment, we transplanted tumours into mice and gave them deuterium-depleted water (DDW) to drink. We found that in 60% of the animals, the tumour could be eliminated. These results were published in FEBS Letters in 1993.

The question was then how to proceed. I thought we should find a new way that could provide the proper funding for the development of this sort of drug. This is the reason, how the company was eventually established in November 1992. It were strange times of course, whereas I took the initiative to accept a salary of a few hundreds of dollars to develop a drug that would cost around 1 billion dollars.

Financing the start-up phase must indeed have been one of the toughest challenges at that time. How did you cope with this?

Even when I was a teenager, it was not my idea to find a new drug, but to find the way how life organizes itself. When we tested deuterium depletion, our conclusion was that the ratio between hydrogen and deuterium would be the key signal of the cell, and that the changing D/H -ratio can switch on and off genes and enzymes, which can simultaneously coordinate all the processes in the

cell. We have also gained a tremendous amount of results that confirmed the initial hypothesis.

When we established the company and needed to obtain capital, it was our prime aim and task to generate more and more results and evidence, and convince the scientific community of our findings. Without clear proof, nobody would invest. However, to obtain proofs, we would need money. It was a vicious circle.

In 1999, we therefore registered our first deuterium-depleted product as an anticancer drug for veterinary use, and tried to get on the market with other deuterium-depleted consumers products. The D-concentration for food products or drinking water is not regulated by the law. When we came out with a food product, we could not claim that this would help against cancer, but it gave us a chance to talk about our scientific results. Slowly but surely, the Hungarian population could learn that deuterium-depleted water could be good against cancer and for prevention. As a result, more and more cancer patients started consuming this special water which generated some revenue for HYD.

In the last 19 years, we have never taken any money out of the company and have reinvested all our earnings into new research to obtain more results and go abroad to present these.

In terms of results, we have for example run a clinical trial with 44 prostate cancer patients over a period of 4 months. At the end, we found a 160 cm³ cumulative decrease in prostate volume in the treated group, and only 54 cm³ in the placebo group. Upon checking the survival rate after 1 year, we further found that 2 people out of 22 died in the treated group, while 9 out of 22 passed away in the control group. This difference was significant.

Right now, we hope to attract an investor as we are planning to start a new clinical trial. We are further also working towards obtaining the GMP standard for our production facility. We are sure that if we complete a new phase II clinical trial, we can proceed to Phase III or alternatively find a license partner to complete the job.

Which cancer will this new trial focus on?

We are still weighing our options. One idea is to go with pancreatic cancer. The other option is to run on lung cancer, because this population is much larger. In my view, it does not matter that much which type of cancer we will operate on, as we are mostly confident about obtaining a two- threefold increase in the median survival time of what has been obtained worldwide.

We have learned that creating the awareness for DDW has been quite a challenge. In 2006, you obtained the award for Most Innovative Food Product at an exhibition in Germany. Was this a big milestone for the company?

Not really, but it was a good feeling to have been chosen among 20,000 different types of food products at this fair. Communication remains very difficult, as our products for human consumption are in food category. Therefore, it was a great honour but unfortunately we could not use the Prize to boost the company's growth.

How do you go about raising awareness then?

We have already been on TV, and communicate through press releases. I have already been in the media for 17 years, but it takes a very long time to spread this type of scientific information in the media.

And in 2002, you were the fifth fastest growing company in the region â?!

After we appeared with our product Preventa on the market in 2000, and it received much attention in the media. After that, we could not produce enough D-depleted water to match demand. It has never been easy though, and have seen ups and downs in terms of growth. In the last couple of years, we have been growing more gradually.

What growth potential do you still see for the company now?

Right now, we cannot reach 1% of the cancer patients in Hungary. If the scientific community and pharmaceutical industry recognize what we have discovered, DDW may become fully integrated in oncotherapy. Pharmaceutical companies could save billions of dollars because the innocuous nature of the deuterium-depleted drug candidate, and it is unnecessary to carry out expensive toxicological, safety studies.

The other important fact to note is that developed countries are facing serious trouble due to increasing healthcare expenses and increasing numbers of cancer patients. Of the GDP, 4% will be spent on tackling this problem. Integrating DDW should offer a new solution in terms of prevention. The oncology drugs that are being used today cannot be used for prevention, as they are too harmful. With DDW, we can reduce the risk and incidence of cancer and therefore also the cost of healthcare.

You mentioned production capacity has not always been sufficient in the past, while you are now pursuing GMP accreditation. Is the capacity now in line with your growth ambitions?

No, and in fact we should invest a lot to cover the current demand. Right now, there is a certain balance but it will change as we proceed through Phase II.

You also mentioned licensing as an option. What type of partners are you looking for?

The bigger pharmaceutical companies are the most attractive partners that have the background and expertise for co-development or in-licensing of deuterium depletion. We believe that there should be 2 different product categories in the market. The first should be in functional food category, where the concentration of D would be closer to the natural level. The second should be in the lower D-concentration category that should be regarded as a drug, prescribed by physicians with expenses covered by the insurance companies.

You mentioned that you still reach less than 1% of the cancer patients in Hungary. How do you now see the company's international footprint evolving?

We have sold DDW to almost 40 countries so far, covering as far as the Philippines, USA, South Africa and other countries. We also have distributors in some countries, e.g. Slovakia, Germany, Romania, I have even noticed that in many of these other countries, including China for example, other companies have recognized the opportunity in deuterium depletion and have now also ventured into this area.

Would you like to add anything else as a final message to our readers?

The grounds of a new type of pharmaceutical and food industry can be laid in the near future, if the huge potential in deuterium depletion will be recognized and widely accepted. When we look at the cell which is about 40 micrometers in diameter- and it contains a 1.8m long DNA-strand it can be imagined that it is impossible to regulate this highly complex system with huge proteins. The cells use submolecular systems for the regulation and the changing D/H ratio directs the expression of the genes.

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