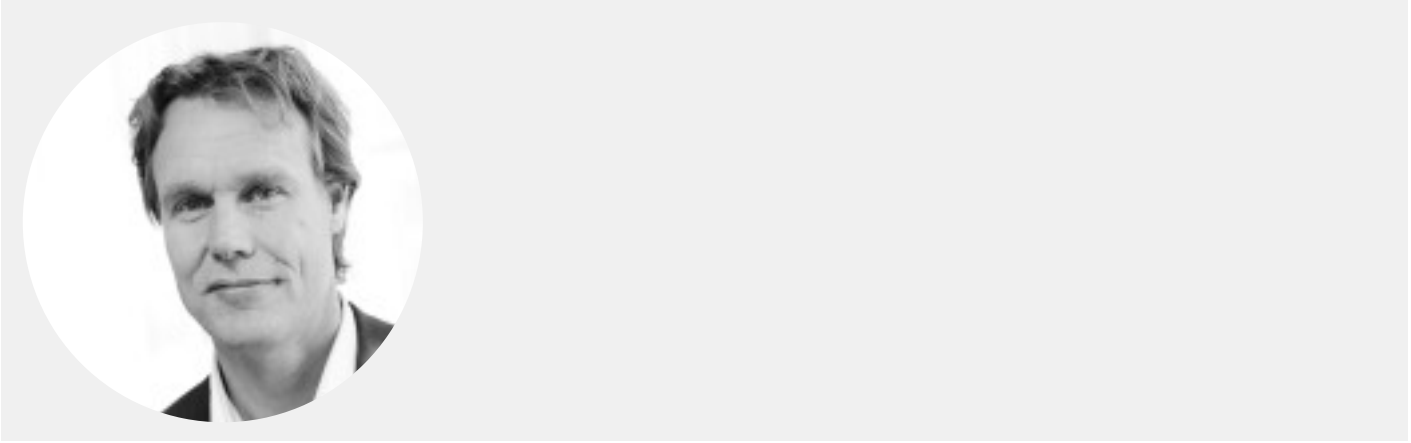
Interview: Erik van den Berg – CEO, AM Pharma, The Netherlands



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AM Pharma is developing an innovative treatment for acute kidney injury, and minority investor Pfizer recently acquired the option to purchase the firms remaining equity upon the completion of a phase II clinical trial.

How competitive do you feel Dutch life sciences in the academic setting are amongst your other European counterparts?

The Netherlands are very advanced in sciences in general, with a lot of research published each year, and in fact the Netherlands is considered to be one of the most effective and efficient countries for research, in terms of the quantity and quality of published research given the level of investment. Currently, the challenge lies in translating basic research into impactful technologies and commercializable products. Today, the biotech industry itself plays a vital role in Dutch life sciences, however fifteen years ago the Dutch biotech industry only consisted of two or three listed companies, a few multinationals, and a few private ventures. This growth was achieved by the government's support and stimulation of the life sciences sector through public-private partnerships that supported the development of technologies coming out of the university system. We now have many well-established and recognized biotech companies, and the industry has brought a significant amount of revenue into the country. Through this process, the Netherlands

has accumulated a strong knowledgebase and growing pool of human capital and experience, a critical mass of infrastructure concentrated around a few clusters such as the Leiden Bioscience Park, and growing venture capital capacity.

Do you feel the public funding helped the industry grow to a self-sustainable size?

Past policies were very successful, and current policy is still supportive, but there are some gaps that could be filled at present. First, there is a gap in very early phase funding, as there is a limited supply of private VC funding targeting early start-ups. In this sense, the government needs to play a role, as if the Dutch government wants Dutch companies to grow and expand over the long run, then they should provide supportive funding in the early phases to grow companies to a stage that venture capital will continue the funding. The second issue is that the biotech ecosystem is currently lacking organization, as there are large numbers of public-private and private-academic initiatives that duplicate each others work and operate with limited coordination. It would be to everyone’s benefit to create a transparent structure that with somewhat better defined roles for public and hybrid public-private institutions, where innovators could be supported in early stages by the government, and investors could have access to companies at a stage where more information was available and risks are better understood.

On the VC side, VC funding peaked at $300 million in 2011 and 2012, and has tapered off in recent years. What has caused this decline, and do you foresee investment increasing again in the near future?

The levels of VC funding seen in 2011 and 2012 may be attributable to the establishment of the OSS Science Park, and associated public investments that stimulated growth and private-investment in the area. It’s also worth noting that VC funds are typically much smaller in Europe than in comparison to the US, with a large Dutch investment fund at about EUR 100 million; as such, it takes time for startups to raise capital as they must approach more investors. Only recently Dutch VC funds are recapitalized based on an excellent exit track record especially in 2014. These funds are often not very liquid, meaning they may have to wait to exit more mature investments before making new ones. Right now we are seeing a wave of companies that have been able to raise funds relatively quickly, and I suspect that overall investments in Dutch-biotech may be on the rise.

Would you consider AM Pharma to be on this faster wave at present, especially considering your current relationship with Pfizer?

We have made a very innovative deal with Pfizer, where they have taken a minority interest position in AM Pharma, but have bought the option to acquire the rest of AM Pharma's shares after the results of our phase II study become available. This structure was created to ensure that we would not need to raise any further financing in the future, and we currently have sufficient funds to complete these phase II trial on hand, so we will not have any need to raise capital prior to when Pfizer will be able to exercise this option.

What were some of the toughest decisions and biggest risks you had to take as CEO to get AM Pharma to where it is today, with an acquisistion by Pfizer on the table?

In the last 8 years, the biggest change was, that after making significant progress in clinical development with an alkaline phosphatase (AP) molecule from a bovine source, we switched to a recombinant form of the molecule. This was a very difficult decision for the company to make considering the fact that we were leaving a clinical stage program to become pre-clinical company again, while in the midst of refinancing the company. In the end, this was the right decision, but at the time it was a very difficult one to make. With this recombinant form of AP (recAP), the company will be able to bring a cheaper and better quality product to patients. Furthermore, patients and potential partners have demonstrated so far that they prefer the recAP over the bovine form of the molecule, which has several associated health risks.

Looking at AM Pharma's portfolio, could you introduce our readers to your human recombinant Alkaline Phosphatase product, and its potential therapeutic impact?

This might be the first pharmaceutical product on the market to treat acute kidney injuries (AKI), which is currently a major unmet medical need. AKI is a widely occurring condition that affects approximately two million patients Europe and North America alone, or nearly four percent of hospital admissions and 40 percent of patients in the ICU. Mortality rates are very high, varying from 10 to 70 percent depending on the severity of the AKI.

In early phase studies with our bovine molecule, we saw evidence that our AP treatment could help return kidney to normal function in a very short time frame. These studies allowed us to safely secure a large financing offer of just under EUR 30 million in 2011, and EUR 12 million again in 2014 to push recAP from the preclinical stage into clinical development, and we have recently started a phase II study with approximately 290 patients. We expect that the results of this study will be available during late 2016 or early 2017, and our investor Pfizer now has the option to acquire the remainder of our shares upon the completion of this phase II study.

Have you yet forecasted a timeline for patient access to recAP for AKI?

We have not yet fully mapped out the timeline for a phase III trial since phase II is still underway, and the next step will be consulting with government regulators when we have the results of our phase II studies. There is an advantage to be considered, being recAP treatment will be an acute treatment used in a critical care setting, and as such a given patient will only need to be enrolled in the study for 90 days, making such studies relatively short.

Alkaline Phosphatase may also be viable as a treatment for hypophosphatasia and inflammatory bowel diseases; what progress has AM Pharma made on developing recAP for these indications?

In the previous phase II study with bovine AP in patients with ulcerative colitis, we found very interesting therapeutic signals proving strong reduction in Mayo and MTWSI scores in these patients in a short period of time. We are currently working on preclinical studies for recAP as a inflammatory bowel disease treatment, and have the intention to develop and oral dosage form for inflammatory bowel disease. There are currently several options to treat this condition on the market, but these have significant side effect profiles.

We recently received an orphan drug designation from the EMA and FDA for the development of recAP for hypophosphatasia.

Given AM Pharma’s ties to big pharma, recAP technology could have been developed outside of the Netherlands. What are some of the reasons the decision was made to develop it here?

This is a home grown innovation that originates from research at Groningen University in the Netherlands that resulted in the original invention; since 2002, AM Pharma carried out development. While AM Pharma has an international perspective and is well connected internationally, given that this research began in the Netherlands, and that the Dutch innovation environment is very fertile, there was no reason to relocate development or transfer the technology to a foreign company. For instance, we find that international investors like to invest in the Netherlands in general, meaning that access to capital is very good for later stage companies, with most foreign investment coming from the US and our major trading partners. It is also an optimal investment location with a strong legal system, excellent human resources with good language skills, amazing infrastructure and an advanced science and research community built around universities in the area. AM Pharma of course procures services from providers worldwide, across Europe and the US, but many of our needs are well met by the Dutch pharmaceutical and biotech development ecosystem.

What are your top priorities in 18 to 24 months from now?

Our top priorities are to conclude a successful clinical phase II trial of recAP for patients with AKI. This trial is currently being ran in 10 countries worldwide with more than 50 sites already open worldwide, and we want to remain focused on getting this trial across the finish line on a timely basis, and hopefully with a positive outcome.

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