Interview: Onno van de Stolpe – CEO, Galapagos, The Netherlands

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After a successful IPO on Nasdaq in May 2015, Galapagos is ready to continue developing its robust portfolio of clinical-stage breakthrough therapies with the potential to revolutionize existing treatment paradigms. The CEO discusses his current priorities as well as his vision to transform Galapagos into a specialty pharmaceutical company.

In May 2015 Galapagos successfully undertook an IPO on Nasdaq ten years after listing in Amsterdam and Brussels. Why was 2015 the right year to list in the US?

Banks had suggested to list on Nasdaq for a long time, but we had declined, as we thought we did not yet have had the size to receive sufficient exposure in the US. However, over time US specialized biotech investors got interested in our cystic fibrosis (CF) and JAK1 programs, which drove their attention to Galapagos. Especially after we entered filgotinib, our selective JAK1 inhibitor in rheumatoid arthritis into Phase II, we received more attention from the US. By January this year we already had nearly 40 percent of US investors, so getting listed on Nasdaq would make sense.

Furthermore, we had also restructured the company to a more US biotech model. Historically we had grown in a hybrid model, with CRO services as well as our own R&D programs and alliances in parallel; however, as we moved along with the development of filgotinib, we decided to sell the

CRO services division to Charles River. By selling this part of the organisation division, we lost half of our staff but became more understandable to US investors thanks to a leaner structure with 400 people and two very high visibility development programs. We thus decided it was the right moment to jump.

The IPO raised over USD 300 million rather than the USD 100 million target you initially filled. What accounts for this impressive increase in value?

We initially received USD 45 million commitment through our corporate partners Abbvie and J&J. That gave a lot of confidence to investors, which resulted in a tremendous interest for the offering. During the road show between the start and the marketing of the deal, it became apparent the demand would greatly overcome the USD 100 million, so we adapted the offering.

What are your strategic priorities for the money that has been raised?

We need the capital to move filgotinib into Phase III, which we are currently preparing. In addition, we'll fund the CF program, which over the years has grown in terms of size and expenditure. We also wanted to have capital available in case we identify new opportunities in the form of new compounds or the acquisition of a company. Well-capitalized biotech companies are able to make smarter decisions, as you have got more options with regard to portfolio and the fields you want to move forward.

According to the most recent media reports Galapagos is actively looking for a new partner for the further development of filgotinib before the end of the year, given Abbvie's decision to hand back the rights to the candidate. How is this process proceeding?

The advantage of having a partner on board before the end of the year is that they can influence the design of Phase III, which needs to be defined with the FDA and EMA. We expect to seal the partnership before the end of the year and are on track to do so, with Phase III trials set to begin in the first half of 2016.

What makes filgotinib an appealing target, and when do you expect Galapagos' first product to reach the market?

What differentiates filgotinib from any other molecule out there is the combination of efficacy we have shown in the trials and the outstanding safety. There is no molecule or biological so far that has a safety pattern that gets close to filgotinib's. Rheumatoid arthritis is a chronic disease, which requires a safe drug. Others cause important side effects, such as anemia, high cholesterol or high

level of infections, and we have not seen any of that. In Phase II the efficacy data were the highest reported up to today, which needs to be confirmed in Phase III, but so far it ranks very well. We estimate to have the product on the market by 2019.

Several of Galapagos partnerships over the past 18 months have ended – Abbvie for rheumatoid arthritis, GSK for lupus, and J&J for inflammatory bowel disease. Why is it the case?

What happens in pharma is that strategic priorities change every two years, especially for large drug manufacturers, which are able to shut down entire areas and sites if they do not align anymore with their internal strategy. It was the case of our previous partner in fibrosis, which dismissed the whole team upon closing one of their R&D sites. We have built our pipeline partly thanks to alliances. Partnerships have been very productive for us and we want to continue building on them for the future.

Our partnership with Abbvie actually continues; what failed was their licensing of filgotinib. We knew Abbvie had a competing molecule in the pipeline, whose timeline was running in parallel with our product. Eventually they decided to select their molecule over ours, and economics played a key role in the decision. We thought it was a fair decision, which in the end benefitted both sides. We continue working with them on CF, and it’s going very well. We are competing with Vertex to identify compounds that correct defects in expression of and/or increase the activity of the main mutations in the cystic fibrosis transmembrane regulator (CFTR) protein, including the F508del mutation, which is the most common with 90 percent prevalence among patients with CF.

In 2010 you told us that “our target discovery engine is absolutely unique in the world; there is no one who even comes close to it.” How true does this claim remain in 2015?

The claim is the same, and I think our pipeline speaks for itself. Filgotinib was discovered with our technology and is our biggest ambassador. We currently have a self-developed program for ulcerative colitis, which is in Phase II, and a program targeting idiopathic pulmonary disease (IPF). Our alliance with Servier in osteoarthritis has just entered the clinical stage and is also based on targets that came out from our platform. And we continue using our platform to come up with new targets for new diseases such as Hepatitis B, metabolic diseases and fibrosis.

Why focus on orphan diseases? What can be your competitive edge in this sector?

Our focus is not solely on orphan diseases, but we think it’s a field where a biotech company like Galapagos may be able to market its own product. In 2010, our CF program was still developed

independently, but we decided to partner because of the competitive threat of Vertex and other pharma players. We thought we needed the financial, scientific, technology and manpower back-up of a big pharma partner. Abbvie came in and invested a huge amount of resources, and together we believe we can compete.

CF is the only area of our portfolio where we are working with a target that does not come out from our discovery platform. The advantage is that much more is known, while the downside is that competition is higher, as anyone can work on it. The improvement in research in CF over the past five to ten years has been dramatic, and it's a race. We do not have a competitive edge with regard to the target, but we can rapidly test molecules in cellular assays to see if they are effective and safe. Also in the orphan space, we develop an autotaxin inhibitor for IPF. This molecule will move into a Phase II trial next year and could eventually be brought to the market by Galapagos. This disease area could be covered by a Galapagos marketing activity, so we might bring it to the market under our name.

Given your foothold in the US now, how do you feel the perception of life science companies differs in Europe and across the Atlantic?

In the biotech segment US companies rank higher than European ones. There is just so many more financial resources available in the US than in Europe. In my opinion so far one of the reasons has been the lack of success stories: we do not have cases that stand out, can help create the same level of excitement as in the US and can generate the same capital flow. We have companies that start getting attention, but we need a further step up. Excitement will lead to more IPOs and to more venture capital, creating a virtuous circle. It's an eco-system that needs big successes to get going.

Galapagos was founded in Leiden but today headquarters is in Belgium and major parts of your R&D operations take place in France. Why was the Netherlands not selected for such key company functions?

Galapagos was founded in 1999 as a joint venture between Crucell and Tibotec, today both part of J&J. Crucell was interested in setting up a genomics division, so we got in contact with Tibotec, in Belgium, which focused on ultra-high throughput screening. It seemed a perfect match to identify new targets. I negotiated to have access to the technology of Tibotec, so we set up shop in their labs in Belgium. There have been discussions to merge the Dutch and Belgian sites, but people in Europe do not move that easily as they do in the US, so we have kept it this way. The Paris R&D site, on the other hand, was an acquisition we did in 2006.

Do you feel like a Dutch or a Pan-European company in terms of business culture?

We are definitely a Pan-European company: I'm Dutch, and the majority of the management team is as well, but the core of our research is in Belgium and we have more than five different nationalities here in the Netherlands and over 17 overall, so – with the exception of the French site – the company language is English.

How do you create a company culture that stimulates true innovation to create game-changing therapies, especially across such a decentralized organization?

Ironically, the fact that we are decentralized helps in this regard. We prefer having four sites with 100 people than the other way around. It fosters the entrepreneurial spirit and creates competition.

What can we expect from Galapagos in the next five years?

My vision is clear: I do not think it's in the benefit of anybody for Galapagos to be incorporated in a larger company, except for short-term shareholders gains. In terms of innovation, people and culture it's not advantageous. I would rather build Galapagos in an Amgen-like model. We have the potential because of the technology platform we rely on and have shown that we can develop drugs all the way to Phase III. We are not there yet, but in ten years time we could be an independent specialty pharma company. That's the objective.

What keeps you motivated after so many years?

The progress the company is making, everyday. Supporting the company in its journey to become an integrated specialty pharma company has been really rewarding. The environment is amazing, and I'm very excited about the group I'm working with. We started being two scientists and today, with 400 people, it's a dream come true.

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