Magnus Corfitzen – CEO, Ascelia Pharma, Sweden

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Ascelia Pharma is a Swedish oncology start-up based in Malmö. CEO Magnus Corfitzen talks about the opportunities they have found in the orphan oncology drug market, the promising phase III study for their lead asset, Mangoral, and his journey navigating the Swedish life science industry.

Can you explain your affiliation to Ascelia Pharma and how you came to be the CEO?

For most of my career, I worked for venture capital firms, investing in life sciences companies, helping them be successful in developing new medical products for patients in need. I was part of the team that founded Sunstone Capital, which is a strong European venture capital firm. When I was at Sunstone, I got in touch with Ascelia Pharma and was extremely intrigued by the product Mangoral, which also had strong interest from key opinion leaders, so I recommended Sunstone to invest in the company.

I then joined the board of Ascelia and was chairman for a number of years, it initially was meant to be temporary. Later on, I was asked by the board to take a full-time position and, having done my due diligence as chairman for a number of years, I knew what was unique and exciting about the product and also what the challenges ahead were.

Since then, we have built a tremendously strong team in the company, we had some fantastic progress, some good data from Mangoral and then acquired another product, Oncoral, which had some very good data recently from a phase I study.

What is the unmet medical need that you are you targeting?

Our main asset, Mangoral, intends to help detect metastasis in the liver. The liver is a vital organ in the body since it works as a filter. As cancer spreads through the bloodstream, and the blood passes through the liver, a lot of metastasis ends up in the liver and that's why, in cancer patients, liver imaging is very important to understand whether the cancer spreads or not to the liver. The liver is the most frequent site for metastasis after lymph nodes. Furthermore, if liver metastasis can be detected early, they can be surgically removed and that has a tremendous impact on patient survival.

All the current products approved for liver imaging are based on a heavy metal called gadolinium – the problem with gadolinium is that in patients with poor kidney function, it can cause Nephrogenic Systemic Fibrosis – an incurable and potentially lethal side effect. Consequently, all gadolinium products carry Black Box warnings and for patients with poor kidney function, the standard of care is MRI without an imaging agent. This, in turn, creates a much lower quality image quality so metastasis can be missed, and the patient will receive the incorrect treatment.

With Mangoral, we are exclusively targeting patients with poor kidney functions that are not eligible for currently available products. That is an open space where there is a significant unmet medical need, where we can make a very big difference. That's why investigators and KOLs around the world are very excited to collaborate with us to bring this product forward and help these patients.

You mentioned that you finished phase II successfully and the recent IPO was part of raising the funds for the phase III study. Can you tell us your strategy moving ahead with the clinical trials?

We are working extremely hard to get the phase III study started and we are on track. We will start enrolling patients in the second half of this year and we expect to have the study completed at the end of next year. It is a relatively short study, we have had discussions with both the FDA and EMA regarding study protocols and we believe if the study is successful, it will be sufficient for registration and approval.
We are also thinking of how we can make it available to patients once we have the registration. We have done a lot of work in commercial preparation and validation, understanding pricing and

reimbursement schemes and opportunities for Mangoral.

We will launch Mangoral into a space where there is no product approved at all because gadolinium products have the risk of potentially deadly side effects in this particular orphan patient population. We need to prove that Mangoral is superior to an MRI without any imaging drug. That is also why we believe we have a strong likelihood of success in this phase III program. We believe in a price that is somewhat higher than the gadolinium products but will still be very cost-effective to the healthcare system.

If you have low-quality images, it’s harder to assess the progression of the disease. And that’s why the images will help guide whether you spend another 50,000 dollars for the next three months of drug therapy or not. That’s real value to the healthcare system and to the patient. We think that is a significant step forward for this patient population.

We believe the global addressable market is $350 to $500 million dollars annually. It is a significant unmet medical need. In the major markets such as the US, Europe, and Japan, it’s about 280,000 patients. It’s surprising to see that there are very few competitors in the area. We filed a patent application that could protect a next-generation Mangoral until 2040. It’s an illustration of our commitment to building a great product portfolio in this space.

Can you highlight what is your strategy moving ahead from Mangoral and the opportunities for your other product, Oncoral?

Our strategy is to help patients within the orphan oncology space, so small patient populations with significant unmet medical needs and we do that with Mangoral and Oncoral. Oncoral is a patented tablet formulation of the topoisomerase I inhibitor irinotecan, a chemotherapeutic drug with a well-established role and strong anti-tumour activity for the treatment of cancer. Irinotecan is given as an infusion that gives a very high plasma concentration and the side-effects are substantial, but it is used because of its efficiency in killing cancer cells. Oncoral would allow patients to take tablets at home instead of visiting the hospital for an infusion and a high plasma concentration. The Phase I data revealed similar types of side-effects but more moderate. This is very encouraging for future development.

We are developing Oncoral for the treatment of gastric cancer, which in Europe and the US is an orphan condition; so, there is a significant unmet medical need.

There has been a trend in Sweden where many startups have had an initial public offering (IPO) at an early stage. How did Ascelia manage to advance this far without the company going public earlier?

We raised money from venture capital firms and private investors to fund development until the completion of phase II development. We launched the IPO earlier this year to raise capital for the phase III studies and we had a very strong interest in the IPO, which was oversubscribed. We have had some great news since the company went public, and we are continuing to deliver on what we said.

You mentioned that you perceived a Swedish environment in which is relatively easy to secure initial funding, but that foreign investment is sometimes hard to come by.

There is a significant amount of interest from international specialist investors for companies in Sweden. For instance, one of our shareholders is a specialist life's science investor based in Paris. I think Sweden is recognized as a good place to look for high-quality life science companies. But the further you get away from Sweden, the larger your company has to be able to attract interest.

Sweden has a very innovative ecosystem, so what do you think makes the environment so special, particularly in the Medicon Valley area?

I think there is a lot of talent and people with experience and track record that can develop new medicinal products and build fantastic companies. You also have a strong academic research base and, comparing to other places in Europe, a relatively strong access to financial opportunities here. That doesn't mean it is easy, but the availability is there. Part of the reason Sweden is so good is that they have a well-functioning stock market but also a lot of people that are successful in investing in these companies. That puts a lot of investor experience in the ecosystem and confidence in backing new companies that can be the next big thing. Also, the legal framework for building companies and investor taxation also plays an important role in making it attractive to build new companies.

You have an extensive background in finance and venture capital, can you give us an overview of how this background helps you lead Ascelia?

Having been a life science investor for almost 15 years and on the board of 12 companies within life science has helped me understand how the outside looks at Ascelia Pharma. Knowing how it is to be on the other side is very helpful when I meet with investors. The other thing I learned from investing is that having the right team is absolutely crucial. That is why I have been very diligent in building the team at Ascelia Pharma, which I’m very proud of.

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