Interview: PaweÅ? PrzewiÄ?Åºlikowski â?? CEO Selvita, Poland

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22.01.2018

Tags:

Poland, Selvita, Biotech, R&D, Clinical Trials, Oncology

PaweÅ? PrzewiÄ?Åºlikowski, CEO of Selvita, the largest biotech company between Germany and India, discusses the first-in-class and pioneer Polish molecule, SEL24, and the future game changing molecule, SEL120 â?? the first ever CDK8 inhibitor for acute myeloid leukaemia with great opportunities for further indications and development. Furthermore, he highlights the companyâ??s diverse services offered to external partners as well as the potential for Poland to be a larger player in the global biotech landscape and driving forward the domestic R&D movement.

As the CEO, what have been Selvitaâ??s major achievements over the last year?

We have achieved three major milestones in the last year. Firstly, the start of clinical trials for SEL24; a Selvita-developed first-in-class dual PIM/FLT3 kinase inhibitor for the treatment of patients with relapsed/refractory acute myeloid leukaemia (AML). These clinical studies are being run in three major US oncology centres and offer treatment for patients with generally poor diagnosis. The project started in 2009 with an in-licenced molecule, and after synthesising around 1300 molecules, we started pre-clinical development in 2015, and subsequently commenced clinical studies in March 2017. We are the first Polish biotech company to start clinical trials in the US and the first Polish company to have clinical studies in oncology for an innovative molecule.

Our second achievement was the partnership established with Berlin-Chemie a member of Italian Menarini Group for SEL24, the first ever partnership deal for an innovative Polish molecule. This agreement is almost five million EUR (5.77 million USD) upfront, up to 89 million EUR (107 million USD) in potential milestone payments and up to double-digit royalties; a classic biotech in-licence agreement.

Thirdly, we managed to secure, in August 2017, a co-fund collaboration with The Leukaemia and Lymphoma Society (LLS) â?? the largest therapeutic haemo-oncology foundation in the world that has a 400 million USD annual budget. This partnership is to help pre-clinical and clinical development of SEL120, a targeted therapy to treat AML, as well as other malignancies connected to cancer stem cells.

The company has recently joined the Warsaw Stock exchange. How has this impacted the business model?

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Selvita was listed on the NewConnect exchange in 2011, and then the main market, the Warsaw Stock Exchange, in 2014. Previously, we were funded by the founderâ??s equity, research collaboration and government grants. We were able to raise money for our services, but were unable to generate funds for original drug discovery as there is no venture capital for biotech in Poland.

Therefore, transitioning to a public company gave us capital for investment, and this has allowed us to fund pre-clinical development and phase-1 studies for SEL24, and has assisted us in becoming a clinical stage company. Furthermore, our staff were able to feel more engaged in the business by buying shares, as well as it ensured a stronger bond with international investors for future collaborations. Additionally, being publicly listed requires a high-degree of transparency, and when competing against private companies for our R&D services, our clients enjoy the fact that we are open about our data and accountable for our decisions.

What is the importance of your services with Selvitaâ??s business model?

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Both aspects of the business are equally important, and we are highly committed to each. Our services provide to us stable growth, though from an investor point of view, the innovative sector gives us a valuation upside as a blockbuster product can be a game changer. Overall, 273 staff members are in services and 140 in the pipeline part, with the planned head count in the future to be 800 in services and 200 in the proprietary pipeline.

What are your service growth drivers?

Mostly it has been the upscaling of our existing portfolio of services; medicinal chemistry, in vitro-biology and structural biology, while in the meantime migrating from our fixed prices business model that previously was our bread and butter, to a structure based around fulltime collaborations and integrated projects where Selvita is responsible for the entire life cycle of an innovative drug. This is definitely our future!

Overall, 10 percent of our service revenues are from Poland, while the remaining 90 percent share is international business; 20 percent from the US, 50 percent from Western Europe, and 10 percent from countries such as Israel and Japan. We are active in establishing our name in the biotech world, being present at international conferences and gaining many clients through word of mouth. We have built a strong foundation through the excellent quality we produce, and now it is a snowball effect as our reputation intensifies.

Thus far, how has the experience been entering clinical studies for the first time with SEL24, and what challenges have you encountered?

It has been really positive! During the pre-clinical and clinical development stages at Selvita we understood the basics and gained a wealth of experience. The partnership with Berlin-Chemie Menarini significantly expanded our pre-clinical and clinical team, which grew to 30 members in four countries and six locations. Furthermore, we benefited greatly from Berlin-Chemie Menariniâ??s past experience in AML studies, and applying this knowledge to SEL24â??s development is a huge advantage that takes us to a global level.

Nevertheless, there are challenges, such as regulatory affairs, and this was a unique experience for us, as well as the fact I was dealing with the US government for the first time â?? a huge market with amazing potential. This meant we were always being compared to the standards of huge international companies, such as Novartis and Roche.

Secondly, we did hit a stumbling block due to patient complications during the initial stages of clinical studies, forcing us to put studies on hold. Though, as mentioned to investors earlier in the year, there is no evidence that links the event with SEL24 and the FDA has already allowed us to resume the studies.

Overall, it is definitely an exciting period, though at the same time demanding as we are treating severely ill patients with a new substance. Therefore, our excitement finds itself in a delicate space.

You have been quoted that you are seeking a significantly larger agreement for SEL120, compared to SEL24. What justifies this higher valuation?

SEL24, more or less, has a predictable biological outcome, despite being the first-ever dual PIM/FLT3 kinase inhibitor that offers significant advantages over therapies offered by other companies, such as Novartis and Incyte.

The first reason for our high expectations is that SEL120 is the first-ever CDK8 treatment that targets cancer stem cells and RNA transcription. a completely different mechanism to any molecule ever discovered. Secondly, it offers amazing potential, not just in AML treatment, but solid tumours, such as colorectal and breast cancer. Furthermore, it combines very well with checkpoint inhibitors. In this regard, we already have preclinical proof-of-concept for SEL120 and PD1 antibodies; therefore, this offers additional development opportunities. Thirdly, we are looking to sign a partnership at a more advanced stage, therefore, incorporating more complete and advanced data, compared to SEL24.

When are you looking to set up this future partnership?

Our strategy, and preferred scenario, is to partner in the middle of phase-2 clinical development, around 2020 or 2021. We are not active yet in this search, and the funds raised from investors and SEL24, will help us invest in SEL120 development ourselves.

Are you heavily focused solely in oncology?

Historically, we are an autoimmune, CNS and oncology based company, though we are narrowing our focus and now the proprietary pipeline consists of oncology molecules. This allows us to build on our experience, and oncology is a very broad therapeutic area, so it offers a great potential for growth.

Poland is not considered a global biotech hub. How do you attract staff to come to Poland, while creating suitable conditions so Polish scientists do not move abroad?

We create a level playing field from an economic point of view, by offering competitive salaries and low taxes, coupled with the Polish low cost of living. This gives our staff excellent disposable income.

Secondly, we offer staff added benefits and stock options, so they have direct investment into Selvitaâ??s success. Finally, the company is an entrepreneurial story that gives the power to our employees to be a major part of innovation and develop a long-fruitful career. Moreover, this is not in slightly incremental innovation, but truly innovative first-in-class drugs.

What more can be done to stimulate Polish R&D?

Poland has 40000 people taking part in biological research, half that of Germany â?? yet Germany is a home to three major pharmaceutical companies. Therefore, there is a disconnection at some point. Poland is in the stage of convergence, and we are slowly becoming closer to western Europe, not only in our overall knowledge, but with a strong emphasis on R&D, and the biotech sector is part of this movement.

All in all, there is no magic trick to success, it is all about harnessing the potential of Poland. The nation is investing in capital and the government is putting policies in place to develop R&D infrastructure towards financing therapeutic drug discovery. With all the correct elements in place Poland will gravitate to an innovation model similar to Spain, and step by step we can grow this innovation landscape, and hopefully within ten years, Polish companies will have innovative treatments registered.

As the largest biotech company between Germany and India, how does Selvita drive forward the domestic biotech scene?

We invest in R&D and attempt to be as successful as possible, which naturally generates for us more capital for future endeavours. This eventually will result in additional Selvita spin-off entities, and the people who work for us now will leave and found their own start up companies. I know that we are the training ground for the next generation of Polish biotech entrepreneurs although I hope that many of them will be a part of Selvita group for a long time.

Furthermore, we are working hand-in-hand with the government to demonstrate how innovation should be promoted and the positive changes that must be made in Polish academia and research institutes. In summary, if each key stakeholder does the extra mile, and thinks about more just than just their individual needs, the Polish domestic biotech sector will flourish.

What are your aspirations moving forward for Selvita?

In the next four years, we should have our own self-funded drug, most likely SEL120, in Phase II clinical studies and we will double the size of our service operations. Furthermore, we will expand the research centers at the life science parks in Poznan and Krakow, and construct our own research facility next year. No time to relax, but very exciting times ahead!

What is the secret to your success that has allowed you to achieve so much in a relatively short period of time?

Firstly, I love what I do, and I am part of more than a company, but a mission. If you have this mission and are motivated, committed and focused on the final goal, it is easy for other members of staff to buy in. Then it is more than just external factors, such as location and salary, but the ability to be part of important scientific discoveries at the Polish and international level for patients in need. Selvita is a Polish biotech pioneer, and has laid down a strong foundation for success, and now we are ready for the snowball effect that will allow us to grow, and continue to be leaders in the nationâ??s movement toward R&D relevance.

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