

Transcript of the interview with Dr. Joseph Carroll and Mats Grahn

You are listening to Vatorpodden, in which we interview executives of Sweden's most innovative companies. Vator Securities has since 2009 provided fast growing companies with financial advice. Our vision is to create a super cluster of innovative companies that have the potential to become unicorns. The contents of this pod should not be considered as an offer, recommendation or solicitation to buy or sell any securities or other financial instruments.

MODERATOR: Today's session of Vatorpodden is been recorded here at Medicon Village in Lund, together with Immunovia's CEO Mats Grahn. We are also excited to have Dr. Joseph Carroll on the pod as our special guest all the way from the United States. Dr. Joseph Carroll is the Senior Director of Business Development and Commercialization at the world renowned Knight Cancer Institute in Portland, Oregon. Today's session will also include a discussion between Mats and Joseph on the topic of cancer and diagnostics but, before we get started, I would like to congratulate you Mats on the successful overnight placement, in which you recently raised 190 million SEK, which amounts to just above 22 million dollars.

MATS: Well thanks for the congratulations on the capital raise which is great because it enables us to broaden the scope of Immunovia's efforts, bringing the test to market.

MODERATOR: In your press release you mentioned that a number of institutional investors are now shareholders of Immunovia. Can you begin by commenting on the implication of having broadened Immunovia's institutional ownership base?

MATS: It helps us a lot to be a reliable and stable partner in discussions taking this forward, because no company can do this alone. You have to work with authorities, you have to work with large institutions, such as Knight Cancer Institute and others, and health care providers, to be able to bring this to market. So having a stable financial base is a prerequisite and it certainly helps getting very well renowned owners into the pictures.

MODERATOR: And securing the funds from this round, I'm assuming that you are now fully funded to implement your new business plan for the coming years. Can you tell our audience what the new business plan looks like and how the funds are planned to be used?

MATS: It's not an entirely new direction for us because we have had the focus on pancreatic cancer, as I think most people know, from the start of the company. And our initial target group to work on are the hereditary people who have familiar higher risk of getting pancreatic cancer, and that is still valid of course as we pursue that plan. However, the second risk group, which is people over 50 who get their first diagnosis of diabetes are also at high risk of actually developing pancreatic cancer and would need to be monitored, or risk surveyed, during a certain period of time. And to address this large group in parallel, which is now very interesting as that market has matured faster than the way we expected, we needed more funds, and this great emission helps us now to be able to address that in parallel to the hereditary group.

MODERATOR: What are the indicators that the market has matured?

MATS: Well, we see as we have built up our key opinion leader network all over the world actually, but focused on US and Europe for starters, that not only the people who work with pancreatic cancer but also some key leaders on the diabetes side has started to address this potential. There are more and more scientific and clinical reports coming out and it's very clear that the risk is about 8 times higher than for normal, if you have your first diagnosis of diabetes and it's also known now that the pancreatic cancer in median happens about one to one and half years after the diabetes happens. So there are lots of facts have come to the table. Secondly, there is a strong interest on the authorities such as National Cancer Institute in US and others, who are about to start larger initiative in the area. Same goes for certain places in Europe actually and we have seen that there is a strong interest for collaborations to make it possible to decrease the mortality in pancreatic cancer for this group.

MODERATOR: Are there any particular triggers that made you want to pursue this now as opposed to maybe wait a year or two?

MATS: From the company's perspective, we have a test that we believe is quite far ahead from the competition at this stage. However, since the interest in pancreatic cancer has been growing over the last years with added focus not only because of the new law in US that was passed two and half years ago, but also because of the fact that pancreatic cancer now has passed breast cancer in the number of people dying per year and is the third largest killer in the US and also in Europe. So there has been a number of triggers that has raised the interest on the markets at the same time. So its legal focus, its funding focus, it's the facts that's coming to more public knowledge, that pancreatic cancer actually is the third largest killer, although being one of the 13th or 14th when it comes to incidence.

MODERATOR: And in a recent press release you mentioned that Immunovia is holding detailed talks about participating in a large consortium that would address the largest risk group of pancreatic cancer, which is as you mentioned earlier, the newly onset diabetes over 50 years of age. Can you comment on this and also provide us with an update and on the progress?

MATS: There are, not only one opportunity in this area, there are similar initiatives on both sides of the Atlantic. When it comes to US there is discussions among the authorities and a number of very large institutions that would provide the patients, and this is a challenging task of course to gather samples from the size of study as required, something between 5 000 and 10 000 patients would be required. So it's an advantage if it's being put together in combination between authorities, number of large centers with patients and players like Immunovia, who can actually provide a tool that would enable the surveillance of them. And there are similar initiatives happening in certain countries in Europe that we also do discussions with. When you have discussions with many players its actually not that easy to predict the exact timing of the agreements, but our ambition is to be able to at least have one of these key, important consortium in place during this year.

MODERATOR: What would it mean for Immunovia to be a part of consortiums and discussions like this?

MATS: Well, it shortens the time to build up such an organization or consortium that would be able to gather all the samples in an efficient manner. We of course do this by ourselves in the hereditary group where we make all our agreements with various institutions that is needed, and that can be done on the diabetes side as well, but if there are already structures being put in place and if we

could piggy back on that and be part of it, it saves us time and effort.

MODERATOR: So Mats, final question for you then. What are the milestones you see this year and for 2017?

MATS: Well there's quite a few actually, and it's going to be an exciting future coming forward. One is already in Q4 - we expect to get the first results from the pipeline side when it comes to the autoimmune/SLE test: whether we can differentiate that from other autoimmune diseases. So that's going to be exciting results. And then of course on the pancreatic cancer side, our main focus; there are several things. Start of the prospective studies, there is the CE marking and accreditation work which is a major milestone during 2017 because that enables us to start actually delivering the test. And then we have the progress on the reimbursement discussions that we will continue during next year and also of course mainly what I think everyone is waiting for, sales start.

MODERATOR: So moving on to you Joseph. I would like to welcome you to the pod and before we dig deeper into questions about cancer and diagnostics, can you briefly tell us a little bit about yourself - who are you and what's your background?

JOSEPH: Sure, of course. Well first of all I want to thank you and Mats for this opportunity, it's my pleasure to be here. So I have a PhD in Genetics and Cell Biology and I now work at the Knight Cancer Institute. My background with my science work has been primarily in pharmaceutical and biotech arena. I spent around 15 years at companies like Millennium Pharmaceuticals and Wyeth and a couple of small companies developing drugs, and using genomic technologies to make better drugs. About eight years ago, I moved back into the academic arena. And now I work at the interface of industry and academia where I help to foster new efforts in commercialization and form industry partnerships, like we have with Immunovia.

MODERATOR: And what made you shift to academia from a more commercial setting?

JOSEPH: Yeah, it was a very rather random decision. I was in a small startup company in Boulder, Colorado that was acquired by Merck. I had just got married and I told my wife that "well we're going to have to move to San Francisco". And she said "oh no we don't, we are staying here". So I had approached the university in Boulder, University of Colorado, about starting a company to stay there with some technology, and as part of that negotiation, they offered me a job. They said "we have this great job, it's in technology transfer" which is what we call in the US, I don't know if it's the same in Sweden, but this is the process of facilitating translation of technologies out of the university sector. So I have done that now at three different medical centers around the world.

MODERATOR: And can you tell us something about the Knight Cancer Institute where you are at today. I am thinking more towards the billion-dollar donation that you received in 2015, and also the role and importance of early detection in the work of the institute.

JOSEPH: Yeah, everyone wants to know about the billion-dollar funding that we got. That's very exciting but it really grew out of our history of personalized medicine. So my boss Brian Druker is the director of the cancer institute and he is known for bringing a drug called Gleevec for use in leukemia patients. And that was really, by most measures, the first personalized drug, meaning it was the first drug where you use a diagnostic test and coupled it with an actual drug.

MODERATOR: And why is that a better approach?

JOSEPH: Its really, these days, its the only approach, because in old days you used to give everybody who had cancer, like breast cancer the same drug. And maybe 20 of them would respond. But in reality there are about 50 different molecular sub types of breast cancer. So, if you want people to respond ideally, you want to get them on the drug that's specific for the subtype of the cancer that they have. So these days to bring a drug through development, and get it through the regulatory agencies in the EU and the US, you really need to have a what's called a companion diagnostic strategy. And this is somewhere we can talk later, about the importance of Immunovia's technology potentially. But we think this is really essential so now, what we've focused on, is largely personalized medicine, that is discovering bio markers around response to drugs and that specify cohorts of patients, that may respond to individual drugs. And we don't make a lot of drugs at Knight Cancer Institute, instead we partner with pharmaceutical and diagnostic companies so to be at the interface of that endeavor. So in 2008, Knight Cancer Institute got a very generous 100-million-dollar donation that allowed Brian Druker to bring together his vision for personalized medicine, and this donation was from Phil and Penny Knight. The Knights founded NIKE, a sportswear company that you may know of in Sweden. So Phil Knight was personally in touch by cancer and it was something that he was very interested in supporting. Brian had been his doc for a short time and so he was committed to the relationship. I think you know, a lot of this is about relationships in the end, so there is as you may know a lot of philanthropy out there right now. There are a lot of people with a lot of money, and I think foundations like the Gates foundation are really transforming how we treat disease and its through being interested in bringing their wealth to cure various diseases. So Phil Knight was committed to cancer, he's also funded a similar sized gift for cardio vascular work at OSHU, Oregon Science and Health University, where Knight Cancer Institute is based. And about year ago, we were running out of funding - two years ago, let me correct that. And so we went around a year and a half ago to Phil Knight and said you know "we have a grand strategy to really end cancer as we know it which is our mission. But the strategy is going to require about a billion dollars" and his jaw dropped and he said "well I don't know if I can do that but tell me about the strategy". And we talk to him about early detection. So the idea of detecting cancer early is really the best way to cure it. You know you go from most every tumor type from 5-year survival rates of 90% if you detect it at stage 1 or before, to if you detect it at stage 4 you might have 5-year survival rates of 5 or 10 or 20 %. So early detection is critical and we thought that we could bring together the right people and the right partners to make real impact. So we were successful. In the end Phil Knights said "well I will give you half the billion dollars if you raise the other half, and I will give you just two years to do it". So we did it in a year and half. We did it in under time. We got funding from every state in the country and a few countries around the world. And now we are looking to invest that funding in bringing the best people to Oregon and establishing the right partnerships to end cancer through early detection.

MODERATOR: So moving on to the collaboration that Knight Cancer Institute has with Immunovia. Why do you think that's important?

JOSEPH: It's important for several really critical reasons. Well let me start with the history, how it happened. We have a collaborator of ours, Jorge Leon, who is a fairly well-known person, powerful in the diagnostics space in the US. And I think he was connected with Rolf Ehrnström and Mats. And Jorge actually made the original connection. It was specifically around our Knight diagnostics lab, so at that time, this was about 2 years ago now, Immunovia was looking for labs in the US that might be able to help them validate the test there, and also sell them in certain geographic area of US. We happen to have a lab that does that. It's got a CLIA/CAP-certification which basically says that it's

doing all the right stuff and that the test they perform, can be used to direct patient care.

MODERATOR: Is that a tough process to go through, to get these accreditations?

JOSEPH: Yes, it's very challenging. You have to document every single step of everything you do in the test, it has to be documented. You have to follow standard operating procedures, you even have to document the data flow, you know how the data is being analyzed in the computer, the bioinformatics you are using. All has to be locked and loaded. Yeah, I don't want to get into the weeds about this, but there are a number of companies you know that are large, like LabCorp - it's the largest one in the US. And they perform most of the tests when you go to the hospital and have a test done. The hospital often doesn't do the test itself, it sends it out to one of these labs. There are fewer labs in universities that do this test collaboratively. We would be one of the few to do that. And one of the very few who actually perform tests. We do that for pharmaceutical companies and other hospitals. So we perform mostly genomic tests. So we didn't have proteomic tests which gets us to Immunovia and we are excited about it, but that's really the function of the Knight diagnostics lab. So when that introduction was made and Rolf came to visit with myself, Chris Colas, Joe Gray - some other researchers at Knight Cancer, we were really excited about the potential of a proteomic test in pancreatic cancer. Actually proteomic technology in general. Because there aren't a lot of these technologies out there. Most of the tests that are used right now for diagnosing and treating cancer, are DNA test. So you are looking at mutations in DNA. Some of the tests are RNA based so you are looking at express-genes that are encoded by the DNA but very few tests are proteomic tests. Proteomics is hard, and we were very impressed by Immunovia's technology. So that led us to have a discussion, to expand the discussion, around how do we begin with maybe just the Knight diagnostic lab relationship. You know, allowing us to help Immunovia to validate their test and then maybe sell it in US. But then also how can we do bigger things. How can we partner on validating pancreatic cancer test. How do we expand the use of that pancreatic test and then - could we look for other cancer? So that's part of I am here today, tomorrow and next days to talk about other strategies and other things we might do together with Immunovia.

MODERATOR: Can you dig deeper into the expectations and maybe some of the outcomes you see from the collaboration with Immunovia.

JOSEPH: Sure, yeah of course - proteomics as I said, is hard. You know the reality is that in order to get a perfect test you're probably going to need to look at DNA, RNA and protein. You are going to need to look at different analytes in the blood. Ideally in the blood. Because people don't want to give you a biopsy for an easily used test. One very attractive thing about Immunovia's technology is that its blood based and very diverse. So we can possibly understand you know how a protein test is, combined with DNA test, and to add on what we are already doing, and come up with maybe the ultimate test. This is out in the future, because no one is really doing this yet, but I think Immunovia will definitely be on that leading edge. So as we think about early detection we want to look at technologies that allow us to analyze all possible molecules in the blood. So proteins are an absolute essential part of the menu of the pallet that we want to have access to. What impressed me about Immunovia's technology is that most proteomic assays and tests that people have are mass spectrometry-based (mass-spec). Mass spec is a technology where you use a very large machine, which basically takes proteins out of the blood, and you are trying to deconvolute in this large machine, based on the weight of the proteins and the spectra that they have in this thing - what actual proteins are in the blood. It's very expensive and very time consuming. And really not practical for a large scale cancer test. There are some labs and companies that are trying this but I think they

are facing challenges, numerous challenges. Even just the regulatory, the CLIA aspect of the lab we spoke to earlier is going to be very challenging. I would say impossible to bring a CLIA-based test, that's a mass spec, protein based test, to use in cancer. That's one reason we like Immunovia's technology.

MODERATOR: Digging deeper into cancer. What's your view on Immunovia's current pancreatic test and what are the other types of cancers that are important for the institute, for Knight Cancer Institute?

JOSEPH: One reason that we are very focused on pancreatic cancer is because it's so lethal. It's detected very late and it's one of those cancer that you don't want to get. If it's detected, it's usually detected at stage 4, when patients present the symptoms of pain and nausea, and they have a 5-year survival rate of 5%. So we want to be able to detect it earlier and earlier in the course of the disease and we think that if we can detect it at the stage 1, we will be able to cure a large number of patients of pancreatic cancer, through surgery. And that's what Immunovia's test does. It allows us to detect the pancreatic cancer earlier in the disease at stage 1 and there is no other technology which is even close to allowing us to do that right now.

MODERATOR: And do you see other areas and other cancer types where Immunovia's technology can be transferred into?

JOSEPH: Well, at Knight Cancer we focus on four major cancer types. So pancreatic cancer would be one of them. The other solid tumor types would be prostate cancer and breast cancer. And the reason for those is because those are the cancers that kill the most people in the world.

MODERATOR: In absolute numbers?

JOSEPH: In absolute numbers, yeah. Survival rates for breast and prostate cancer is getting better and better because of the treatments, but as more of us are living longer and longer, men are getting prostate cancer, women are getting breast cancer and each of them have subtypes or variants that are very lethal. So we want to be able to look for earlier detection for those. We also focus on hematologic malignancies, that is blood cancers. For those I think early detection is more, because they are blood cells, we can detect them with simple blood test, by looking at aberrant cells. But for solid tumors like prostate cancer and breast cancer it's going to be really important to find blood based markers and tests that will allow us to know when somebody has early stage of the disease and whether they are responding to a drug adequately.

MODERATOR: So with that I would like to reintroduce Mats to the microphone and invite him to a discussion with Joseph into the opportunities for Immunovia and the collaboration going forward.

MATS: Right. So one thing when making partnerships or collaborations is of course that you have a match, that you fit together and have complimentary technologies and skills and resources. But there is another very very important thing and that is you have a cultural match that makes it work over a longer period of time and that's one of the most important things that we found with this collaboration. We had long discussions on the agreement but it was very constructive, and we have continued to work and even in the agreements built in structures and measures to make sure that the collaboration lives and develops over time.

JOSEPH: I agree Mats. You know at the end of the day this is about a relationship and you know we have numerous interactions with potential partners and there's a certain alchemy to whether or not a partnership is really going to work. You can have synergies on paper, but whether you are getting the same synergy in the room when you are discussing bigger ideas and potential for the science and how to get to the patients. It's not always so easy. It's nice, we definitely have that with Immunovia. Every time we get together we come up with more and more ideas that aren't distracting Mats from getting his current test to patients, but it is allowing him to look for some broader opportunities as well.

MATS: It is, and one practical measure is that one has to meet face-to-face regularly that's why we have a structure where we meet every half a year with key people in a steering group, discussing the future, collaborations and current status and so forth. And in between that of course we work over the phone and skype, but there is an important element on meeting face-to-face as well.

JOSEPH: There is. We try to get people to come to Portland in the summer, because its beautiful weather there, so that's when we hope to have more interactions, also in Sweden I imagine summer is nicer to be here in Lund, although it's very beautiful now in September. And I think something else Mats I would say about partnership is that it is important to leverage your strengths. So we are a medical center, and you know the big thing that we have, our big product if you will, are patients. We have patients that we need to treat, we have to bring new technologies to these patients. So one thing that we need to do in partnership is you know be able to help Mats and the Immunovia team to validate their test by getting them access to our patient samples, but at the end of the day, we want to bring this test to our patients because that's why we are in business, that's how we get street cred if to use an American expression.

MATS: yeah, that's actually one of the main challenges for us and our technology and every technology actually - to develop a technology, you need access to very good bio banks with clinical data that is of high quality. And you need them in rather large numbers as well, and that's not easy to get. So you have to work with institutions that have patients and have a stringent way of collecting, in our case, blood samples.

JOSEPH: Yeah. It's very true Mats. We have this problem in every disease we look at. So in breast cancer we are looking at potentially joining a consortia where they want to get access to 100,000 new breast cancer patients a year. It's crazy. But you actually need that because you have so much variation and so many subtypes of breast cancers that if you are going to get every woman on the right drug, you need to be able to look at a lot of patients to be able to come up with the right tests for those 50 molecular sub types. This is something that I think we will do with Immunovia. They are going to need access to thousands of pancreatic cancer patient's samples and they have done a phenomenal job in my estimation at approaching not just us but other medical centers around the world and we are always happy to be included. And on the other hand, we are doing that ourselves. So we announced last year a partnership with Cancer Research UK, which is the largest private funder of cancer research in the world next NIH/NCI in US. They are very excited to partner with us for early detection and we have already talked them about Immunovia. So we would hope that, I already know that Immunovia has partnered with some institutions around the UK. But we would hope that increasingly as we move forward with one partner like CRUK, it allows us to leverage our relationship with Immunovia and bring that benefit to Immunovia as well. Because we do nothing alone, whether its us at Knight Cancer or Mats. We are in partnership.

MATS: Yes it's very true. And it's what we discussed before on complimentary skills and resources. We may have the technology but it's basically impossible to develop new tests without access to samples and the data and at the later stages to the real patients, where you validate and do the prospective studies. So that's why such a collaboration is crucial for bringing new tests and ultimately bringing higher survival rates to patients. And talking about that there are other areas in cancer treatment. Cancer treatment is going through a revolution right now say with the new immunotherapy drugs coming to the market or approaches and I think there is a place for technologies like ours in that space as well.

JOSEPH: Absolutely Mats, cancer immunotherapy is changing the face of how cancer is treated. It's a relatively recent last 5 or 10 years' kind of discovery that you can actually just allow patients own immune system to attack their cancer. Cancers are devious and they have ways of actually turning off the immune systems. So many, in fact mostly all pharmaceutical companies and biotech companies that work on cancer now have an immune strategy also. That strategy is based on harnessing the patients own immune system to attack its cancer. One potentially large area for Immunovia in this regard could be an immune based test where because the current platform that Immunovia has, has a lot of immune markers in it, that you could actually use an Immunovia-test to monitor the immune system in the blood as a sentinel for cancer detection. Its really exciting because probably the first cell in your body that knows you have cancer, is an immune cell, and in theory, if u could harness a test that could detect those sentinel rights, so now a test to detect the immune cells, that could be the most sensitive cancer diagnostic ever.

MODERATOR: Thank you Joseph and Mats for the insights on the collaboration between Immunovia and Knight Cancer Institute. On behalf of Vator Securities I would like to thank you both for your participation on Vatorpodden, and finally congratulate you for a successful partnership and wish you good luck for the coming future.