# Nanoform Capital Markets Day Dec 16th, 2025, Helsinki

**Capital Markets Day press release:** https://www.nanoform.com/en/wp-content/uploads/sites/2/2021/10/press-release-nanoform-capital-markets-day-december-16th-2025.pdf

**Capital Markets Day presentation:** https://www.nanoform.com/en/wp-content/uploads/sites/2/2025/12/Nanoform-Capital-Markets-Day-December-16th-2025-Helsinki.pdf

## Capital Markets Day Agenda and AI-transcript below:

***Moderators: Director IR - Henri von Haartman and Chief Commercial Officer – Christian Jones***

***09.00 CEO Edward Hæggström, Chairman Miguel Calado and Board Member Jeanne Thoma: Nanoform Strategy 2026-2030***

***09.10 CFO Albert Hæggström: New midterm business targets 2030***

***09.20 Director Intellectual Property Winfried Ness: Nanoenzalutamide European IP landscape***

***09.30 Dr. Katja Dreyer, Director Onconcept & Specialty Generics, Helm Pharmaceuticals GmbH: Nanoenzalutamide European roadmap and commercial launch***

***09.40 Kurt Nielsen, Managing Director Expert Insights: Nanoenzalutamide US launch roadmap***

***09.50 Chief Quality Officer Johanna Kause: Nanoenzalutamide regulatory strategy***

***10.00 15 min break***

***10.15 Chief of Business Operations Antonio da Silva: 3 Nanoformed medicines launched by 2030***

***10.30 Steen Vangsgaard, CEO A.forall Group NV and Tiago Geraldes Investment Director IMGA: Why we invested in Nanoencorafenib/Brafmed Ltd***

***10.40 Sreevatsa Natarajan, Co-Founder and CEO Revio Therapeutics: GLIORA partnership with Nanoform***

***10.50 Senior Scientist Ari Kauppinen, Senior Engineer Tuomas Malve and Senior Scientist Petteri Helander: Nanoform's CESS® rocket science -***

***11.10 15min break***

***11.25 Chief Development Officer Peter Hänninen: A large biologics market is forming in subcutaneous delivery of monoclonal antibodies***

***11.40 Director Biologics Maria Lume: Working with large pharma - What we have done and learnt***

***11.50 Q&A***

***12.15 Closing remarks - Lunch - Factory Tour***

### Nanoform moderator IR Henri von Haartman (slide 3):

Good morning and thank you for taking the seats on time. It's 9:00 am. Thank you for being here today. We have a great list of attendees today. We also have Nanoform management of course here and the board and the commercial team. Yesterday we turned 10 years, and it was a great day for us. Today we will discuss the next five years. This is what it's about today. This is our first in person CMD here at our

headquarters at Nanoform and the commercial site where we have the key manufacturing areas in this building. We have a thorough agenda (slide 3). In three sections, each presentation is 10 or 15 minutes. There's one 20-minute presentation, with three gentlemen talking. We will have two breaks in between. The toilets are there. Between here and the reception, and there's also toilets back down there. We kindly ask you to stay in this area. It's called Plaza. If there were an alarm today, then we have protocols for this. Then we ask you to follow Edward, Albert, Tom and me, and will take you to the assembly point which is outside there. We will finish the presentations with Q&A at 12:15. After that there will be lunch in mingle format and then there will be factory tours for those who want to do it. I have several sign-ups, but if there are more of you who want to do it and haven't signed up, just let me know during the breaks. You're most welcome also to grab coffee and drinks and cinnamon buns during the breaks. OK, with these words, can I please have Edward, Miguel and Jeanne up on the stage. Thank you. Edward is our professor, he is our founder and CEO, and he's also the largest shareholder in Nanoform. Miguel is our chairman since 2020. He joined the board in 2019. And Jeanne is a board member and joined in 2021. Both Miguel and Jeanne have extensive global pharmaceutical experience, and we are truly honored to have you on the board. May I ask you, Miguel and Jeanne, to say a few words before the presentations start.

**Nanoform Chairman of the Board Miguel Calado:**

Hi, everyone. Good morning. I'm Miguel Calado and just a few words about myself. I was born and raised in Portugal. My career started there and I have served as a member of the Board of Directors of Aveleda S.A. and OutSystems S.A, been President of iMAX Diagnostic Imaging Business Unit, Vice President of Hovione S.A., Vice President and CFO of Hovione S.A, various positions at PepsiCo, Inc. including Vice President and CFO of PepsiCo Foods International. It's been a pleasure to be a board member and chairman of Nanoform. Just a few words saying that I really look forward to today. I'm sure you'll enjoy it. I think you'll see the progress that we have achieved in recent years, but more importantly, I think you maybe have a good appreciation of what the strategy is, the business targets for the coming years. You will also meet the people that are behind the strategy and are going to take it forward. I hope that you'll have a great day with us. Again, thank you and welcome.

**Nanoform Board Member Jeanne Thoma:**

Good morning. My name is Jeanne Thoma, and as mentioned, I have quite a bit of experience in the pharmaceutical industry. I started my career about 30 years ago in BASF in their pharma ingredients business, and then I spent 10 years in Switzerland, at Lonza. My last operational role, I was the CEO of SPI Pharma, which is an ingredients company in the US. The last five years I've been doing exclusively board work for public companies including Nanoform and one private company. I've really enjoyed being on the board at Nanoform. It's been a very dynamic and exciting experience. It's a great team. I find them to be very agile, very creative. And as I mentioned yesterday at the 10-year celebration, very brave. They've made great strides in the last 10 years, and they continue to build on those successes and I'm looking forward to the next 5 to 10 years when they continue to strive for their goals of bringing this technology across the pharmaceutical industry.

**Nanoform moderator IR Henri von Haartman:**
Excellent. Thank you very much, Miguel and Jeanne. You may sit down now with the audience. Thank you. Edward, please, let's start the CMD.

**Nanoform CEO Edward Haeggström - Nanoform Strategy 2026-2030 (slides 5-6):**

Welcome on my behalf also. My intention is to reveal to you what was said in the press release this morning and give you a little bit of background. To do that, I will have several of our talented directors here giving their uncensored viewpoint. Next slide. Chairman, with your permission, let me reveal and start the process of this. Thank you, Sir. We call it a breakthrough strategy where we will break the wall in two places, on the small molecule side and on the large molecule side. Next please. Here you can see the small molecule side, we will place products on the market that patients have bought. On the large molecule side, we will generate clinical data with commercial relevance to set us up for the next five-year period going forward from that. The last five years have been about building. The next five years will be about cashing in. Thank you. Now let's go on.

**Nanoform moderator IR Henri von Haartman:**

Thank you, Edward. Albert, may I have you on stage. Albert has been a board member since the company was founded. He became the CFO in 2018 and as you know, he's very business savvy and he's very instrumental to what we will present to you.

**Nanoform CFO and Board Member Albert Haeggström - New midterm business targets 2030 (slides 7-18):**

Thank you. Welcome also on my behalf. It's nice to see so many familiar faces and let's go into the business targets for 2030. Before we take the targets, I want to talk a little bit about what has happened in the past years since we did the IPO. On the left you have the graph we showed in the IPO, number of approved novel drugs in the US during the years and what you could see is a sort of a trend going up where you almost reached 50 by the year 2019. You could also see biologics starting to get traction. Everybody hoped, of course, that this trend will continue. Launching 50 products with all that money is not that much. Well, what has been the realization during the last five years from 2020 to 2024, we have here. So, it's still the same 50 drugs that has been approved, no improvement. Actually, on the small molecule side, there have been fewer. So, the biologics have been growing, but the small molecules have been actually going down. Why is that? Is that a lack of money? Well, certainly not. Again, here you can see on the left-hand side that when we went for the IPO, the industry spent $180-185 billion on R&D per year. And we're expected to grow to $213 billion by the end of 2024. On the right-hand side, you can see the realization, the money has exploded, COVID and everybody starting to bring money. So, actually the number for last year was $306 billion. No improvement in the number of approved drugs. The industry spent 50 or $100 billion more money. The reason for this is, of course, the biologics are very expensive, but it's also that the efficiency in the pharma industry is not where it should be.

The following thing is what has happened to the approval rates in the industry. Well, I

can tell you that they're still poor for the small molecules. This is a familiar graph for you. 2% of the projects go from preclinic all the way to market and on the biologics side it is 4%. However, on the reformulated side the 505B2s have a 10-time higher approval rate or a success rate and this is of course where we have started to focus more on, we take products and we make them better rather than trying to come up with totally new. This is our strategy for the coming five years on the small molecule side. This is the way we will break the wall on the small molecule side and put products on the market. Timelines are much shorter. Success rate is much higher.

What we have also learned during the last five years when it comes to one of the key aspects that has been disappointing for us during the last five years and that is going from preclinic to GMP (clinic). We should have seen more transition. That's what we thought. In the IPO, our assumption was that we would have the same probability of going from preclinic to GMP as to industry, meaning 20-25%. What we have learned the hard way, but also talking to people, a common number when you have a new technology that does not yet have a commercial license, it's more like 5%. It takes time before the industry accepts the new technology and then the probability of going from pre clinic to clinic increases. We also know that when you have a mature technology and you have a focus, you can reach very high numbers. We have met CDMOs that are focused on very certain mature technology, and they have internal targets that are even higher than 50% from pre-clinic to clinic. These are numbers we did not know about when we did the IPO. Our target now for 2030 is to reach the industry number by the end of the period. Now we have been between 5 and 10%. We also believe that the number of projects will increase from 100 in the last five years to 200 more in the coming five years. We will continue to see more projects coming, both on the small molecule side but also helped by the large molecules, where there is clearly more drive and as the transition rate goes up, we will see more GMP projects.

What will this mean as a graph? Cumulatively pre-clinical (non-GMP) projects, we are now above 100 in the last five years. We will go, from the start, to more than 300. The number of clinical (GMP) projects will go from about 5 to about 30. And you have the share of projects moving into GMP going up from 5% to about 20-25%. Actually, we believe that 2024 was the lowest year. This year should already be better, and we would reach the industry number of 20 to 25% by the end of the period. Here we have the first target, and the first target is to launch three medicines on the market by 2030. These will be small molecule medicines and of course the following five years with a higher transition rate. We will not need 300 projects to get the three, the following three and the following three. That's also key, but the target is now to get 3 products on the market by 2030.

A little bit about income potential. What we have also learned is that there are very many boxes where we can achieve income. When we started, we only thought about small molecules and we had preclinical work. Here we have identified many boxes where we can get significant revenue from all the boxes. €5m + €5m on non GMP for both small molecule and biologics going to GMP projects, which increases the value when they go through the phases, but also then we will start to get development milestones, we will get commercial milestones, we will have a commercial supply income when the products are on the market. And then of course we have the exclusivity fees, the royalties and the profit shares starting already in this period and

these could be more than €50 million per year. If you compare that to the numbers you see in the US companies like Elektrofi and others, these numbers are not very big. They can be bigger, but this is, according to us, realistic. If you add up all this, you still get quite a good number, big number and if we reach a fraction of that, we can actually reach this, which is our second target revenue of more than €30 million by 2030. Plus cumulative milestones or more than €30 million in the coming five years. This is the kind of money I really like because you don't need to do the work, you just get the money. They pay a milestone or a fee, and you don't need to do any work in the QC or in the GMP area. It's very high margin business, it takes a little bit of work from Finance and Legal, but all in all this would mean that the income growth, the target, which is the second target, is that it grows more than 50% annually in the coming five years. Interesting fact, and this is not what it feels like to you or to us. The five-year number from 2020 to 2025 is actually 45%. That we have achieved, but now we want to do more than 50% annually.

Then we come to the margin side and the third target. One important thing which has happened in the last five years is that we have built everything and it took a lot of resources, a lot of money and a lot of time to build a factory that has achieved the commercial license. We have installed and we have scaled up the technology. You will see the guys today present. We have amazing engineers; we have a vertically integrated company. So, we have not used that many consultants, but of course some, but the core knowledge and technology is in-house. We have built the brand customer base, SAP, implemented Scada, Workiva, TrackWise, eQMS, ISO 27001, all these things that make us a very high-quality pharma company, a pharma manufacturing company. When the big pharma clients come here, they tell us, wow, you look and feel like us.

This makes it easier for us to achieve our goals in the coming five years. But also, the fact that we have done this will mean that in the coming five years we believe that the growth in cost per year will be less than 5%. If you combine top line growth with more than 50%, costs growing less than 5%, we believe that we can achieve an EBIT margin above 30% by the end of the forecast period (2030). We would be a very profitable company. This is possible in an industry like this.

To end up my presentation and in time. We will have launched 3 medicines by 2030. We will have income growth of more than 50% per year in the coming five years and therefore combined we will have an EBIT margin of more than 30%. Thank you.

**Nanoform moderator IR Henri von Haartman:**

Thank you, Albert. Our next presenter is Winfried Ness. Please come up on the stage, Director of Intellectual Property. We call ourselves CDMO Plus and the plus means IP. This means that we can make extra money and Winfried has more than 20 years of experience in IP and strategic IP positioning, from Helm, Teva, Grünenthal and Ratiopharm, and now he's with us. Winfried, please go ahead. Thank you very much.

**Nanoform Director Intellectual Property Winfried Ness - Nanoenzalutamide European IP landscape (slides 19-31):**

Good morning. What you can see here is a structural formula of a compound. I would like to talk to you a little bit about this. It's a beautiful structure, but it's a complicated structure, and this structure is called enzalutamide, and I would like to talk a little bit about the history of enzalutamide and what we are doing with that compound here at Nanoform.

So, if you look into the history and we're starting around about year 2000, there was no real good medicament available for prostate cancer. And prostate cancer is a disease which is increasing very much, especially in the future with the growing age of the population. So, therefore there was a foundation in the United States, the Prostate Cancer Foundation, and this foundation started to look for new substances. They researched for new substances. And then they found a substance, and this substance was then called enzalutamide. This substance overcame at that time the old therapy for prostate cancer with the medicaments like leuprolide or bicalutamide. They had big disadvantages and in 2005 the first patents for that new substance, enzalutamide, were filed. The research was sponsored, as I said, by PCF, and the main work was carried out at the University of California in Los Angeles.

This substance enzalutamide had, and that's the first “but” here in my presentation, problems. Enzalutamide created big problems. On one hand, the development of a pharmaceutical formulation was very difficult because of the intrinsic properties of that substance. This substance had a very, very poor solubility. There was a tendency of crystallization of substance and the substance itself had stability issues. So, per se the substance was not suitable for the development of a medical, but nevertheless there was a big need, a big medical need and the time to market was challenging. The old substances were really not very good. The time to market was key at that time, but it lasted a long time until the first compound with enzalutamide came into the market. And this product which entered the market was a 40-milligram gelatin capsule. The gelatin capsule was not a simple capsule, it was filled with a liquid and that liquid enzalutamide was dissolved because as I said enzalutamide has a very poor solubility.

And last but not least, in 2012, that means seven years later, the FDA approved for the first time enzalutamide and enzalutamide entered the market in that year at the end of 2012. And what's also important, we have a 40-milligram soft gelatin capsule, but the daily dose of this medicament was 160 milligrams. So, what we have here, we have a product which could enter the market. It's the first urgent clinical needs were met. But the substance still has the disadvantages. This formulation did not overcome the poor aqueous solubility, it did not overcome the tendency to crystallize, and it did not overcome the stability. And the capsule itself, which was already in the market in 2012, had also disadvantages. Namely, it had disadvantages because it was difficult to swallow that capsule. You can see here this capsule 40mg and you can see the size of that capsule. So, the capsule was 2cm long and the outside was gelatin, so it was a high pill burden, but beside that fact.

The gelatin had dietary restrictions. Not everybody can eat gelatin. There was also a religious restriction to that capsule and the capsule filling technology. It was a liquid inside. It was costly and labor intensive. What to do? Only one technology at that time was able to solve that problem, and this technology was called the Amorphous Solid Dispersion Technology, ASD.

I think that's important today, the ASD, but in 2012 ASD was not good enough. It was

already known that ASD exists, but it was not good enough and therefore we had to wait. Five to six years more until a new product entered the market and this new product was a tablet and the tablet was based on that ASD technology.

So, I'm summarizing here. In 2012 we had the four capsules. Then a little bit later, the first tablets came into the market, and I kept here more or less the ratio of these tablets. And it was really a good progress with respect to the tablets, but the tablets have still disadvantages. They have the disadvantages. They are still too big, and the daily dose could not be brought into one tablet. So, you still had to take either four of this 40 milligram or two of the 80 milligram tablets.

Another point in my presentation, the tablets were patent protected. That means if you have the patent on that tablet, you can prohibit others from entering the market with a tablet. So, putting everything together in 2019-2020, we have two topics to tackle. The first one is the patent hurdle, and the second one is the technology hurdle. And I would like to start with the patent hurdle.

What you can see here are the two most critical patents of lead. In 2005, the substance was patented and I have here depicted the situation for Europe, but the tablet enters the market, as I said. It is a patent protected tablet and that's the second patent here. So, the difference between the substance patent and the formulation patent, how we call it, was for five years and this is an amorphous solid dispersion patent ASD.

It was based on the ASD technology, and it is the most critical patent. Why is it the most critical patent? Because from a technology perspective, it's nearly impossible to develop an alternative. A lot of companies have tried to do that, to overcome that solid amorphous dispersion technology. In other words, it's nearly impossible not to infringe or not to fall into the scope of that patent. And the question is. What to do?

The first thing I would do is I would like to get rid of it. And that's what a lot of companies did. These eleven companies in Europe tried to get rid of that patent. They tried to nullify that patent in front of the European Patent Office. And what was the outcome? All 11 failed in two instances. They failed in the opposition, and they failed in the appeal. In addition to that, they tried it in parallel in some of the European countries, like the Netherlands, like UK, like Germany, and again they failed. So, this technology and this patent on that technology for enzalutamide created really a very, very high hurdle, a very high patent hurdle.

And if you look here, we have a similar situation also in the United States. And what I want to tell you here is that this formulation had not only in Europe and in the US, but you can see here this situation reflects all of the major markets we know. But is there a way out? Is there any possibility to make enzalutamide tablets? Is there a possibility? Is there room for improvement? Yes, there is.

And then imagine this. Polymer embedded nanoparticles pens. These pens are an alternative technology platform to ASD. It's completely different from ASD. And this technology performed in the meantime and this technology is in the meantime patented by Nanoform. We have our own patents on it, and it also gives the possibility to have further patents on substances like enzalutamide, like apalutamide. They share the same bad solubility. And what is really important is that this technology is outside, outside of the teaching of the ASD. It's something which is completely different. And it

has one additional advantage. It has the same bioavailability and bioequivalence as the ASD technology. So, if you use the pen technology and make tablets out of it, we have the same bioequivalence, bioavailability, but you are not in the scope of that patent. So, it's simply better. Now what you can see here is that.

This technology enables you also not only to be better in the sense that it has the same bioavailability and same bioequivalence, but you can also put much, much more API into one tablet, so our tablet is here 160 milligram, in more or less the same size like the 80 milligram extended tablet and therefore we solved it the pen technology the technology hurdle.

I talked about it in the very beginning here, but what about the IP hurdle? The IP hurdle looked like that and because we are not making, so to speak, the use of the teaching of the patent, it disappears. We don't have to take care of it. So, it's possible to develop an alternative without infringing. And that could be done by our IP protected nanoparticles. Thank you very much.

**Nanoform moderator CCO Christian Jones:**

Thank you, Winfried. It gives me great pleasure to introduce our next speaker. My name is Christian Jones and I'm the Chief Commercial Officer at Nanoform and I'm going to introduce the next line of speakers who are our customers and our partners. So, on the stage next is Doctor Katja Dreyer. Katja joins us today from Helm Pharmaceuticals, where she is Director of Specialty and On-concept Generics. Katja, would you like to come to the stage.

**Dr. Katja Dreyer, Director Onconcept & Specialty Generics, Helm Pharmaceuticals GmbH - Nanoenzalutamide European roadmap and commercial launch (slides 32-37):**

Thank you. I'm happy to be here today to guide you through our European roadmap for launch readiness for Nanoenzalutamide and commercial supply. Before doing so, I would like to share some insights about me so that you understand better why I'm here. I have more than 20 years of experience in the generic industry, having different roles. My current role, as explained by Christian, is that I'm responsible for the Helm development team globally and all regulatory, scientific and commercial aspects. Our focus is on the generic products as well as all kinds of differentiation improvement in the generic products. Within this role, I'm responsible for our partner management, the alliance management. OnConcept® is a cooperation which was founded in 2019 with three well known European B2B generic players who joined forces to create a meaningful oncology basket of oral medicines. Nanoenzalutamide is our most important product currently, with Nanoform being one of the key players in the consortium. We at Helm help both being located in Germany, having a virtual setup with a great market access network, expertise, a customer network and having with us as a European CMO helping us to realize one of the values. OnConcept® in the meantime has about 25 molecules in the basket, of which a third has already reached the global market, and 2/3 are about to be launched in the years up to 2032. The most important molecule for all of us is Nanoenzalutamide With that one, we merged the generic power of OnConcept® together with the innovative power of Nanoform.

This slide shows our value proposition. Applying this best technology of Nanoform, we are in the position to really have patient needs, patient friendliness and patient convenience combining the commercial value. So, we are in the position to really offer a flexible dosage regimen, to have the once daily 160 milligram small tablet, which is the most important strength, not yet on the market because Astellas and Pfizer have not been in the position based on their amorphous solid dispersion technology to really offer this size in a smaller way. On top of this we are offering down dosing patient friendly 120mg, 80mg, and 40mg strengths for those patients who are not in the position to endure a high API amount.

You always need to remember that our tablets are smaller, and we are smaller because of the Nanoform CESS® technology, based on nano particles.

It's great to have a patient convenience benefit, but it's even greater to have a commercial benefit here as well. As Winfried said, with our way of manufacturing the tablets, we are outside of the scope of the formulation patents. We are in a unique position to offer a tablet that can enter the market as soon as Loss of Exclusivity of the Drug Substance in 2028.

This is the roadmap. This reflects the milestones we have achieved from the start of our cooperation with the outgoing plan until 2030. Operations started in 2021 when Helm knocked at the door at Nanoform. And we were looking for a company who is in the position to create nanoparticles, because we were sure that nanoparticles will provide the solution to have something mimicking the performance of the marketed solid dispersion formulation. Nanoform was for us a good choice because we've seen the potential for investment upscaling. Even though we needed to be some kind of visionary at that point, because Nanoform at that time was small but as we know small is powerful.

We went into a proof-of-concept study and with a positive outcome, we could convince our two other partners, Welding Group and Bluepharma, to join the story with us.

First big milestone was achieved in 2023, when Nanoform created the first time GMP material which was used for the first human pilot study with very positive outcome in 2024. This step really gave us the confidence that we are on the right track. For sure, there were a lot of improvements still needed in regard to yielding throughput, having some tweak on formulation and processability, but we were convinced that we were on the right track.

You can see in 2025, this was and still is a year of high workload, but of great milestones which we could achieve. In 2025, Nanoform generated a three-digit KG scale of GMP material, which was the base for our submission scheme to manufacture all the batches needed, the multiple batches to serve a submission for the European Dossier. So far, they've done this exercise in regard to Finished product manufacturing. We have conducted two pivotal European studies and we also, as a very great achievement, we had our first contract signed with our preferred European customer and I would like to highlight here that we are looking for preferred ones, not any generic. We want to go for those commercial partners who understand the value of our product, who are really putting it in a high pricing model, so very good local players on the specialty segments. Licensing agreement signings will be continued as

we move forward in the relevant countries and geographies. This is where we are right now. The outline is for sure 2026, the submission of our dossier, concluding further licensing agreements, a market launch in 2028 and then a robust supply from 2028-2030 and for sure beyond.

Why are we doing that? What is the value behind it? And I need to disappoint you. I will not share any figures of our forecasts, but I want to show here what the study is, what is our reference product doing? What is the behaviour here in the market?

Xtandi® is the flagship product of the Astellas - Pfizer prostate cancer collaboration. It is still growing. It had outstanding global sales of 6.2 billion U.S. dollars in 2024. Which was generated by 2.5 billion in US and another 2 billion in Europe. It is like Winfried told, it's a cornerstone prostate cancer therapy molecule. It is still growing because it has an extensive indication, a regimen. It is a lot more extended compared to the last generation and the future generation in the cost of therapy. Therefore, we are confident that excitement will still grow and will remain to be a stable molecule on the market when generic layers are going to market.

Now generic entry will be possible in 2028, but only for those who are in the position to circumvent the patent formulation. We will be for sure one of those because our IP position is clear  we are prepared for the best scenario where we are the only one in the market in addition to the Originator and we are also prepared for where there are more than one generic entrant.
What remains to be done? We want to reach our target of influence in 2028. What is most important for that is to secure the marketing authorization. Without documentation, without authority approval, there will be no product on the market. So that is our activity right now.

We are compiling the documentation to have a flawless and quick procedure.

We are seeking regulatory consultancy now to reconfirm our clinical data set and to reconfirm our sufficient approach.

We are securing the slots to speak with the European authorities, which is not easy nowadays to have that secure, so that we are in time to have a Marketing Authorization prior to our launch.

Next to that, for sure, we are going to maximize our market value. We are continuing signing deals with the commercial partners that we think are the best for the European performance of our product.

And then just tiny logistics, it’s just strategic planning. It is to have the demand planning ready to serve the customer’s needs. All this will be done from 2026 until 2027 to ensure that the API is there, the API which we need, to be Nanoformed and to be manufactured into tablets. We are allowed commercial API to touch European ground six months prior to the loss of exclusivity.

That means API will be there at the end of 2027, beginning of 2028. Nanoform will be ready to start immediately with a non-infringing commercial manufacturing process and Bluepharma is ready to perform the commercial tableting manufacture.

On the last day of the SPC, we have the goods ready to be picked up by our customers and with that we will reach day one, the target which we're all looking for. And have then the robust and new product supply where I'm no longer responsible because then I am heading our Product Services team.

Thank you for your attention and thanks for the last four years of great collaboration.

**Nanoform moderator CCO Christian Jones:**

Thank you, Katja. That was an insightful presentation into our European roadmap. And now next up we have Doctor Kurt Nielsen, Managing Director of Expert Insights. Kurt joins us online from the US. And Kurt supports the commercialization of Nanoenzalutamide. So hopefully in a couple of moments, you'll see him pop up here on the screen and then he'll take the next presentation.

**Doctor Kurt Nielsen, Managing Director Expert Insights - Nanoenzalutamide US launch roadmap (slides 38-43):**

Good morning, everybody. It's quite early in the morning here in the US. First of all, it's a real pleasure to be part of the team that's presenting to all of you. And just to give a little bit of background and context, we really want to get everyone also oriented to the US market so that you can compare to what Katja just told you as well as Winfried. And they did an exceptional job laying out the facts and circumstances around not only the IP landscape but also the European market. For my presentation today, I'm really going to speak to you from the standpoint of an industry veteran. I can hardly believe it these days. I have been in the business here in the United States 3 decades.

I've worked for some absolutely fantastic companies, including Nanoform. I've launched over 300 products in the United States alone. In those 30 years, I was at Teva, Sandoz, and URL Pharma. And Lupin and then also at Catalent where we had a product ventures group and then at Pii.

From the standpoint of US business there is a massive opportunity to treat a condition that still will benefit from this product Xtandi® and there's a there's a real opportunity for Nanoform to satisfy non met need with this product so that you can go from a multiple tablet dosing regimen, as Katja and Winfried outlined for you, to a single tablet dosing regimen and it also avoids some of the known precautions and warnings that are on the prescribing information, the approved label, for Xtandi® here in the United States. So, the nanoenzalutamide product directly addresses and solves these very real challenges. And it does it in a way that is patient centric and fully supports patient reported outcomes. I mean these are again, these are not abstract ideas. These are very real. They influence the prescriber's decision around what product to give their patients, and those issues are going to continue until the nanoenzalutamide product is launched in the US. Couple key concepts for you all in the audience. First one is that we'll talk about an AB rating or auto substitution. This is a very important concept in the United States pharmaceutical market when a product has this AB rating, it is auto substitutable at the pharmacy. That is the lowest friction or frictionless way to get a product into the hands of patients.

For products that are not AB rated, you need to go through an additional step, not unlike the way that the products are sold in Europe in that regard as brands or branded generics. So again, two very powerful concepts to be successful in the US market, AB rated or auto substitutable or have a productthat's got differentiation.

So, let's talk a little bit about what we've done so far at Nanoform. And again, you heard some, you heard quite a bit about you know the journey that we've been on in Albert's comments, but we've got a GMP ready formulation that is suitable for late-stage development. So, we're well past the feasibility stage and we're in the later stages of development, we've got not only pilot PK data, but we've got human pivotal PK data, and you can judge for yourself. But from Winfried's comments, we certainly have very clearly and comfortably established a very strong non-infringing IP position.

And when you have a non-infringing position on patents in the US market, it can lead to multiple years with years of exclusivity. And I've personally worked on products where we've had exclusivity for multiple years with successful non-infringing IP strategies. This product we manufactured on scale and you heard that from Albert and look equally as important are the comments that Katja made. None of this is happening in a vacuum. We have very sophisticated accomplished US commercialization partners who understand to the 10th degree or the nth degree what it takes to be successful in the US market, not only from the standpoint of channel access and distribution but also intellectual property and patents and the importance of the interplay between those two.

So, what are we gonna do? What's our strategy? As I said before, those are all important concepts in the US market where we have AB ratings and differentiations. So, like any smart company, we have multiple regulatory pathways that we're pursuing in parallel, avoiding obviously the perils of a single bet. We're preserving our flexibility when it comes to how we launch our AB rated product. There's a couple of options, again, that are available to us. You heard about those from earlier speakers in the ANDA or 505J application route or the NDA route. There's a very specific type of NDA called the 505B2. And we certainly have the ability to not only pursue AB rated options for the ANDA and the 505B2, but if necessary, we can also pursue a differentiated strategy as well.

Look, we're very, as I said before, we're very clearly engaging with the right type of partners and again we're being quite selective about who we work with. Again, we're very much focused on not only the commercial aspects of what makes our partners successful, but also their ability to understand, execute and see around corners, which with the Hatch Waxman dynamics, that's the law in the United States that really created the modern generic industry in the US and really sets the framework for how the patents are in fact dealt with in the US and how exclusivity is also handled at least the government backed exclusivity.

The other thing that we're seeing is that given these dynamics around intellectual property that you know very likely the generic product in the United States or the or an AB rated product in the United States would certainly enjoy you know market share above what would be a baseline market share for any typical you know AB rated or generic product in the US. They typically have outside the exclusivity period, the

government backed 180 day exclusivity period have anywhere between 5 and 10% market share, but really what we're talking about here is something that's more of a duopoly type market where you'd have the non-infringing nanoenzalutamide product, (the nanoform product), on the market and then you'd have the brand product.

And I'd say, oh, by the way, none of this excludes a last-minute deal with a brand company to license our product. So, what does it look like here, you know, in terms of the future value capture?

Again, we've got to take this regulatory progress and turn it into a commercial product. We're focused on selecting the fastest approvable US pathway from the multiple pathways that we're currently pursuing.

I'm certainly looking forward to engage with the FDA early, so we can not only accelerate approval, I mean accelerate submission time, but also reduce any approval delays and/or be most efficient as we can with the those approval cycles.

And we've talked a lot about the IP strategy and the very clear competitive advantage that we will have because of our unique IP position. It's a non-infringing IP position and we have some adaptability and agility around how we commercialize the product with our partners, whether that's an AB rated product or a differentiated product and we're also getting in a very good position to continue to engage with US stakeholders on how the market continues to evolve both for AB rated products, whether they're approved via an NDA or ANDA route.

And again, I think you know the takeaway from at least my perspective for the US market is a massive opportunity. Because it is fully enabled by a non-infringing strategy that is very likely to lead to an extended period of de facto exclusivity. There's very real patient-centric differentiation in these products to go from a multiple tablet dosing regimen to a single tablet dosing regimen and then there's demonstrated capabilities for manufacturing and development where we've got our human PK data and we're marching down our pathway to get our product approved as quickly as possible and I think it's a real pleasure to work with the Nanoform team with not only a creative, smart and ambitious culture, but very much focused on execution and I think we're doing all the right things in order for us to capitalize on this massive market here in the United States. So, thanks for the opportunity to speak with you, Christian, back to you.

**Nanoform moderator IR Henri von Haartman:**

Kurt, it's Henri. May I ask you to repeat your pharmaceutical experience again, please?

**Doctor Kurt Nielsen, Managing Director Expert Insights:**

Yes, of course. 30 years of experience in pharma, start off with a PhD in chemistry and I've launched over 300 products in the US market alone, whether they are generic products, brand products or consumer health products and I've done that with the likes of Teva, Sandoz, Lupin, URL Pharma and then also with a couple of pharma services companies, some of you may know Catalent. And the other was Pharmaceutics International. So that's my background. I've been doing this a long time, got a lot of

gray hair and it's late enough or early enough in the day that I might just keep going, grab a cup of coffee and keep going.

**Nanoform moderator IR Henri von Haartman:**

Excellent, Kurt. Thank you so much. It's great to have you with Nanoform. Thank you so much. Johanna, can I ask you to come up on stage. Our next speaker is Lady Q, Johanna Kause, Chief Quality Officer. Johanna and our Head of Manufacturing, Dr David Rowe, were instrumental in us achieving our commercial license in November this year. And that is a significant milestone for Nanoform, Finland and for the pharmaceutical industry. David, do you want to stand up and say a few words?

**Nanoform Dr David Rowe, Head of Manufacturing:**

Thank you for the introduction. Johanna will shortly speak about our GMP commercial license. What does this license represent? Quite simply, it enables us to help patients. And from a personal perspective, every one of us is a patient at some point in our lives. My own father passed away from glioblastoma. A devastating disease with a 100% mortality rate. That experience shapes how I view the importance of what we do. I want to emphasize just how exceptional Nanoform’s technology is. In recent animal studies using a nanoformed medicine, 40% of the animals survived, and the glioblastoma was completely removed. This is the kind of impact our technology can deliver. I hope this gives you a sense of what we are capable of, capabilities that truly set us apart. Our technology is unique. Thank you for your time. I’m grateful for the opportunity to share this with you.

**Nanoform moderator IR Henri von Haartman:**

Congratulations to you Johanna and David, on that achievement and now we're going to hear Johanna’s presentation. Please go ahead.

**Nanoform Chief Quality Officer Johanna Kause - Nanoenzalutamide regulatory strategy (slides 44-50):**

Thank you, Henri. Good morning, everyone. Great to see you all here. Couple of words of my past career. I've been working in the pharma industry in quality management for about 25 years now. I've been with Nanoform 6 years. But before joining Nanoform, I used to work at so-called mature companies, big pharma and smaller pharma.

The past five years at Nanoform have been incredible because not everyone gets an opportunity to build things from scratch. I really enjoyed that. But now I have to say that now that we're actually starting to talk about product launches, that is something that is super exciting and we are very close to that. So, let's start off with some terminology. I'm going to shift the focus a little bit. The previous speakers, Winfried, Katja and Kurt, they've been focusing on the final product. But as we are now here on Nanoform's manufacturing site, we will focus a bit on the drug substance. The drug substance is the thing that provides the therapeutic effect in a drug product. Drug product of course can be then the final dosage form tablet capsule, cream solution for injection, whatever. But now in my presentation, the focus is on the drug substance.

So why do we talk so much about the commercial license? Of course it was a great achievement for the company, but it's also vital in our ability to move forward because without the commercial license we would not be able to get products on the market. That's the thing that is needed. That's part of the foundation. In the past five years, we've had quite an intense inspection frequency. We've had four authority inspections within the span of five years. That's quite a lot. Because we've been progressing so much, we've always had something new to show them going forward. And of course, now the focus has been in the EU because we are in the EU and the regulatory authority is the Finnish Medicines Agency in our case since, we're located in Finland. But now going forward, we are looking forward to welcoming also other authorities to our site. First and foremost, US FDA, then potentially Japanese authority and others depending on how the story goes forward.

One of the main upcoming things from that perspective is that we currently have our commercial authorization for one of our production lines and then of course we would like to expand that to ensure that we have enough capacity also in the coming years. So again, a little bit of terminology, but I think this is important from the understanding perspective. When we talk about regulatory strategy, of course the marketing authorization holder is the one who decides what the regulatory strategy for the drug product is. For the drug substance manufacturer, there is not that much room to maneuver, but we do have some choices that we can make.

For example, the active substance master file, as it's called in Europe, or drug master file as it's called in the US, form a part of the marketing authorization application. It's not mandatory to have these. The other alternative would be just to include the drugs drug substance part in the application itself. One of the reasons we've decided to take the DMF/ASMF route is data protection. In these dossiers there is an open part which is shared with the marketing authorization applicant and a closed part which is only shared with the regulatory authority. So, if we want to protect our technology, that's a good choice for us. In the US, there is also an opportunity for the drug master file holder to submit the drug master file already before the application itself. And why this is a good idea is that if there's, for example, some technical issues with the drug master file or any other issues, those can be sorted out already before the actual application is submitted and in that way the drug master file doesn’t in any way slow down or hinder the actual application process.

In addition to our drug master file, there will also be another drug master file because of course, as you well know, Nanoform doesn’t synthesize, we don't make the active ingredient here. There's another company who is responsible for that and they will also submit their own drug master file.

The red box is where we are today on this site. Those of you who will participate in the facility tour will of course see in even more detail what the manufacturing site here looks like. The reason that I wanted to put the picture of our supply chain here is that in the pharma industry, supply chains can be short, or they can be long and complex. I'm sure that all of you are aware that in the past years, maybe even decades, we've had serious issues with security of supply. There have been a lot of stock outs, products not available on the market and that's of course horrible for the patients, horrible for the physicians treating them and for everyone involved. The idea here is that when you get the marketing authorization and you put the product on the market,

you should be able to keep it there. And because of that, one of the things that we pay a lot of attention to is the supply chain.

In the case of Nanoenzalutamide, actually Katja already explained a little bit how that goes. So here it is in a maybe more colorful format. And then on the bottom of the slide, you can see what I was just talking about when I was talking about the active substance master files and the marketing authorization application. As I said, there's not that many strategic things that a drug substance manufacturer can do from the regulatory perspective. But it doesn't mean that we can just not do anything. I already mentioned the first thing, so the security of supply. We need to make sure that we remain compliant. We keep our licenses of course, that's self-evident. And then security of supply means that we also need to be vigilant with our partners that provide us with materials.

Nanomaterials and nanotechnology are something that's not new. It's potentially not that different from all aspects, but anyway it is something that's not fully traditional, so we need to make sure that our internal expertise in that is at a high level. There needs to be a strong scientific foundation also for the Active Substance Master file, Drug Master file. It is our responsibility to make sure that we have that. Educating regulators may sound a little bit strange, but the fact of the matter is that we are the only ones in the world using this technology to manufacture nanoparticles. So, it is highly likely that when we submit a drug master file or active substance master file, which is the first time the regulators will ever hear about this. We also need to be sure that we make them understand what this technology is about. To summarize, if I think about the regulatory strategy, not just for nano enzalutamide, but for all the other products and product kernels that you will be hearing about is that we need to make sure that we work in a cost effective way to ensure that we are a reliable part of the supply chain.

To close with this slide. This is of course reflective of what Katja was talking about already earlier. We will be ready for the submissions when required by the project timelines. And then the interesting thing here of course is 2026 to 2030 as this is the sort of timeline that we're now talking about. We are looking forward to leveraging the template that we now generate with Nanoenzalutamide to apply it to our other programs.

**Nanoform moderator IR Henri von Haartman:**

Thank you, Johanna. Our next speaker is Antonio da Silva, our Chief of Business Operations. Antonio has a great experience from Hovione in Portugal, a company that has launched many medicines. It's a CDMO. They don't have the technologies that we have and that's why Antonio is with us. Antonio moved to Helsinki in 2019 with his family. It's great to have you here with your family in Finland. Antonio is a true master in quality operations, which he will talk about now. Please go ahead.

**Nanoform Chief of Business Operations Antonio da Sliva - 3 Nanoformed medicines launched by 2030 (slides 51-55):**

Thank you, Henri. So good morning, everyone. I'm Antonio da Silva, Chief of Business Operations here at Nanoform. I will discuss how we plan to launch three nanoform medicines by 2030.  So, we have, if you look back now at the presentations before,

the power of the technology and what it enables. It enables IP, smaller pills, better outlook for the patients and properties that allow us to enhance the medicines out there.

How do we materialize this into value in our company? By picking the best fit for our technology, and from there to build our own pipeline.

The nanoenzalutamide that we have been focusing a lot on, that's where we are closest to the market launch, but we also have other medicines that we are able to materialize and enhance through our nanotechnology. So, on top of nanoenzalutamide we have another prostate cancer drug, nanoapalutamide. We also have a melanoma drug, and we have the glioma drug which is treating the glioma indication. A lot of opportunities can be generated.

We have also some biologic molecules there, but we'll talk about biologics later. Now what we'll focus on our product kernel pipeline. So, this is what is disclosed. We have more in the pipeline. In order to materialize something, we need to understand how to reach the goal, how to actually get it materialized and operationalized in our facility.

You are inside a pharmaceutical manufacturing facility, you will be able to visit it after the presentations, and I recommend that you do. We have certified EMEA stamps which enable us to be an EMEA approved commercially licensed manufacturer site. This is the first step and Johanna explained about that.

To materialize things, we need to go through a pathway. The good thing about knowing the pathway is that you can be a proactive company and not a reactive company. So, we can predict our future, and this is why we can claim that in 2030 we will have three medicines at market.

You have to go through a long way, and it was explained before by the previous presentations that you have the regulatory hurdles you need to overcome. You have IP obstacles that the technology is able to avoid and to overcome. And then there is also the strategy and the know-how of our people, which add a lot. So, through our commercial team that is out there today, they can materialize the opportunities and make the connections to enable us to have valuable partners that you have heard about today and you'll hear more about after my presentation and that's really an important step how to materialize things. So going through the pathway, the blue box there is really the enabling factor. Our technology is now commercially approved which can produce nanoparticles. This nanoparticle technology together with our nanoformulation process allows us to do things that others can't do. We can do small tablets which are patient centric. We can introduce more plugging into the tablets and we can add a lot of commercial value as we go forward through this pathway.

So, there are a lot of small steps there and then there is the big picture. But basically, what we need to do is to be ready for the markets and to be approved by the regional authorities. FDA and others, the EMEA is the European authority, and also in Japan. We will do the pathway, and we are very close already with nanoenzalutamide and all the other ones, they follow the same method and methodology. I'll not go through the details, but this is what it means. So, if we know the pathway, we can predict our future

and how do we translate that into production, capacity, manufacturing and reaching the goal of 2030?

In 2030 we will be producing in the green boxes commercial material for those four projects that you see and those are the ones that are disclaimed. Then through our pipeline, which we cannot yet disclose, we already can predict the blue boxes as development steps and then the yellow boxes as the clinical supply where we will prepare our lunches for new products. So, we will ensure that our material is approved and then we have a strategy on how to implement those into the market.

So, we claim that we will launch three medicines by 2030, the pipeline is growing and then you sustain it from 2030 onwards. By knowing the pathway, we can predict the future, and we can be proactive in that sense. So, we are here, as I said, in a facility that is an approved facility. My main job is to make sure that we reach our goals for 2030 and that we walk through all the details and boxes. To reach this target and to sustain the launch of the products that we have shown you in the pipeline. And with that, I will finish my presentation. Thank you.

**Nanoform moderator CCO Christian Jones:**

Thank you, Antonio. It gives me pleasure to introduce our next speakers. We have two gentlemen that will be talking about why they invested in Nanoencorafenib and the Brafmed Limited company. Brafmed Limited is the company where Nanoform entered it's Nanoencorafenib drug candidate and who A.Forall and IMGA invested in. The investors are Steen Vangsgaard, CEO of A.forall Group and Tiago Geraldes, Investment Director of IMGA. I'd like to ask Steen, if you're online, if you could share your screen and introduce yourself. And your presentation. Thank you.

**Steen Vangsgaard, CEO of A.forall Group - Why we invested in Nanoencorafenib / Brafmed Ltd (slides 57-58)**:

Yes, good morning, everyone. Steen Vangsgaard here, thank you very much for inviting me. You may not know A.forall Group. We are a pharma house that specializes in developing and commercializing generic value-added medicines. We are what is in the industry known as an acid light specialty pharma company. What does that mean? Well, it means we don't own manufacturing. We don't own the technologies, the unique technologies that we use to develop and apply in our generic medicines. We partner exactly what we're doing with Nanoform. We partner to get access to these unique technologies. We partner with the specialists who have developed and who know how to operate these technologies. We are experts in formulating, getting the development phases, going through the development phases, compiling the dossiers and getting them registered. And ultimately taking them to market and as we take them to market, we also need to be able to supply. So, we specialize in setting up and managing the supply chains. As I mentioned, we don't own manufacturing ourselves. We prefer to invest in the development of molecules and to develop many molecules instead of just doing a few and owning everything. As such, the partnership is a is a great example of that. How do we define value added medicines? Well, value added medicines really have three components to it. It has to be of benefit to patients, to the physicians who use the medicines and the payers. It's obvious I think that for patients and physicians there should be benefits, but sometimes we don't necessarily include the payers. And

when you talk about payers, it's easy to think that it's just about cost. They just want the cheapest one. And often that is a significant component. But the other dimension which is sometimes forgotten is that unless you have patient compliance, meaning they take the actual medicine, complete their courses, they will not have great patient outcomes.

And in the area of oncology that often leads to untimely death and as such the payers also want to see presentation formats or medicines are efficacious safe, but in presentation formats that patients can actually continue to take and complete their courses. Otherwise, there is no need to spend the money on treating patients.

Actually, I was asked to just say a few words about my own background. You know, I love to talk about myself, but I think what suffices to say is that in the past 20 years I have worked in various organizations where we did development, launch and commercialize molecules, both going direct to market ourselves but also in a B to B setting where we would out license and partner for commercialization. And that experience of course is reflective of the experience we now bring to the partnership with Nanoform.

If we talk a bit about Nanoencorafenib and why we've chosen to go with Nanoform and this technology, I think the patient benefit is obvious. You reduce the pill burden from 6 to 1, which truly enhances patient compliance and ultimately leads to better patient outcomes. It may seem as a strange thing that if you are potentially dying from cancer, why would you not take your medicine? The reality is many patients cannot swallow, have limited capacity to swallow, and for various reasons, perhaps just think of yourselves. Have you always completed your treatment course that the doctor prescribed you or did you after five or six days think, actually I'm feeling fine, I don't need to take the tablets for the remaining 2-3 days. We all do it and unfortunately that leads to various not so favorable patient outcomes. So, there's significant benefits to reducing the pill burden.

There's also a significant competitive advantage for the originators. It's a great lifecycle management tool. It's IP protected. It extends the IP protection, and it brings patient benefits. But even in a scenario where it doesn't become a lifecycle management tool, just as a pure very competitive approach it has significant competitive advantages. So even in what you commercially would consider a worst-case scenario, it has great competitive advantage.

We have looked at micronization technologies for a couple of years, and the reality is most of them, if not all of them, have a mechanical component to them, which really in many cases ruins the molecules. The yields are relatively small, where in this case Nanoform’s technology has very high yields comparatively. Nanoform’s technology is also a very clean approach, a very clean technology to apply and it has the promise of broad application. We don't just look at it as one molecule that we can take to market together. We really see it as an investment in the longer term, but we can hopefully work on a number of molecules that we overtime can take to market together.

And the Brafmed co-operation, well, the IP really speaks to our mutual strengths. You know everyone applies their particular expertise and strength and when we come together it has significant synergies. The project itself is quite favorable in the risk

return. But also importantly, as I said, we like to have many horses in the races, not just a few molecules. And this model, this approach to developing medicines offers an opportunity to have more molecules in the races and continue to push more medicines through our pipeline.

**Nanoform moderator CCO Christian Jones:**

Thank you, Steen. Just a question before Tiago introduces himself. Steen, how many products have you launched in your career?

**Steen Vangsgaard, CEO of A.forall Group**:

Well, first of all, it depends on how you count them. Is it one molecule in one country then we're talking maybe 10 000, but if you're talking molecules, just individual molecules globally we're looking at between 800 to 1000.

**Nanoform moderator CCO Christian Jones:**

It's incredible. Thanks very much, Steen, and it's great to have you on board. Tiago, would you like to introduce yourself and share your screen as well? Thank you.

**Tiago Geraldes, Investment Director IMGA - Why we invested in Nanoencorafenib/Brafmed Ltd (slides 59-61):**

My name is Tiago Geraldes and I'm here to represent IMGA, one of the investors in the Nanoencorafenib/Brafmed project. IMGA is or was the asset management of BCP, which is the largest private bank in Portugal, and it got spun off and bought by a different asset manager, thus becoming the biggest independent asset manager in Portugal. By independent I mean not dependent from banks and so. Well, running asset management of around 6 billion EUR and this is a product of 35 years of experience, which is, I must say, mostly in mutual funds, meaning the typical bond funds or equity funds that you all know of. We are mostly a retail organization in the sense that we distribute our products with the retail networks of banks in Portugal mostly, but indeed in 2021 a decision was made to launch a private equity venture capital branch. In that sense, I was hired. I previously worked at investment banks in London, in Paris and also in Lisbon, and I was hired, as I said, in 2023 to come to IMGA and set up this new private equity venture capital arm. What happened since was a couple of funds that are very specific in nature, but most importantly we developed the Futurum Tech Fund, and this fund is quite important to us. Currently it is our flagship fund. We focus on late-stage venture capital companies.

We should focus on two principles, let's call it investment theme aggregators, future tech and life sciences. As for future tech, not so much a theme of this conversation, but there's a few items there that you might recognize. As for life sciences. Indeed, biotechnology has been one of the things that we wanted to invest in from the beginning. It became a big thing in our fund, and I can currently say we should close the fund at the end of this year, but I can currently say that biotechnology will be more than 50% of our fund. Just to let you know why this happened, just about three years or four years ago, I came across a few Portuguese biotechnology entrepreneurs. I actually did some M&A transactions with them. Some of them are quite public, but

that's not the point of this conversation. And this is how I got into biotechnology and love to understand the sector in the end. And as you probably already realized, I'm just a financial investor who has a keen interest in a few of these themes and a very big interest in biotechnology as a sector. We always look for market validation, and the IP factor was the most important one given that everything that Nanoform produced before relative to the technology is the essence. What then became the Brafmed project and what we're trying to do at Brafmed.

Most importantly, when we took the decision to consider Brafmed for investment, we decided to do the due diligence, as always is the case, and we traveled to Helsinki to meet the team. And what we found there was indeed a team that not only had a very, very strong scientific background, but also had what we always look for in a more scientific lead team, which is entrepreneurial spirit, the ability to take it into a corporate venture to take it to a profitable business, which is the most important thing for us in that sense. What we found was quite promising and we've found since because we've been doing Brafmed for at least in terms of as an actual operation for a few months now is a confirmation of what we had figured to be the team of Nanoform and A.forall, thus the team for Brafmed.

Also of course cutting-edge products and technology. We spoke about nanoform technology. We've listened to Steen discuss the differences and the advantages of the product that's going to be produced or we expect to produce at Brafmed. And so that also was a plus. In the end, let's be clear, biotech is a risky business typically. And the fact that the product would come to market sooner rather than later became for us quite interesting points that we should count as positives. Again it did not require huge funding needs, which is also important in the sense that there has there has been always a very defined financial plan which we could follow and try to understand where we would be able to produce some actual revenues and where we will produce actual results. For us, it was very important always to be able to acquire a high percentage in venture capital by venture capital standards and so a 20 plus stake was very interesting and as it was possible that also was a very good decision for us and a good one for us.

I don't think I need to speak much further in the sense that of course the fact that it is based on an IP that will have some crucial decisions in the next few years leading it to become a more open market and then leading to the Brafmed product to be able to establish itself as a value-added product and also and this is quite important for us and this just shows our tentative approach and how things panned out in this investment stage with Brafmed, which is why we actually had decided to do half of the ticket size that we were supposed to do in terms of investment or that we ended up doing in terms of investment and then we add them in the middle of our negotiations were quite interested in the team, in the product and what was being presented to the point where we established the idea of doubling our investment and this is what happened. This is why we actually now have a very important stake in Brafmed, which is part of our fund, which is part of our biotech portfolio and we're quite happy about it.

Regardless or inevitably, we as a venture capital fund will seek to have exit strategies and also we do believe that the timeline that is being presented in terms of the go to market timeline enables us to have multiple exit strategies and this is for us of course is very important. Overall, as a financial investor we look for these things. We found

very, very good responses from the Brafmed project from the teams involved and as such we expect good things from this investment and expect not in the same sense as Steen was saying regarding the product roll out because we will have terminated the investment in this fund. But we hope to be able to continue to work with the teams at A.forall and Nanoform in future projects. And so, I conclude my presentation. Thank you.

**Nanoform moderator CCO Christian Jones:**

Thank you very much, Tiago. And we too are equally excited about this, this opportunity and yet again another Pfizer product on the development pipeline. Now it gives me great pleasure to ask Sreevatsa to turn your screen on, please and your camera, and I'll introduce Srivatsa Natarajan, co-founder and CEO of Revio Therapeutics, to discuss the GLORIA partnership with Nanoform. That's so great to see you on screen.

**Sreevatsa Natarajan, Co-Founder and CEO Revio Therapeutics - GLIORA partnership with Nanoform (slides 62-71):**

Excellent. Yes, pleasure to be here. Good morning, everybody. It is a great pleasure to talk about the GLIORA program and our collaboration with Nanoform. I'll start with a very brief introduction about myself being in the industry about 25 plus years across various different therapeutic areas, evenly split between US and India you know and I have contributed to countless NDAS and NDAS and I NDS over the course of my career. Key highlight companies being PPD which is a clinical you know development organization Vertex Pharma where I worked on multiple therapeutic areas and then several other innovator companies in India. We have a team that is comprised of experts across product development, clinical and regulatory and together all of us have constituted Revio Therapeutics.

I'll just quickly introduce Revio before we jump into the GLIORA program. We are a specialty product development company. You heard from our previous speaker about a virtual specialty organization, asset light. We're a very similar organization. We're very asset light. We're product development experts focused. Focused on developing hybrid 505B2 products. So why do we do hybrid 505B2's? Because we believe existing medicines often leave a residual unmet need on the table that needs to be further covered. You heard about the previous case, a program offering an opportunity for converting multiple pills into a single pill and making it easy for the patient and so on and so forth. So that's an example of a residual unmet need and we're covering a similar one in the GLIORA program. So, these kinds of approaches give us untapped opportunities for improving existing products or repositioning them into new indications and how we do it. We have of course an AI engine that we've developed internally that allows us to ideate on new product opportunities, how to develop them, do the development planning, analyze the opportunity across various stages and so on and so forth. So that we're able to execute efficiently and like I described, we bring substantive product experience across various domains in being able to do that.

We are relatively new company, and we've already built out a pipeline of such partnerships and companies, GLIORA being a key jewel in our pipeline and our pipeline are essentially our AI platform independently has validated. The Gliora

opportunity as well. So, moving forward, I have a bunch of slides introducing Gliora and Glioma, so I'll sort of stick to the key highlights on the program. The slide has a has a lot of content for sort of offline reading as well. Why have we chosen glioma? So, glioma is an orphan indication. There are not a lot of people and patients with glioma. It has a prevalence of roughly 0.3 to 0.4 million in terms of high-grade glioma and glioblastoma forms a majority of that subset. Roughly about a quarter of a million people in the US and obviously much more globally. But relative to some of the more common indications, it is an orphan indication. Despite the fact that it's orphan, the unmet need is substantive. Patients are often diagnosed pretty late in in stage 4. And when there is very limited scope for actually curing the tumor. So, patients go through a surgery, a surgical resection of the tumor, then they're allowed to recover from the surgery for about four to six weeks and then the standard of care is radiotherapy and then temozolomide which is essentially a chemotherapy given orally. So, the evolution of care has not changed substantially over the years because it's just been a very difficult disease to treat and at our diagnosis patients have usually had a prognosis of survival of no more than 12 to 14 months even with temozolomide.

So, what we're trying to do is address this unmet need of improving the survival for these patients, but also improving the recurrence because the gap between surgery and radiotherapy of four to six weeks and the subsequent therapy duration is where the tumor recurs. And if you're able to stop the recurrence, we're obviously able to improve the survival and unmet need. So that's the background. So, how does this change in terms of how we position GLIORA? So, what we want to do is to provide a treatment that is local, long acting and place it in a hydrogel format with the two API’s. So, I'll walk through each of the different components of how GLIORA is then conceptually constructed.

Why do we need a long-acting treatment? So, we are developing GLIORA as a 12-week treatment to address two things. One is the lack of treatment during the post-surgical window four to six weeks and as an adjunct to the radiotherapy which is subsequently given for six weeks. So that's why it's a 12 weeklong treatment. Why is it locally delivered and intratumoral? Because systemic chemotherapy often causes significant side effects and only a fraction of that reaches the tumor. Instead of post-surgery we're delivering the drug locally into the void space. So that way we have high tumor concentrations or high concentrations of the tumor and very limited systemic spillovers. Why is thermal responsive and hydrogel? Because we want to be able to make it easy for the surgeons to be able to handle the drug and place it into the tumor void space. So, they just take it as a liquid that's presented in a prefill syringe or with very minimal preparation steps. And they place it in the in the tumor void space and then the treatment really just jellifies upon physiological temperature. That's a property that we're trying to build into the product, and I'll talk about that in a moment. So, it jellifies and stays in place for those, you know, 12 weeks. And most importantly the formulation contains two API’s that are already proven in glioma. Temozolomide is of course approved for glioma. Olaparib has been tested in glioma with success. So, by going locally we're limiting the systemic toxicity with both of these drugs.

Now coming to the most operationally important slide in in this presentation, why are we partnered with Nanoform? So, you can imagine you know putting a drug that is adequate drug for 12 weeks in a in a small volume in a resected tumor space requires that we pack enough drug in there and last that entire duration of treatment. So

obviously nanosizing of the API becomes important and to nanosize it reproducibly efficiently by a validated GMP process and considering these are on core API's to be able to handle those on core API's that requires a fairly sophisticated technology capability. Then of course comes the IP cover on the process and the API so that it's differentiated from the other nanosizing approaches both technically and IP wise and making sure that we're non infringing in terms of any kind of limiting IP. Then of course, you know developing the actual formulations itself, putting them into a hydrogel with sufficient IP cover so that it lasts in the tumor space for the sufficient time and can deliver drug. And of course, having you know all of this in the context of the GBM disease area. So, when we went out seeking partners with this concept, Nanoform checked all these boxes for us because of the fact that they have the Nanoforming capability, the differentiated IP, the ability to develop hydrogels as well and prior experience with doing the GBM area. So, clearly, they checked all of these boxes, and the previous speaker also spoke about the limitations of other nanosizing approaches which are often mechanical versus the Nanoform approach. So naturally there was a partnership here and that's what we have forged. We have synergistic capabilities. We bring the clinical, the regulatory and the product development piece and together we've been able to build out the full spectrum of skills required for the for the program which are essentially complementary and we've forged a co-development partnership.

Over the course of the last few months, we've been very successful in in generating pivotal data that is supporting or validating our product concept. We have filed IP on the on the combination product, the combined API into the long-acting hydrogel. So that's covered. Freedom to operate and that IP can be extended across several other cancer types where such an approach could work beyond glioma. We have shown synergy between these two APIs in glioma cell lines and that has been established with substantiation potentiation of activity of. We have shown that the nano sizing approach actually gives the release profile that is required for a 12 weeklong acting release that has also been demonstrated and of course Nanoform has experience with developing hydrogels in the GBM space. So, we believe from a product development standpoint we have covered sufficient ground from a prototype perspective. We are in touch with the KOLs who are established in the space and who have a very good understanding of the disease pathology and treatment paradigms. So, they have validated our concept. We have a detailed development plan in place. We have a regulatory strategy to approach the agency for how to develop the program and we also have the road map in terms of partner CROs and all of that articulated.

Very quickly, I'm just going to go into why we believe GLIORA will succeed. So, you know, obviously we're taking two APIs that are proven in this space. So essentially, you know, we have very minimal clinical risk that these APIs will not work. Temozolomide and olaparib are proven. So however, you know, we've also got the product development risk addressed as well because you know Nanoform's a proven technology, the hydrogel concept has been proven, and we have experience developing this kind of a long acting approach. The KOL's have validated this. There is sufficient IP cover and because it's an orphan indication, we're eligible for orphan designations and exclusivities. And the competitive landscape is favorable. For the last 20 years, no new drug has really shown efficacy beyond temozolomide in this in this glioma space. So, what we're doing is taking an existing proven drug but making it much more better. So that we're potentially giving an opportunity for an improved outcome for these patients. So, in terms of path ahead, we've got a fairly detailed

development plan. This is a program that is likely to come into the market by 2030. For the year 2026, we've got some prototype animal studies that are planned, regulatory filings to initiate clinical trials. We've begun preparation of those activities towards that and we're aiming to sign up a commercial partner through 2026 and then through 27 to 29, there'll be GMP manufacturing and clinical trials. Followed by a product filing through 29 and 30 and a launch in that in that same time frame. So broadly there is a DDS development plan ahead in place. That's pretty much all I have for my presentation.

**Nanoform moderator IR Henri von Haartman:**

It's Henri here. Thank you for the presentation. This is a newly announced partnership, and we appreciate you and your team. You're highly experienced and senior and we are really, really looking forward to make this a success. Thank you for your presentation.

OK, our next speakers. Rocket science. Can I ask the gentlemen to come up please. We have two senior scientists and one senior engineer. Ari, Tuomas and Petteri have invested more than 15 years in total in to create and develop our CESS® rocket science. CESS® stands for Controlled Expansion of Supercritical Solutions, innovated by our CEO Edward back in the days and these gentlemen are really super scientists and engineers and they will show you things that are amazing. Please go ahead.

**Nanoform Ari Kauppinen, Senior Scientist - Nanoform's CESS® rocket science (slides 72-74):**

Thank you for the opportunity to get to talk at this venue. My name is Ari Kauppinen. Bit background on myself. I have a master's degree in physics and a PhD in pharmaceutical technology. After academia, I have nine years' experience in pharma industry, both in Finland and abroad. The last five years I've been working in Nanoform as a senior scientist. Today I will give a bit of background to what's happening behind the scenes and about the process development.

As I said, I've been working in Nanoform for five years, mainly on two projects called Magnus and Atlas, with the ultimate objective to increase process throughput. In essence, how fast can we produce material in the small molecule CESS process.

Next about the process itself. First, on the left side we have the bulk liquid CO2, which is guided into the process with the high-pressure pumps where the CO2 transforms into the supercritical form at high pressure. Supercritical CO2 is guided into the dissolution vessel where the micronized bulk API is located. There the API dissolves with supercritical CO2. After the dissolution phase, there is the collection chamber and nozzle where the pressure releases to the atmospheric condition. In the nanoforming phase, nanoformed particles are created and collected.

And within these last five years, we have come up with a successful recipe. This is a simplified recipe to improve process throughput. There are 4 main factors contributing to the throughput. These are the API nature, pumping capacity, API saturation and collection efficiency.

First factor is the API itself, basically the molecular properties dictating its intrinsic solubility into the supercritical CO2. But also, API solubility is a function of pressure and temperature. Factors that engineering tools can alter. Basic principle; higher pressure, higher temperature, higher solubility.

Second factor is the pumping capacity. Meaning how much CO2 is going into the process. The more the flow, the more the mass we get out.

Third factor in recipe is the API saturation. This might be a bit crypted, but it is not actually. API saturation means how much of the API is actually dissolved compared to the solubility of API in a given pressure and temperature. Basically, you can think of something like cocoa with milk. If you mix, more cocoa is dissolved into milk.

Fourth and final factor is collector efficiency. This is a percentage of those nanoformed particles that are collected compared to all nanoformed particles. The fraction that is not collected goes into exhaust and to the waste and thus does not contribute to collector efficiency. These four components contribute to the process throughput, and we have come up with this recipe during these five years journey. Not much of this was not known at the beginning, and we have learned a lot in the process.

As you may see, there are quite a lot of engineering possibilities to improve the process throughput. Pressure, temperature, pumping capacity, dissolution capacity and collector performance are all under engineering opportunities to be manipulated in favor of producing more material.

This slide depicts how CESS process throughput has evolved over the years. Bear in mind that the scale is in logarithmic scale with a normalized baseline in year 2021. Since then, we have been able to ramp up the throughput of about 100000-fold. That is quite a drastic improvement. Meaning also that the cost of production has gone down. This graph shows clearly that the process is very scalable. On a professional level it is highly motivating to look back on this journey and the development we have achieved. I am really honored to work with Nanoform and privileged to push the envelope day and day out. Thank you.

**Nanoform Tuomas Malve, Senior Engineer - Nanoform’s CESS® rocket science (slides 75-77):**

Although I'm here as a senior automation engineer, I actually have a background in physics as well. A master’s degree from the university of Helsinki. I joined almost seven years ago when it was only 25 of us. So, I've seen quite a few things developing here. I will introduce you to some of our automation work and how we got here.

So over the years as we built process lines, we have always built the control system with our best knowledge at the time and that eventually led the situation where we have like 20 process lines with more or less different control hardware on each line, which makes it difficult both for the operators and the engineers, and developing new features becomes really challenging as you need to navigate the differences. Two years ago, we launched a project to standardize this hardware. We selected a technology based on modern standards which enables industry 4.0 and integration with IT systems so we wouldn't limit our ambitions in the future. This year I've been

super happy with the performance, and it has made my job a lot easier as now I can have one platform to manage instead of the 20.

Then about our control room. As we've grown as a company, we eventually found ourselves in a situation where we have multiple process lines running the process each day. Back in the day we had one or two operators on each process line to manage the process, and this of course wasn't feasible going forward. So, three years ago, we introduced our control room which brings all the control and visibility to a single room where a single operator can monitor all the lines simultaneously. And this has brought efficiency, but also more situational awareness when we have one place which has real-time knowledge of status of the plant. Also, safety is a factor as we now have constant visibility of the lines and people operating them.

And then about our data flow. When I joined the company, one of the most vivid memories I have from that time was when I was shown how the process is run. I couldn't get over the fact that people were writing the values down in a notebook by hand. Not only did I not want to do that, but more importantly I wanted to have the data in a digital format to be able to analyze it on my computer. So, one of the first things I did here was to program a custom cross control software which stored the data to the cloud. Over the years we replaced the software with more industrial standard software. And here I show you our current data pipeline. We have two dozen process lines. We then have over 1000 sensors and actuators which are continuously recorded in our data historian. And of course, many people in different parts of the organization rely on this data for their work. For that we have set up this custom browser-based data access tool where people can see the process data along with the analytics results.

**Nanoform Petteri Helander, Senior Scientist - Nanoform's CESS® rocket science (slides 78-80):**

Morning. I'm Petteri Helander, a Senior Scientist here at Nanoform. I've been with the company for seven years. I also come from University of Helsinki with a Master's degree in Material Science. Here I work with the CESS® technology as well as the CESS® theory. So, I may be called a half-theoretical physicist. While the two previous speakers talked about speed and quantity, I have a short look into quality and precision and getting to show some of the coolest in-house science results that we have done.

On this slide, I have an illustration of the CESS® process. The coarse powder goes in, and the fine powder comes out, and to characterize this, we have strong standard tools to do it. However, when we look deeper into the heart of the process, things become more challenging. The extreme conditions, and the steel pipes of the line, which prevent mostly any view inside.

This is where physics comes in. Over the years we have developed the knowledge to model the system, and this is how we can almost see inside: going from 1000 bars to one bar, how the system goes from solution, through suspension and finally to solid mixture and aerosol. This understanding has been critical for scaling up the technology and applying it across a wide range of APIs.

Here in the middle, I have the pressure-entropy phase diagram of carbon dioxide. This is the map that you use to navigate the thermodynamic pathways of CO2-based processes. Internally we have used a metaphor that this landscape of pressure and

temperature is a mountain, and you come down the mountain and how you choose your path of descent determines, firstly, how CO2 behaves and also how the API behaves. And on the right, I have some examples of this controlling API polymorph and morphology.

And then, I think, the title of the presentation was “rocket science”. So, here I have something on that: it is a CO2 jet. And it just happens that the exhaust of the rocket engine has all the same physics. However, there's a difference: even in modern rocket engines, chamber pressure only reaches 300 bars. The CESS process goes much higher, up to 1000 bars.

Finally, this last slide is my personal favorite. Earlier I said that it is difficult to look inside the process. Here we have done just that: I have two videos where we look through one-inch-thick quartz windows into a solution of API and supercritical carbon dioxide. On the left, I choose a pathway that creates large crystals. They are not that useful, but look very beautiful, almost like snowflakes. And then on the right, another pathway, where I choose a different descend path in the thermodynamic landscape, and this creates a nano suspension. You can see the video turning dark: this is the suspension scattering all the light. And towards the end, you can see the suspension dwelling and settling inside the view cell. And then in the figure we have something bit more quantitative: UV-vis scattering of the system. As far as we know, these are the only videos of nanoparticle formation in such a high-pressure system. And it's science like this that has kept me intrigued in the technology from the day one.
And that's all from us three. Thank you.

**Nanoform moderator IR Henri von Haartman:**

Thank you gentlemen, and congratulations on the amazing work you have achieved. Two presentations left and then Q&A. Overall, today we started with the strategy. We've been talking about small molecules. Now we're going to a new era, and our next speaker is Peter Hänninen, both General Counsel and Chief Development Officer in the company. Peter is the youngest member of the management group, but he has accomplished really a lot and before Nanoform he was a business lawyer and he's talented in IP strategy and development and he will talk to you about our next big thing, which is Biologics. Please go ahead.

**Nanoform General Counsel and Chief Development Officer Peter Hänninen - A large biologics market is forming in subcutaneous delivery of monoclonal antibodies (slides 81-90):**

It's a difficult thing to go on and talk after a lot of good science being presented, but I'm very happy to be here and I'll take a step into biologics. From Nanoform's perspective, the company was founded around the small molecules technology. Edward and the team were thinking early on back in 2018 and 2019, to start looking at biologics as well. And of course, back then we didn't know where that would end up. We didn't really know what nanoparticles would mean for drug delivery in biologics, but we are fast learners, as we always say, and we are adaptive and we at least try to think of ourselves as clever. And that has now opened up really big opportunities also on the biologics side.

We strongly believe that the future for delivery of biological medicines will be subcutaneous suspension-based formulations that enable these ultra-high concentration formulations and therefore low injection volumes will be the leading choice of technology within subcutaneous delivery for biologics. Both we, our customers, and even our competitors all acknowledge that particle properties are absolutely critical for the performance of these suspensions and that makes us very confident that we will be able to establish Nanoforming as a technology of choice within this market.

Biological medicines are fast outpacing small molecule drugs and will really be what leads value creation now going forward in the pharmaceutical industry. And although there is a lot of talk about cell and gene therapies, about antibody drug conjugates and so forth, monoclonal antibodies will be clearly the biggest category also in biologics going forward.

There are many good reasons why to do a subcutaneous product instead of IV, and in reality, for most biological medicines, IV is not the preferred choice, but really a necessity due to the lack of enabling technologies. Subcutaneous alternatives, as we can see from real world evidence, is faster to inject, it has a better safety and tolerability profile, it's a clear preference for both patients and physicians and I think very importantly also as a taxpayer, they can provide substantial savings to healthcare systems when you compare it with an IV. And I think it's important to note on this slide that these examples that are here, they are with this hyaluronidase-based formulations that are not actually at home administered. The patient gets these over multiple minutes at a doctor's office. Even then they are clearly better than IV of course, but they don't give the promise of at home administered subcutaneous product.

So why do we not see more subcutaneous products then? The root cause has really been that when you increase the concentration of the protein, you get stability issues and you get issues with the viscosity.

And for this reason, there are currently no products on the market with more than 200 mg/ml of concentration, and most products are clearly less than that, closer to 100. This means that there is a pressing need for innovative approaches that goes after the root cause and that is what we believe that the second-generation technologies of high concentration suspensions do. Meaning that they take on this challenge of concentration, viscosity and instability.

This is also not a niche problem by any means. So as I said early on, monoclonal antibodies will continue to be clearly the biggest category for biological medicines. And within the group of antibodies that are on the market or in late stage development, the clear majority are high dose, meaning that it's absolutely necessary to have an enabling technology in order to have a subcutaneous product.

And what are those enabling technologies potentially then? This is a slide presented by the head of pharmaceutical development for biologics at Merck a few months back at the at a big conference. And they put nanoform squarely at the center with three US based companies around. We humbly agree. This is the small group of companies that will pioneer the shift from IV to subcutaneous delivery for biological medicines in

the future. To date, really the only alternative or the only solution has been to use Halozyme, which is also on the slide. That technology to break down the tissue under the skin in order to enable a higher volume of fluid to be injected. But as I said, this first-generation solution didn't really go after the core problem.

There are two major forces that are shaping the market for subcutaneous delivery of biological medicines. One is the big opportunity to go from IV to subcutaneous, as I said, and the other is the limited availability of enabling technologies. This means for those companies that are developing biological medicines that they need to place strategic bets either through exclusive arrangements with the technology developers or then through outright acquisitions. And here the latest example was the acquisition of Elektrofi by Halozyme for close to a billion USD.

During the past 10 years, Halozyme has really created a market around subcutaneous delivery of biologics. They have 10 products now on the market or 10 partner products on the market and they've done this by drafting target-based exclusive deals with their customers. This has been extremely profitable business for them, but at the same time for each of these target receptors they've left the other companies with products thirsty for alternative technologies that can enable a subcutaneous product. And we of course see a tremendous opportunity in this to work together with those drug developers, many of whom we are already engaged with on either small molecule or the biologic side or even both in some cases to provide an opportunity to have a competitive product subcutaneously on the market as well.

And I think it's safe to say that we at least are confident that in the next 10 years a lot of these boxes that are currently white there on the screen will also have a subcutaneous product on the market and through that give them alternatives for both patients and physicians and for healthcare systems.

And before I hand over to Doctor Lume, our Director of Biologics, to talk about the science and technology, I just want to reiterate still where I started off. So, we strongly believe that subcutaneous delivery will become the dominant standard for biological medicines going forward. These nanoformed suspensions that enable ultra-high concentrations will be the technology of choice because they enable lower injection volumes. And because of the fact that particle properties are so critical for the performance of these suspensions, Nanoform has a good position to become the technology of choice within that field.

**Nanoform moderator IR Henri von Haartman:**

Thank you, Peter. Maria is our Director of Biologics. She's been with the company since January 2018. She's got a PhD in Physiology and Neuroscience and a Master in Gene Technology and she has actually built up our biologics business from scratch. Well done and please go ahead.

**Nanoform Director of Biologics Dr Maria Lume - Working with large pharma: What we have done and learnt (slides 91-100):**

Thank you very much. It's a great pleasure to be here and thank you for the opportunity. Indeed, as Henri said, I joined Nanoform in 2018 and at the time was

employee number 17. Over the seven years I've seen the company grow tenfold and next I'd like to show you what we have accomplished during this time with our team.

The first years were dedicated to setting up the technology. At first, the throughput was modest and the yields as well, but on the positive note, we submitted the process patent and in 2021 initiated our first customer projects. During the last four years, we have scaled up quite a bit, processing 50 grams in 2021 and more than 20 kilograms in 2025. We have also gained valuable experience from several customer projects, and we have set up a broad range of analytical methods that enable us to characterize the nanoformed peptides and proteins better than before.

Next, I'd like to walk you through our process. Unlike in CESS, we do not use supercritical carbon dioxide, but the API is usually in an aqueous solution. It's pumped into a nebulizer where fine mist is formed and mixed with the carrier gas. Thereafter, the mist is transported into the drying chamber and dried, using low temperature drying gas. Particles are formed, charged by mild ionization and captured onto the walls of the collector using electrostatic precipitation.

Over the years, we have learned to control the process parameters in a way that we can tune the particle size according to the needs whilst maintaining their round shape as you can see from those SEM images (SEM stands for scanning electron microscopy). In the upper row, there are three examples of three different particle sizes, and in the lower one, our customer Takeda has provided us with data, where they compared 3 different technologies: nanoforming, spray drying and lyophilization, using identical feedstock formulation. While the starting material was the same, you can appreciate that the outcome in terms of particle shape and size is rather different - nanoformed particles are the smallest and the most round.

We have also investigated, how do our particles look like from inside. In collaboration with the University of Helsinki Imaging Unit, we applied FIB-SEM, which in short is a combination of an ultrafine scalpel, which cuts layers by layers, and a high-resolution camera that takes images after each cut. From this video it's evident that nanoformed particles are compact and dense from inside. What is it good for? Well, Peter already mentioned this might be good for packing a lot of material into small volumes. In other words, high concentration suspensions.

Here is our workflow. First we produce the dry powder, check that the API is in specs and thereafter prepare a high concentration suspension, where nanoformed protein particles are put in a non-aqueous solvent. Next, we can test the injectability of the suspension using the prefilled syringe.

We have shown that we can reach protein concentrations exceeding 400 mg/ml and that the suspensions are stable even after being stored at room temperature for 6 months.

Our high concentration suspension work has also been validated by Takeda. We produced an IgG suspension with the concentration of 400 mg/ml and showed that whilst the viscosity of the suspension was 70 cp, the injection force in a 25G needle was below 10 Newtons. On average, the acceptable injection force is below 20 Newtons for subcutaneous delivery.

Another application for the nanoformed particles is pulmonary delivery. In order to reach deep lung alveoli, the particles need to be of the right size and shape. We are switching gears in terms of particle morphology because here, as you can appreciate, they're not that round anymore, but this is done on purpose. The particles are formulated into not being round to enable their flowability. If you happen to play golf, you can see a similarity with the golf ball that has a slightly crumbled surface and not a smooth one.

Using a GLP1 analogue semaglutide, we have shown that the dry particles produced in our BioLine are stable for 6 months when stored at 25°C, no impurities nor aggregates were detected. The powder was also tested using an NGI (next generation impactor). NGI is an instrument which is used to evaluate if a patient uses an inhaler, how much or the drug reaches the lungs and where it would be deposited. The different stages mark different locations in the lung, having most of the semaglutide deposited in Stages S4 and S5 means that they are predicted to reach the alveoli.

And last but not least, I would like to also show you some *in vivo* data produced in collaboration with Takeda using an enzyme called A1AT. A1AT is short for alpha 1 antitrypsin, an enzyme used to treat a severe genetic disorder. A1AT was administered to mice intratracheally and monitored over the course of 2 days.

What could be seen was that the drug administration was well tolerated in mice and that lung exposure was reached in all animals that were tested. On the left image you can see the A1AT concentration in the lung and on the right image A1AT levels in serum.

Overall, quoting Markus Weiller from Takeda, these data show that in addition to high concentration suspensions, also pulmonary delivery of nanoformed material constitutes a promising targeted therapeutic approach.

With this, I hope I have given you some insight into what nanoformed particles of biologics can be useful for, and I thank you for your attention.

***End of CMD transcript***