



Orion Pharma

Orion Pharma presentation delivered at the 43rd Annual J.P. Morgan Healthcare Conference on Thursday, January 16, 2025 at 8:15 AM

Facilitator: Good morning, everyone. Welcome to the 43rd Annual J.P. Morgan Healthcare Conference. Today, we have the CEO of Orion Pharma presenting, Liisa Hurme. We also have CFO, Rene Lindell, and Head of IR, Tuukka Hirvonen, joining for the Q&A. Over to you, Liisa.

Liisa Hurme: Thank you, [indecipherable] , for presenting us. First of all, good morning to everybody. Thank you for the organizing JP Morgan Healthcare Conference for the opportunity to present Orion Pharma here.

Orion Pharma is a company on strong growth path with solid growth projections based on our innovative molecules and legacy products. The usual disclaimers that everybody definitely understands.

I will start from the beginning because I think not many of you know Orion Pharma. We are headquartered in Finland, a Nordic company. Established in 1917. We are already, this year, 108 years also. We are not a start-up and far away from a startup.

We are a very diversified company, though, and I will talk about that a bit later. We have 3,600 employees in more than 35 countries across the world. Our last 12 months' net sales was 1.429 billion and our operating profit, 417 million.

Our R&D is focused in oncology and pain and our products, both innovative and our legacy products have an effect and change lives of millions of people globally every day.

To the diversified structure of the company. You might think that if you do approximately 1.5 billion revenue, you would be very focused, but you can see here that we have five different divisions. We think that that's the secret of our 108 years. We are very balanced in our different divisions.

We have the innovative medicines where the flagship product is Nubeqa, a prostate cancer product that we have partnered with Bayer globally, and that contributes 23 percent of our net

sales.

We have a division branded products, which consist of our legacy products that have once been innovated by Orion but have lost their patent protection, however, have hold their brand value brilliantly.

There we work with inhalators for asthma and COPD, with Parkinson's disease and women's health, and have own sales operations across the Europe and Asia Pacific, including Japan. Again, a bit more than 20 percent of net revenues come from branded products.

The oldest part of the company's legacy products is the generics and consumer health. Geography there is very much Nordics and Eastern Europe. As it is the oldest one, it still contributes for the 40 percent of our net revenues.

Animal health, a very different type of a business. No reimbursement, people pay out of the pocket, it gives some freedom to us. A very global business, both for livestock and companion animals.

Then, Fermion, where we manufacture APIs for our own innovative molecules, branded products, but do a lot of business-to-business with most of the big top 10 pharma companies around the world, not to mention all the midsized companies. Fermion is one of the few European API manufacturers that are left.

These figures speak for themselves when I started that Orion is on a strong growth path and has a good growth projection.

When we look at our underlying business, and with underlying business and net sales, I mean net sales without milestones. Milestones are very integral part of our business model as we have partnered with big pharma, sometimes midsized pharma. We do receive both development milestones and sales milestones.

When we look at the underlying business without the milestones, we've grown, since 2021, with 7.7 percent. When we include the milestones, the integral part of our business model, 11.1 percent. These are excellent figures if you look at the pharma on average.

Even more astonishing is our operating profit growth plus 16.4 percent. On the operating profit, you can very clearly see the effect of milestones since that's down on the last row or last line.

That's clearly seen there.

Now that I'm talking about growth, we just upgraded our 2024 figures yesterday. Our operating profit for 2024 will be 417 million, which is here as well, but our net sales, net revenues, are 100 million more than last 12 months. The growth is very strong, as I started with.

Where does the growth come from? It's a combination of many things. It's both a result of geographic expansion from being a Nordic Eastern European then Central Europe, pan-European company.

We expanded in early 2010s to cover the all European countries when we understood that this is definitely something that any pharma company has to do to manage their risks, different type of risks, and also to be a lucrative partner for other pharma companies.

In early 2020s, we expanded in Asia Pacific, Malaysia, Thailand, Singapore, Australia, New Zealand, and the last expansion in that area is our subsidiary in Japan this summer.

The geographic expansion is based a lot on repatriation of our own product rights from our partners, like for Japan, we've repatriated our rights for Parkinson's disease drug, Stalevo, from Novartis and aim to build a neurology portfolio around that product.

Regarding R&D, that's very centered in Finland in two different locations. Few years ago, we opened an R&D hub in US to strengthen our clinical study and regulatory contacts here in United States. That has proven to be a very, very good strategy for us. This is the biggest single market for pharmaceuticals, and we need to be here when we develop products.

In addition to sales, R&D, and operations, operations, all our manufacturing sites for human pharmaceuticals are in Finland in different locations. For animal health, we have a manufacturing locations in France and Belgium after we acquired a livestock company few years ago.

In addition to this, we are present in India and China, in Mumbai and Shanghai, where we have our support and back-office operations for a regulatory, some CMC company procurement, and that type of activities. When I say that the growth is really a result of geographic expansion, it's, of course, also a result of innovation and new products, and I will get to that in my next slides.

The result of geographic expansion and the launch of new innovative products can be seen on this slide. Our revenue split from different regions now resembles more of that of the bigger

markets, and it should actually do develop to that direction later on.

The share of Nordics has come down somewhat. At the same time, the share of sales coming from United States and rest of the world have increased. Europe, as a whole, here has stayed rather similar.

Now, I'll spend some time with our innovative medicines, which is, of course, the northern star for us and where we are investing and putting our R&D efforts. Nubeqa, as I said, is our flagship product. It's an innovation by Orion from the mid-2000.

We started our Phase I studies in 2010 and eventually partnered with Bayer when we started phase III studies to have a bit more muscle behind the program, prostate cancer indications are big and need several studies.

Bayer is the best choice, and we've been extremely happy with our partnership with Bayer. We've been able to get the product to our patients and customers as soon as possible, driving the clinical programs with their power.

Product was launched 2019 in US for its first indication for non-metastatic castrate-resistant prostate cancer. We also have another indication for metastatic hormone-sensitive prostate cancer, and Bayer has just recently filed and submitted globally for the third indication for metastatic hormone-sensitive prostate cancer without docetaxel.

Now, we can use it for that group of patients, both with docetaxel and without docetaxel. The deal with Bayer is such that we receive annually tiered royalty, which is on average 20 percent currently.

At three billion, which was originally the potential peak sales that Bayer announced in 2022, the royalty rate would be around 25 percent. Annually tiered means that towards the end of the year, the royalty rate, of course, increases, and that was one of the reasons that we upgraded our outlook for 2024.

Of course, the growth rate here, plus 92.7 percent during the past three years is really amazing. You've probably heard Bayer's presentations that already more than 100,000 patients have been treated with this drug, and they expect this to be probably most widely used prostate cancer drug in future.

This is not all. We have another prostate cancer drug called opevesostat. It doesn't yet have a brand name. We have two phase III or our partner, Merck has two phase III studies ongoing with opevesostat for a different indication that would be then a metastatic castrate-resistant prostate cancer. It's not cannibalizing Nubeqa by any means.

There is a gene mutation that they target, and also an all-comers group in that study. And a bit of a similar structure as with the Bayer. Again, I think this was the best choice for this type of cancer to bring a product as fast as possible to the patients.

Both of these molecules act on steroid hormones. Nubeqa is an androgen receptor inhibitor. It binds to the androgen receptor inhibiting testosterone binding to that receptor and failing the cancer to grow. Whereas opevesostat is a CYP11A1 inhibitor that inhibits the biosynthesis of corticosteroids altogether. It's a real hardcore treatment for this type of disease.

Then regarding our branded products, our legacy products, which are also based on Orion innovations from several decades ago, we do have CNC, which is based on entacapone for Parkinson's Disease, women's health.

In this slide, I want to bring to your attention Easyhaler product family, which is a device proprietary to Orion with dry-powder inhalation powder in it. We have four single molecules, molecules are generic to treat asthma and COPD, and two combination products.

Currently, when you look at the growth rate, it's amazing. When I look at this year's growth rate for budesonide-formoterol, that's close to 30 percent. In Nordics, we are the market leader.

In Europe, depending on the country, we are in a position three to five. I think we are proceeding extremely well with this device and with this product family. The advantage is that when you start your treatment with a single molecule and if the disease proceeds, you can use the same device all along.

The other advantage and part of the secret behind the growth is that this is a carbon-neutral device. Many of the health authorities these days in the countries have set very tight targets for themselves to limit carbon emissions so that we are providing a solution for them with our device.

That's not all. Here, you can see I'm not going to go through all the products. Here, you can see all the innovations that Orion has done during the last, say, 40 years. We actually started with oncology.

Fareston was a product for breast cancer, not prostate cancer. We've circled back to the cancer then in 2000. In the meanwhile, we also developed products for intensive care for sedation, for heart failure, for Parkinson's Disease.

We know quite many areas and other company in Europe who know how to do the market access in all the 28 countries as we have a long track record on that one as well. Nubeqa, I forgot to mention, has reached the blockbuster status this year and exceeded one billion sales already in September. That's, of course, a big historical step for us for having Orion innovation exceeding that milestone.

Then for the clinical development pipeline. Now, this is only for the innovative medicines. Of course, we have a lot of clinical development and programs around the branded products around Parkinson's disease and neurology as well as for generics.

Those are two very different things, and I'm not going to concentrate on that one, but there are tens of products all the time underdeveloped for those divisions. On this one, we clearly see where the focus is with our partners, it's in prostate cancer with the current products and the coming product opevesostat.

Let me focus more on the new ones now that we've already dealt with Nubeqa and opevesostat. We have a new oncology molecule ODM-212 in our pipeline in phase I and also a product for insomnia. Somebody might ask, "All right, what does Insomnia has to do with oncology or pain," but it does have a lot to do, especially with the pain.

Let me explain. ODM-105 is an alpha-2 agonist, and it's a sedative. We know this mechanism for many decades. One of our sedatives that I already mentioned for intensive care units is based on the same mechanism of action.

Also, one of our animal health products is based on this mechanism of action. We do know that this brings good sleep and sedation. It's also an anxiolytic and it gives analgesic effect as well.

What we've also seen is that it gives a natural sleep pattern and we do understand all that there is a huge need for such a medication, even though there are a lot of medication for insomnia, but they have side effects, drowsiness next day, dry mouth, and you name it. We know from history, this is a very safe mechanism of action. It brings a natural sleep pattern.

We are excited while we wait for the phase II results now this year to see how it works for this indication. When I mentioned that this has to do with pain, so pain is often a comorbidity with the insomnia. Insomnia might lead to pain or people might have pain and then have insomnia.

Then, to oncology and ODM-212, which is very new. Now we step out of prostate cancer. That's been our focus, breast cancer and then prostate cancer for many, many years, and there are some reasons for that. We can discuss that later on.

This is a very new mechanism, it's TEAD inhibitor, which attacks the Hippo pathway in cancer, which is involved in many, many different cancers. We think that we have in our hands a best-in-class molecule. Of course, we are not there alone. There is a lot of competition also for this mechanism of action.

We have seen already efficacy in our dose-escalating studies in phase I. We filed an IND in December for the phase II and plan to start, hopefully, by the end of this year at the phase II studies.

This could be used, our theory now is as a monotherapy for EHE, which is a very rare cancer endothelial cancer but also for mesothelioma. There are treatments, but are they good enough for that indication? We also have data on head and neck squamous cancer.

What's really interesting is that since this Hippo pathway has to do with many different cancers when they escape the treatment, is that you could combine this therapy with the existing other therapies like EGFRs or immune-oncology or KRAS mechanism, which then would open the door for much more bigger indications. That's about R&D and innovative drugs and also other divisions.

Now, we move to talk about financial. You've seen that we are growing. That's a clear thing. We've also set clear targets for ourselves until end of '28 so that our compound annual growth rate would be at least eight percent and that our operating profit would grow even faster.

With the Nubeqa revenues, and even investing more to R&D and our future products and our geographic expansions, we are going to see that our operating profit also grows.

Equity ratio, at least 50 percent and return of equity at least 25 percent to be sure and keep us under a strict framework that we invest in a wise way. Orion is known to pay dividend. It's one of the companies in pharma industry and especially if you look at globally, a very Finnish

phenomenon to pay dividend.

We also say that we will pay increasing annual dividend, but we put a cap to it that it can't be more than 100 percent. It can be as low as 50 percent payout ratio. It gives us room if we need to invest more to our projects or do acquisitions, which are, of course, also on our to-do list to grow in the future.

What are the key takeaways from my presentation? It's really the growth. We have a projection beyond 2030 to grow with Nubeqa, hopefully with opevesostat, and also to grow with our products in our pipeline.

We don't publish our research pipeline. That was only our clinical pipeline, and the next molecules that we have there for oncology will be biologics. We hope to push them forward to the clinical stage during the next few years, so there is more to come.

Innovation, we definitely have a good track record on that one, as I've already shown. Stability, 108 years and the legacy business brings us a lot of stability if something goes wrong.

We've already seen it with the LOE of Parkinson's disease products portfolio that when we do have a strong branded products and also the generics business, those can be pumped up quite quickly to stabilize the situation. As you saw, we have really delivered the financial results as we promised, and we have a high shareholder appreciation.

These are my key messages about Orion Pharma, and I thank, at this point. I think it's time for questions, if anybody has questions here. My colleagues, Rene Lindell, the CFO, will join me here, and also our Head of IR, Tuukka Hirvonen. I think the floor is open for questions. I'll try to answer, and my colleagues will help me at their best.

Facilitator: Thank you very much for the presentation, Liisa. My first question would be actually, if you would be able to tell us a bit more about why you think Orion has been so successful in the new treatments for prostate cancer?

Liisa: A very good question that we receive quite often, but what's the secret for that? Because actually, if you think that there are many scientists who work for many decades and they never have such a success. We have actually a group of scientists that have now too, if I count Nubeqa and opevesostat to that.

It's a long story, but I try to make it very short. We once had, and actually, we still have women's health therapeutic area business. We are very well into hormone receptors. We worked for a long time with estrogen receptors to develop new HRT also for men. Everybody remembers what happened to HRT market when the WHI study was published early 2000. It collapsed.

We realized that probably we are not going to develop any HRT for men with androgen receptors. Probably, we could use all this knowledge with androgen receptors to treat prostate cancer, and we screened our molecules and work more, and we were able to find, of course, there were a lot of failures as always when you develop drugs, but we were able to find Nubeqa, darolutamide, for that.

On that same path, opevesostat, is actually, we are just moving even back on the chain on the steroids synthesis route but it all really generates from the knowledge of hormone receptors. When I mentioned Fareston from 1980s, that's also actually acting on the estrogen receptor.

I think that's been part of our core competencies. That's a lot of our R&D strategy. Even today, is not that much on indications. It's really on the disease biology. We tend to do and work with things that we know, and it's really yielding a good result.

Facilitator: Then another question would be, you mentioned during your presentation a little bit about the collaborations with Big Pharma. Do you have any further insights that you could share with us on those?

Liisa: I think both collaborations, of course, with Bayer, we have already worked 10 years. We've celebrated our 10-year anniversary. I think even that tells a lot that we celebrate the anniversary for 10-year collaboration that it's been a brilliant collaboration.

We couldn't have a better partner. We have very clear roles. We do co-promote in Europe together. Then in the rest of the world, Bayer sells the product themselves. We share the development costs based on our shares agreed in the agreement. The collaboration is, it was originally so well structured that all the teams work well. Even on a personal level, it's a very close collaboration.

Same goes with Merck. It's a licensing deal, and they now bear fully the cost of their global program and development. We are then entitled to get royalties when the product is commercialized. Also, their collaboration is very close and tight all the time.

For certain indications, you really need a lot of experience a big machine running the phase III programs, and we need to be realistic that it would not have been possible for us.

Facilitator: Then, we have one question from the audience on animal health. Is that core for you, or would you consider divesting it?

Liisa: A very good question. When you looked at my slide on other divisions, anybody could think that that might not be our core, having three divisions for human health and then one for animal health, but we consider that there are synergies between human and animal health.

We have molecules and products that have been first developed for animals, then later on for humans, and other way around. Especially within R&D and operations, we have a lot of synergies. That said, of course, who knows, in future, that might be something that we would consider. But right now, it's a very important business for us.

[pause]

Facilitator: Thank you. Any further questions from the audience? If not, thank you very much for the presentation.

Liisa: Thank you.



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