



H. Lundbeck

H. Lundbeck presentation delivered at the 42nd Annual J.P. Morgan Healthcare Conference on Monday, January 08, 2024 at 10:30 AM

James Gordon: Good morning. I'm James Gordon, J.P. Morgan European Pharma Biotech Analyst. Today, I got the pleasure of introducing the Lundbeck presentation. We're going to hear from Lundbeck's new CEO, Charl van Zyl. Thanks a lot for joining us today. Look forward to the presentation.

Charl van Zyl: Thank you, James. Good morning, everyone. Thank you for joining today. It's, of course, my pleasure to represent and present Lundbeck to you today. As you know, I joined Lundbeck in the fourth quarter of last year.

It's an opportunity for me to today set more context around the direction of the company -- where are we going, where would we like to take the company, and how do we see the long-term future of the company, in a sense you already get a hint that we see an opportunity to pivot towards being a more focused innovator.

I will certainly share more of those thoughts and how we think we can get there in the long term. Before going ahead, I would like to just put our company disclaimer that what we discuss today is subject to change going forward.

Again, as I said, today is an opportunity to set direction, where do we go as a company? How do we see the long term future? I want to at the start position it very clearly that we are a pure play neurology-focused company. We will remain that very focused company, in a sense, treating patients with high unmet need.

Our intent is to continue to pivot towards being even stronger, focused innovator going forward. I will explain a little bit how we believe we will get there going forward. Having said that, we will also be very careful in terms of how we think about our capital allocation to maintain a sustainable long-term growth potential as well.

Now, in my first 90, 100 days, we've gone through a strategic review. That is still ongoing. I am happy to share some of those thoughts with you today. We addressed three questions.

First one being, can we grow more with the assets we have? The second question was what is the strength of our innovation engine and our pipeline? The third question was can we create more financial flexibility inside the company with the means we have to essentially address the success scenario of investing more in R&D to become a focused innovator.

Through that, we have also, of course, listened to the questions from investors. We have an inside-out view, but also an outside-in view. Those three questions are very much reflected in the core of our strategic review exercise that we have done in the first 90 days.

The first question there really is, can we grow more through the midterm LOE? You know that we are facing an LOE in 2026, and can we grow with the existing assets that we have through that LOE and focus our efforts more in the long term?

The answer to that is, "Yes. We can grow more. We will explain also why we can grow more." On the innovation side, you would have seen from our R&D day that we have a strong emerging pipeline that is more weighted to the early stage.

Also through this exercise, we wanted to address how do we think about external innovation? How do we build a more sustainable pipeline for the long term? The final question in our strategic review was around financial flexibility.

How do we fund a success scenario? What are the abilities for us to be able to create that operating flexibility to address scenarios where we have a more successful pipeline in how we invest in R&D for the long term. I will address those in the most subsequent in more detail.

Again, it's very much around being very purposeful around our capital reallocation as we look at this going forward. In my 90 days, of course, I also had a chance to the review of the company. I will just share a few quick thoughts with you.

First of all, on a product level, we have two very strong strategic assets, with Rexulti, and then also Vyepiti. Certainly, from what we can see today, and what we have in our hands, we believe we have more growth potential there. I'm really confident around the assets we have and the ability for those to grow even further into the coming years ahead.

The second area is on pipeline. What I of course, have seen, and I'll speak more to that, around the real transformation that has happened in our pipeline, and we see significant potential there.

Of course, we know that that pipeline is more weighted towards an early stage and will come into play more in the latter part of this decade.

Certainly strong pipeline potential and a strong innovation engine. We have strong capabilities around partnerships. We are a company that has partnered in the past and will continue to partner. I see that also is an important strategic lever for the company going forward, so very confident to see that already well-developed inside the company.

Finally, in a sense the essence of the company, the reputation, the strong organization, the people we have has really given me a lot of confidence. We have a strong organization in the US where we believe we can grow further and with more investment.

We have a strong innovation-science-led organization. We clearly have a strong reputation and consistently ranked as a really strong company in the space of neuroscience. All those elements, in a sense, give me a lot of confidence in my first 90 days that we have great promise in the company and the potential to be poised for success there.

Now I want to go a little bit more into the strategic direction. As I said, today's presentation is very much around setting direction for you and where we believe we can take the company. We believe there are three pillars that we are addressing in a very systematic way. First is looking at securing the long-term growth of the company. We see that being able to be driven through three areas.

We believe we can grow more with the existing assets we have. We have a current assumption of building with the understanding of what we have today, the knowledge we have. We believe those assets can grow even more beyond what we see today.

Secondly, the growth for the long term will also be driven by a very systematic approach to business development, a programmatic approach. I will explain more what I mean by that. Thirdly, of course, as the organic pipeline today emerges further, we see that bringing, of course, a lot of growth potential in the next decade for the company.

The second pillar is really around building that innovation engine. Of course, a lot of work has happened with the transformation. I am walking in the footsteps of others here. I believe certainly we have a strong potential to further build on that balance of our innovation investment, also towards more early stage. Be very clear on where we play as a focused innovator.

Through the approach of being open to partnerships with a success scenario in the pipeline, we will also be able to partner more of our assets in the longer term.

The third pillar really is around for shareholders delivering that sustainable, profitable growth. I want to confirm again today that we believe with the means we have, with additional flexibility in our capital allocation, we can confirm our target-adjusted EBITDA of 30 to 32 percent.

We believe that we can also do that through various means, both operating efficiency but also in our commercial footprint in other areas, to create that flexibility for preserving that margin while also investing in R&D. Let me go a little bit more into each of those just very quickly to set the scene and the direction for you on those. Maybe firstly on the growth of our strategic assets.

Here, I want to again emphasize, as a focused innovator, we're making very clear choices here that these two assets will be our top of our list in terms of investment focus both in Rexulti with its new indication, of course, in agitation associated with dementia and Alzheimer's disease. Then Vyepti, which is our severe migraine asset, which we've also seen promising growth in '23.

We feel confident now that it's an opportunity to do more there in terms of investing. Our prioritization from a geographic perspective will be to invest predominantly in the US behind these assets to really see the growth there.

We are really exercising very clear focus with the clear levers of investment in Rexulti more around the breadth of our prescriber base, coverage of our healthcare professional base, but also activating now the disease awareness with DTC. In Vyepti, of course, we've learned a tremendous amount around the specialty model, how we serve these more severe patients.

Patient resource managers in areas where we believe we can grow that model even further in terms of our reach will give us a lot of confidence. The feedback we receive certainly from the field and from key opinion leaders that we have the best CGRP in this class here. A very strong promise there.

That translates roughly to what you see on the right-hand side of the slide, which is really what today is a 30-percent contribution of revenue of these assets to essentially doubling those by '28. We feel very confident that we can grow through the mid-term LOE to focus the efforts of the company very much on the long-term strategy that we want to solve.

I think that gives me again the confidence, and hopefully, you, the confidence that our focus as a

management team is really around the long-term success and long-term focus of the company.

Then going a bit more into the innovation bucket of our focus, and I will not go through the pipeline in detail today because we have done that during our recent R&D day. I want to just make a few comments here, and I speak under the leadership here of Johan in the room, that this has been, since 2019, a transformation of the research engine.

We have now five new molecular entities, novel mechanisms. We have filed 60 patents. We have, not reflected here, but 17 new research projects and 13 approvals. We have seen that productivity ramp in the pipeline significantly. This is, of course, an effort over a few years, and we are starting to see the green shoots of those efforts.

Also, in here, you see that we are very focused on four biologies. Where we understand the biology well, the pathobiology, and through the work that Johan has done, we also feel now confident that we can early understand the risk profile of assets even in the pre-clinical stage, and therefore, predict more success in the later stage.

Very promising in terms of pipeline, but having said that and as I said earlier, you can see clearly here that it is weighted towards more phase 1, phase 2. There is a balance that we need to strike with external innovation, more business development strategy to, in a sense, balance more the late stage of the pipeline.

That's why I would like to go now to the next slide which is really giving you more of a sense of how we think about business development. We are learning here from others. We are learning from my past as well that a more programmatic approach, a more systemic approach with a series of deals is how we would like to address M&A, not one single deal, but a few and the string of pulls concept.

There is three clear sandboxes we want to play in building on our strength. The first is in the psychiatry space. Of course, we are commercially very clear there. We have a strong organization, so we will continue to look externally at assets in that space to build that synergy, but also the effectiveness of our current relationships in the field there.

The second bucket is around neurospecialty. Of course, with the launch of Vyepti in severe migraine, we now have learned a tremendous amount in this space around how to address those severe chronic conditions treated at the specialty centers in neurology. We will continue to look in that space to build on top of our model of Vyepti, a strong position there with additional

acquisitions.

The third area is in the space of neuro-rare. As you know, this is a high unmet need area. We have a number of programs in our pipeline that will lead us in that direction, and so we will also continue to scout in that space.

As a final point to say here with this focus, we look at our assets that have the potential at this point to launch by '27, '28 into the market. It's more weighted towards late-stage opportunities that cumulatively will give us the potential of peak sales of one to one-and-a-half billion US.

Also, here you can see as a focus innovator, very purposeful around how we think about M&A, and how we will address that. Having said that, also today, we are in a very strong position from a cash flow generation. We have completely deleveraged, and so we have the firepower also to execute on these very targeted deals going forward.

The third pillar I just want to highlight at this point, and we will go into more detail in the future on this, is really around capital allocation and how we think about this. Through our strategic review, we have identified roughly 20 to 25 different initiatives that we believe will allow us to create that flexibility while maintaining a certain commitment to our profit targets.

To create that flexibility inside to invest more in R&D, that is essentially what we are trying to do. We are doing that through a number of areas being very purposeful around our commercial footprint where we place our investment and where we will de-prioritize in certain geographic areas.

Secondly, we see opportunities in operating efficiency, manufacturing, certainly also how we allocate R&D investment across the spectrum, and other areas where we believe we can generate that flexibility. What I have seen so far with the 25 or so initiatives, I have a lot of confidence that we can create that flexibility to fund that success also in the pipeline going forward.

The final part is a cultural part, I would say, the mindset of the organization, how we think about return on investment in a very purposeful way. Organization that is data driven, and I believe we have already elements of that, but it will require us to continue to transform in that direction.

Giving you, in a sense, just these three pillars that I believe are clear important areas for our strategic direction and how we see the company evolve. Final few comments I want to make

more on our sector, space of neurology, of course, and I think you know it well, but it is important to reiterate that this is an important sector of course.

An area of very high unmet need, and we are well positioned in a sense to address those unmet needs. It's also a very strong growing market, and we want to participate in that growth. It's become probably a bit more interesting also with the recent acquisitions in this space. It is an attractive area, an area of high unmet need.

The final reason why we are confident about this is that the understanding of the science and the biology has significantly improved. Biomarkers, the ability to take large molecules across the blood brain barrier, all the elements that we have in our toolbox, in a sense, will also be able to help us in our discovery process.

We feel very bullish about the space, and therefore, being a pure play neuroscience-focused company is where we would like to continue to build from. In a sense also, our experience, of course, and our strength in the neuroscience space is important. We have two elements here.

On the left-hand side of that slide, you see the deep scientific expertise, the legacy of the company, 70 years in neuroscience. The engine of discovery that we have now established is really a strong asset for us. We are also, of course, very targeted in our discovery process around AI-enabled approaches towards discovery.

From that perspective, that scientific expertise, we want to build on that strength, and we see that in neurology we are well poised to do that. Commercial, of course, is important today as well.

We have now a long history of course in neuropsychiatry, but also built through the acquisition with Vyepti in migraine, a more specialty focused model. We believe we can now build on that model by also acquiring in that space to strengthen that as well going forward. That's a little bit around the space.

I want to conclude with a final slide that gives you a bit more of a view of the horizon and how we see navigating through this. In a sense, the first years ahead, which I would term focus today, is really around being that focus innovator, how do we make those choices.

We are now making those around being very purposeful around the geographic footprint, where we invest for more growth of our strategic brands, Vyepti and Rexulti. I feel confident that we have found the path to do that.

Very clear on our transparency of capital allocation and where can we reallocate, and we have identified those initiatives.

We'll focus on delivering those, and of course, the innovation of our current pipeline, but also being very purposeful around focusing on our business development efforts around being very programmatic, very systematic around a series of deals is what we will see now sort of phase of focus becoming that focused innovator going forward.

We see, through that potential to scale into new areas, with the advance of anti-pay cap with our development phase of that going into 2027, it becomes a very strong opportunity to build on top of Vyepti, a new mechanism that can broaden our reach into the severe migraine space, as well as in the neuro-rare space where we already have pipeline assets there.

We see a company in this window of scaling more through partnerships as well, both on an R&D level, but also commercially, remaining focused on how we reach more and an operating model of a company that's lean, transparent, but very focused on being purposeful around where we invest in how we invest.

As we look a little bit further out into that phase of where we see the success of the organic pipeline, we see an opportunity to accelerate into the next decade. Our focus is on that LOE that we have in 2029.

With a combination of our business development efforts, together with an organic pipeline, we feel we have the ingredients to be able to grow into that next decade, with the work that Johan is doing, remaining a top level best in class neuroscience discovery platform.

As a final point, we come from a position of strength, strong cash flow generation. Today, we see the firepower evolving even more. Today, we have about two to three billion, but we see that even evolving further with the cash flow we have and a growing strategic set of assets.

We have this ability to execute this plan in a systematic way and deliver on the long-term-growth perspective of the company. I want to pause there. I think we now have a chance to take some questions.

Again, thank you for your attention today and for hopefully a clear message. We'd love to hear your questions going forward. James, I hand it to you. I would like to invite also Tom Gibbs, our

head of the US, who could certainly answer more questions for you on Vyepti and Rexulti, and then also Johan, our R&D head, to join me here.

James: Thanks very much. We'll now kick off the Q&A. Does anyone have any questions they'd like to start with?

Audience Member: Thanks. I have a question on Rexulti with Alzheimer's agitation. Would you say the sales or awareness penetration rate is, in that space, just due to the fact that to some degree it's been used off-label for some period of time?

Charl: The work that we've done to date really confirms that there's a significant unmet need that exists with AADAD. It also confirms that it's a nascent market that needs to be developed over time. As we look at the progress that we've made, we're actually very pleased with the progress that we're making today.

If we look at our baseline prescribing based upon claims data, our prescriptions are up 140.2 percent as of October. Claims data, really driven within the long-term care setting, over 300 percent growth there. Within the community setting, 68 percent. With that said, I think we're really just scratching the surface there.

We have significant work to do as it relates to really raising awareness and appreciation among caregivers of the burden of AADAD as part of their Alzheimer's and really galvanizing them and activating them to drive their loved ones in to seek treatment. That's what we have been doing. We've launched our DTC campaign in October.

We're starting to see some good progress there as it relates to what we see in the December time frame. Does that answer your question?

Audience Member: Yes.

James: If I could just ask a follow-up question to that, which would be, we've seen some quite encouraging data that you presented looking particularly at older people where there has been some acceleration or some expansion of use.

The overall prescription data looks fairly steady at the moment. When do you think in the overall prescription data for [inaudible] we might start to see the inflation?

Man: I honestly have a little bit of a different view when we look at the overall prescription data. If you looked at the market share in the May timeframe, it was flat at about 1.79 percent. If we see the most recent weekly data, market share was at 2.08 percent.

We have seen a meaningful impact of the AADAD indication I think driving the overall brand performance. I talked about market share but if we look at our NRXs, for example, we reached another all-time high December 8th for NRXs as well.

James: Thanks. One heads up...Bigger picture question. I think you talked about growth to 2029 but how fast do you think the company can grow? I think a while back there was a comment at least to '26 that the company could do at least mid-single-digit growth. What sort of growth potential do you see out to that loss of exclusivity?

Charl: Thank you, James. I think at this point we are probably not going to give you specific guidance, but we feel with the assets we have that that sort of hypothesis can be confirmed and so we want to at least be in that mid-single-digit potential. Of course, we will provide more specific guidance in midterm as well.

James: Sure. One other piece of longer-term guidance or medium-term guidance I think before the company had said that a margin of 30 to 32 percent could be achievable...If I remember rightly that was maybe, previously, it was a medium-term target but I think you said longer term.

Is that still a target that could be a '25, '26 target or is that more of a longer-term target and what is longer term to Lundbeck?

Man: For us, that 30 to 32 percent we feel is competitive in the peer group, allows us some flexibility to invest in a success scenario with more R&D. Of course, in that success scenario we enter more into phase 3 that will ramp up our R&D cost so we want to stay within that corridor. I believe that's also a healthy balance between profitability and also investing in innovation.

James: If I understand correctly, are you saying that you think that the company could remain in the 30 to 32 percent from now all the way out to the end of the period that you were talking about?

Charl: Of course that we need to validate a bit more in a sort of a bottom-up approach but that would be an ambition we would like to put out there.

James: Thanks. It sounded like there were quite a few initiatives that you were looking into. How will we as the market get more visibility on that? Will it be at some point say potentially with four-year results, you will say, "This is a cost savings program and we're going to save this amount of money," or something like that?

Is it more just generally as things progress, you will keep spotting opportunities?

Charl: To be very transparent, we have gone through a strategic review where we have essentially identified a certain range of initiatives that we believe...I wouldn't call them cost cutting but really where do we purposefully reallocate inside the company towards growth or towards R&D.

Of course as it is in my first 100 days, we need a period of validation of those but we believe certainly during the second half of this year we can be more prescriptive around what does that mean, what is the degree of transformation we expect from those. It's very much a staged approach over a multi-year to build that flexibility.

James: Might it be that you communicate an actual total amount of spending that you're freeing up to then invest elsewhere?

Charl: We would like to do that once we validated but I think that would be a helpful measurement, yes.

James: Maybe switching to the pipeline. I went to the R&D day towards the end of last year and there was quite a lot going on. A lot of it was quite early and so has a reasonable amount of risk attached to it but if you were to say like one or two things that you think of the highest probability of success and that you're most excited about.

Man: Thanks for that question. I mean obviously it is an early pipeline, primarily it's a phase 1 and phase 2 pipeline when you look at the new programs. The shape of the pipeline is quite different from what we had traditionally.

It's more neurology assets for various reasons but there are also assets where we have substantial possibilities to de-risk early with pretty convincing biomarker readouts, etc already in phase 1B studies in patients, etc.

What we're progressing now into proof-of-concept studies are actually a set of assets. Obviously,

we passed already the PACAP proof of concept with an IV infusion, and now we're doing more dose finding with subq. I think that's an extremely interesting program that we are going into full development with after we do the dose finding studies.

That's going to be [inaudible] migraine franchise stronger, migraine position stronger. We have a number of follow-up activities around that. That's going to be a very strong R&D position in migraine, which it's pretty unique, I have to say.

When it comes to other earlier programs, something we are really interested in progressing and see where we can take it, because it's a great opportunity is our CD40 neuroimmunology asset, which is a very, very potent mechanism that already been de-risked in a number of indications, autoimmune diseases.

We started a TAD study right now which is a neuro-adjacency indication where we'd like to take it, but obviously, we have many more opportunities there. Very, very early asset also is our ACTH antibody, which is something that really speaks to that early de-risking.

You can look at biomarkers immediately in patient studies, and we've done that. It's just a few patients yet, but it's a really interesting mechanism, and we're going to take it into a couple of indications. We already started congenital adrenal hyperplasia, but we're going to head also in caching, and that's going to be very, very interesting to see that moving forward.

James: Are we still going to get this alpha-synuclein data this quarter? Is that one very high risk?

Charl: Yeah. Everyone knows chronic penetration is a hard one to crack if you want to do disease modification, but we're seeing some light in the tunnel, of course, in the amyloid field and Alzheimer's disease.

We have a great antibody, alpha-synuclein. We decided to take it into multiple system atrophy. Obviously, it's anything with alpha-synucleinopathy, so it could be Parkinson's. This is enormously high medical need, rapidly progressing.

We did a small, very tailored proof-of-concept study, and we're going to have the readout now in the Q1 period. We'll see how it goes, but we have biomarker and clinical readout in that fairly small study.

James: Thank you. Maybe a question on BD. What's the urgency on BD? If I saw the pillars, it

looked like, if I remember correctly, that you'd put the BD ahead of the pipeline, internal pipeline. Should we read that as that's going to be the bigger driver of the faster longer-term growth, or you're poised to do something big soon?

Man: Thank you, James. Yes, in a way. What I would like to say here is that again, our focus and our strategic intent is to solve that long-term growth also with combination of organic pipeline and a combination of external innovations with BD.

Having said that, 2029 seems a long way but we need to act now. I think it's a series of deals, potentially already scouting this year and into next year as well that will have the potential to launch in that '27, '28 window and commercially contribute together with the pipeline into the long-term growth.

BD is an ongoing process, but we start now with a very disciplined approach and be very programmatic around how we do that. We don't see one single event necessarily, but more a series of events.

James: You mentioned there have been a few deals recently in the broader neuro space. Does that mean valuations have gone up for neuro assets?

Man: Yeah.

James: Does that make these assets become more fashionable to...?

[crosstalk]

Man: I think the valuations that we saw on those larger deals were anyway outside of our scope of size of deal. We are looking more at assets that are in the 500 to 800 million peak sales, which are also, I would say, more in the mid-cap space, which makes sense for us.

Again, I can't comment on valuations in that space, but it's certainly probably in a space where there might be less competition versus the larger pharma.

Charl: I think it's interesting to see those deals coming through now, because we've been very bullish about being in neuroscience for many, many years, and all of a sudden, there's a very, very big interest in neuroscience.

If you look at the US\$191 billion in deals last year, neuroscience was in second place with US\$21 billion. Obviously, it's a lot of deal making being done and some were very spectacular, but there are many other opportunities in the space. Neuroscience is back, definitely.

James: Maybe a silly question to someone who works in R&D, but have you got big enough R&D budget? Has the company, for all of you, under-invested? Are you going to need to really ramp up R&D spend in 2024?

Charl: Obviously, you like to be in a place where your biggest headache is to fund great programs. Then you have the positive problem of choice, which is really where I like to be, because the more opportunities you have, the more you have to prioritize, the better your portfolio becomes.

I don't necessarily see our size and our budget an issue. We can run many different programs. We have a fairly rich early-stage program. If that expands, of course it will be good investments to make. I think we have a budget for R&D that is sufficient for what we like to progress right now.

Man: I would just add to what Johan said. Of course, it's a cyclical situation as we go more into late-stage, there will be this choice we need to make around which of those we fund ourselves and which of those we partner. I think this is a scenario ahead of us that we will deal with as we get there.

Charl: It's also important to recognize that we go through those cycles and we had a cycle when we actually spent quite a bit on brands to expand them. We have done that great in the Rexulti case, for example. Vyepiti was a big investment also initially. Now that is contracting a little bit and we can free more money to innovation pipeline. It's actually in some manner a good place to be right now.

James: Should we think of 2023 as a little bit exceptional in terms of how little you spent and now you need to accelerate, or can you manage by reallocating between projects?

Charl: Yeah, a little. We had a substantial R&D spend, of course, in '23, but I think it reflects that shift and timing of events. It's really no signal that we're reducing our R&D investment, but it's the phasing, I think. I think '23, '24 should be.

James: Unless any final questions?

[background sounds only]

James: Great. In that case, thank you very much.

Man: Good.

Charl: Thanks.

[applause]



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