Lundbeck

Acquisition Announcement

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Transcript

Speakers:

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Charl van Zyl

Good afternoon. Thank you again for joining our call today on very short notice. And we want to use this time together to engage with you on our definitive agreement that we've announced to acquire Longboard Pharmaceuticals. This is a significant step for us, forwarding our journey to become a focussed innovator.

But before we go to the more detailed points on the deal, let me go to the next slide, please. On this slide, again, I want to make you aware of the forward-looking statements. These include statements regarding the transaction between Lundbeck and Longboard, and are subject to various risks and uncertainties and subject to change. If we can go to the next slide, please.

And before we then talk about the deal itself and the agreement we've reached, let me highlight a few of the following points. The tender offer has not yet commenced, as highlighted in the press release, and this call is therefore only for informational purposes and neither an offer to purchase or solicitation to sell any of the shares of common stock of Longboard. I just wanted to make you aware of these points as we go into the next discussion about the deal. Let's go to the next slide.

I want to say again here that I'm really pleased that we could announce this deal today for Lundbeck to acquire Longboard Pharmaceuticals. And there are three and four important points that I want to highlight for you again, around why we believe in this deal. First of all, it's building on our future as a focussed innovator in the space of neuroscience. And what this deal brings us is a real perspective on long-term growth for Lundbeck in the future and in the next decade. It's really built on our strategic ambition to build strength in the neuro-rare space going forward. This complements other areas we have, like amlenetug with alpha-synuclein, in MSA, that is also part of that programme in the neuro-rare space.

What is important in this asset that we are acquiring today, bexicaserin, is that we are acquiring an asset with breakthrough therapy designation and the potential to address a number of severe and rare epilepsies in the space of developmental epileptic encephalopathies.

The final point I want to make is that, based on what we know today, this asset and the programmes that we will develop it in will have the ability to deliver peak sales in the range of 1.5 to 2 billion. And complementing our existing mid-stage and late-stage pipeline and building, therefore, a strong position for long-term growth for Lundbeck.

If we go to the next slide, what I would like to again emphasise, as you have heard from us many times, and from myself, these are the pillars of our focused innovative strategy. The one is to

grow what we have, grown in the mid-term our strategic assets, and we see very strong results there, as we have communicated in the first half of this year. And that continues to be a key focus of growing through the mid-term with our existing strategic assets.

We focus very much also on our capital allocation towards innovation for the long term. And this is where our deal today with the acquisition of Longboard fits very well. It fits into our focused innovation strategy to build sustainable growth for the long term. And what we bring into the pipeline now is an asset that is going into Phase 3, and Phase 3's trials are being initiated with the ability to launch in the fourth quarter of 2028.

The final pillar, that we will discuss in more detail also during our upcoming capital markets event, is our ability to also reallocate capital and fund that future in a very sustainable, profitable way.

If I then go to the next slide, just a few words on Lundbeck and Longboard, and I first want to take a moment to thank the Longboard employees. This is a tireless effort that this team has worked in advancing the science in this space and bringing this level of innovation into an area of very high unmet need. I'm sure that the team is very proud of their achievements, and we very grateful that we can now build on that legacy and bring this to patients in the future.

What you have here is bexicaserin, which is a very selective 5-HT2C agonist with a broad potential. And we see that potential in areas like Dravet, Lennox-Gastaut, and other rare developmental epileptic encephalopathies. This is an area where we see really a number of patient populations that can be addressed by this very selective mechanism. We have seen compelling Phase 2 results that lead into Phase 3, with also breakthrough designation. That is compelling in terms of its efficacy and safety profile that we believe could be a best-in-class treatment in this space. And the fact that the Phase 3 results were compelling also means scientifically that it's de-risked. And we have a high confidence that it will come to the market and will contribute to a 1.5 to 2 billion peak sales potential that we see across these multiple indications.

To now talk a bit more about the strategy and the strategic fit. I would like to hand over to Maria Alfaiate, who is our head of corporate and commercial strategy, who will share a bit more her perspectives on the deal and the strategic fit for Lundbeck. Maria, over to you, thank you.

Maria Alfaiate

Thank you very much, Charl. And as we have been, or as Charl has been mentioning, this acquisition showcases a perfect strategic alignment with our focused innovative strategy that we've been sharing with you for a while. It also showcases our

ambition to continue to bring leading innovation to patients within neuro speciality and neuro-rare diseases. Charl has already alluded to the fact that this is a de-risked asset, with several potential indications, with compelling evidence, convincing evidence of what could be potentially a best-in-class for Dravet and Lennox-Gastaut, but also first in class for other DEEs.

The significant IP protection also gives us considerable runway where we can drive the success of this asset. Of course, it has a strong fit with Lundbeck's strategy. It enhances our dedication to neuro-rare, and also to the established presence that we have in rare epilepsies in the US. We expect launching in Q4 2028, as already has been alluded to. And I would move on to the next slide, please.

You've also seen from the press release that Longboard Pharmaceuticals has an interesting profile. They have been experts in this area. And with the initiation of the Phase 3 DEEp SEA study evaluating bexicaserin in Dravet syndrome, that is scheduled for this year, we will be playing into this rare epilepsy field.

On the assets you've read before, bexicaserin, we believe that this could be a best in class within the modality. We are going for a broad range of indications, many of those that are currently very underserved. This asset is, in reality, a pipeline in a product. And I will let Johan tell us a bit more about the profile of the asset itself.

Johan Luthman

Thank you very much, Maria. Let's turn to the next slide. Before I go into some more preclinical and clinical details about bexicaserin, I'd like to orient you a little bit in the indication space we're operating here. This is antiseizure medication, intended to work in a certain group of epilepsy patients. Epilepsy, as you know, is a very, very broad category of diseases with still enormous unmet medical need. It's estimated that around 30, between 25 and 40% of epilepsy patients are not really reaching any good therapeutic effect with the drugs that exist today. They are what we call resistant to seizure medication.

If we look down in how we classify different epilepsies, we still work with a classification on how the onset of the seizures start. Here we have the two different groups of focal and generalised seizures. This is actually a fairly new classification in terms of epilepsy, with previously talked often about partial onset seizures when we talked about the focal seizures, but it really now recognises the focal onset in, say, the temporal lobe or some other, more defined, unilateral region for the focal seizures. The generalised, or as indicated by its name, something that broadly emanate from the whole brain, both sides of the brain. There are also mixed patterns of onset of seizures,

and then, unfortunately, there are a number of unknown reasons for it.

If I then drill down on the DEE group, the developmental and epileptic encephalopathies, they can occur. The genealogy [?] of them are basically based on three different broad categories, acquired, syndrome or genetic. The genetic ones are best illustrated by Dravet syndrome, where we have dominant mutations in the sodium channels. When it comes to the acquired ones, they could be due to brain trauma, tumours, and other effects of the brain, like infections. While the syndromal come across a number of different syndromes that are metabolic or due to other causes.

If you look at the DEE space, it contains a lot of different causes of epilepsy, seizure conditions, and it's only actually four of those that are today treated with any medications. It's a big sea of these that are not reached today with approved therapies. Dravet syndrome, I just mentioned that the dominant mutation in sodium channel primarily, in this case. Here we have a number of drugs in several years back. Lennox-Gastaut is actually a more narrowed down indication space than it used to be, and it's more defined through its ED recordings, but it's also quite well served by drugs. But still, many, many patients that are not responding to treatment well.

Tuberous sclerosis complex is an indication where we recently have got a couple of drugs to the market, but is still tremendously underserved. Then we also have seen a new drug in the CDKL5, or CDD disorder very recently. But as you can see on this list, which is just an example of the many different DEEs, there are many that are not served by approved drugs. Next slide, please.

Then if we look at the numbers of patients here, you have the approved therapies in darker blue here on the left side in the four indications I just mentioned. But as you can see, there are many other DEEs that are not served today by approved treatments. And that's approximately 100,000 patients today that are not served by any approved therapies. Bexicaserin has the potential to address across all of these, and that's why we are particularly interested in this drug. Next slide, please.

Then, if you look a bit, what made us very interested and excited about this drug. First of all, it has a very unique selectivity for 5-HT2C receptors. This is believed to be the validated receptor for its efficacy. And the interesting thing about the selectivity here is that it's conveyed by a pretty well understood structure, given the relationship. It's in the tricyclic structure with the main [?] group on the eight [?] position that really conveys that selectivity. Selectivity has also been seen by the major metabolites of the drug, which is very important to also look at. This means that this

drug avoids some of the in-built liabilities you see with 5-HT2B or 5-HT2C agonistic properties. Through that selectivity, it doesn't have any major in-built liabilities to have any of those cardiovascular and [13:14 unclear ?] pathology liabilities or psychiatric type psychosis liabilities that may occur also due to agonistic approaches.

The preclinical evidence is pretty standard. There are a number of animal models that have looked at this, and it showed good efficacy across a number of models. And that triggered a clinical development programme in the Phase 1 programme that looked at the safety, food interactions and drug interactions, which are very important, because patients are often on the multi-drug therapies for the drug therapy, so it's very important to see that it doesn't interfere with standard of care.

Built on this, the PACIFIC study was done, which was a Phase 1b, 2a proof of concept study with multiple DEE populations. And the top line data were communicated early this year, and that triggered our interest. And it was well recognised by the scientific community as well. This also triggered the company Longboard to continue with initiating a Phase 3 programme. There is also an open label part of this specific study that has been quite recently reported. I'd like to drill down a little bit more on the results of the PACIFIC trial. if you go to the next slide, please.

On the left side here, you see from the PACIFIC study the overall effect of bexicaserin in reducing the countable motor seizures. Here, we're looking at one type of readout, which is the most clinically relevant when you look at motor induced seizures. Basically, epilepsy that leads to motor effects. And here you see quite a pronounced effect against placebo. And I like to call out the placebo here are patients on standard of care. On the overall population, we see almost a 60% reduction in the countable motor seizures versus 17% in the placebo treated standard care patients.

If one looks a little further at the different subpopulations, and this was a mixed group study, so obviously it varies a little bit how many patients that we included in the various subgroups. But I think this is very interesting to look at, because if you look at the bigger group, Lennox–Gastaut, it was still a very robust over 50% reduction of the countable motor seizures. In other DEEs were quite a sizeable group of patients also included. There was a 65, almost 66% decrease in the countable motor seizures. And then, interestingly, in the smallest sample of patients that were involved, this was a very pronounced reduction of the countable motor seizures.

This is very interesting data and is the basis for the initiated Phase 3 programme. It also interested the FDA, because the

company has obtained a breakthrough therapy designation on July 1st for these, for patients two years or older age. With this, I'd like to hand over to Joerg for the next slide.

Joerg Hornstein

Thank you, Johan. This is truly a transformative and value creating acquisition, accelerating our strategy to become a focussed innovator. From a transaction details perspective, we're talking about a purchase price of US $60 per share in the form of an all cash transaction. The US $60 per share constitute a 54% premium to the closing price of Longboard Pharmaceuticals as of last Friday, October 11th. The total consideration for this transaction amounts to US $2.5 billion net of cash, which is approximately DKK 17 billion, thereby making it the biggest deal in Lundbeck's history.

We fund this transaction basically through existing cash resources and existing committed credit facilities. We see this transaction carrying deep value for Lundbeck, and believe bexicaserin is a de-risked asset with compelling Phase 2 data from its PACIFIC study. The Phase 3b program has been initiated last month in bexicaserin as an opportunity for a series of indications supporting continued growth due to its unique pharmacological profile. It can deliver an unprecedented efficacy and safety profile across the DEE patient population.

We estimate peak sales potential between US $1.5 to 2 billion. The Longboard acquisition will significantly bolster our late-stage pipeline and drive growth through the next decade. We expect closing for this transaction in December 24, and we expect to recognise integration costs in the amount of approximately US $80 million, which amounts to roughly DKK 550 million, which predominantly will impact 24 and will be adjusted for in our adjusted EBITDA financial reporting. As a result, we do not see an impact to our full-year 2024 adjusted EBITDA guidance.

This transaction is also attractive from an EBITDA accretion perspective that we estimate to be two to three years after launch in Q4 2028. Bexicaserin together with other programmes in our current portfolio, such as anti-PACAP, amlenetug and anti-ACTH, complements Lundbeck's long-term growth potential, while addressing the LoE of Rexulti at the same time.

From a capital allocation perspective, we do not see any significant impact to our priorities. We remain committed to our dividend policy, targeting a payout at the existing 30% range of net profit, as well as the maintenance of an investment grade rating at all times. Even that, this is a very sizeable deal for Lundbeck, we still have capacity for additional BD from a debt perspective, in line with our focussed innovator strategy. On all of these topics we will elaborate further at our Capital Market event on October 23rd next week. With that, I will hand over to

Charl for some closing remarks.

Charl van Zyl

Thank you, Joerg. And if we can go to the final slide before I invite you for questions, let me just leave you with the key points. Again, it reinforces our strong position in neuroscience as a focused innovator. With this acquisition, it will perfectly fit into that strategy and contribute significantly to our long-term growth perspective. We see an adequate risk profile. In fact, scientifically quite de-risked as a late-stage asset with multiple indication opportunities. It really builds depth and strength in our neuro-rare portfolio as one of our key pillars we want to continue to build as a future option for Lundbeck. And, as Joerg had mentioned, also strong, solid balance sheet here, also post-transaction.

With that, I would like us now to go to questions and open up back to the operator. Thank you.

Operator

Ladies and gentlemen, we will now begin the question and answer session. Anyone who wishes to ask a question may press star and one on their telephone. You will hear a tone to confirm that you have entered the queue. If you wish to remove yourself from the question queue, you may press star and two. Questioners on the phone are requested to disable their loud speaker mode while asking questions. Anyone who has a question may press star and one at this time. One moment for the first question, please.

And the first question comes from James Gordon from JP Morgan. Please go ahead. Mr Gordon, your line is open now. Seems like he may have issues with his microphone. Then we will go to the next question, which comes from Charles Pitman-King from Barclays. Please go ahead.

Charles Pitman-King

Hi, guys. Thanks very much for taking my questions. Two from me, if I may. Just to get started, can you just give us, Johan, maybe a little bit more information around how we should be thinking about current standard of care for these rare epilepsies and how the competitive environment has developed over time, and why, particularly, bexicaserin is well placed to beat these out? Where in the treatment paradigm should we really be expecting it to place?

And then just secondly, a question in terms of the premium suggested to be being paid for this asset. What is it about this asset that makes the roughly 80% premium seem appropriate? Is this the level that we should be expecting for valuations of focussed, innovative biotech deals that you would be looking to do in future? Thank you very much.

Johan Luthman

I can start with your first question then. Thanks, it's a really good question. And obviously, we think it has a pretty unique space in

the field or standard of care, because its profile, the binding profile, etc., of this molecule. But if I walk you through a little bit more of what we have in terms of competition, there is no drug approved for this broader label of DEE. And what one would be aiming for here is an indication for DEE, basically, for children above two years or something of age. That would be a very encompassing indication label, which if you look at the specific different diseases, Dravet has had a number of drugs on the market for many years. Epidiolex is there since 2018, and fenfluramine also came 2020.

There are some pretty efficacious medications out there. But the little data we have so far on the molecule in Dravet syndrome indicate that it has, if you eyeball the results, very impressive reduction of the motor seizures. That's why we hope to see more data in the company. Longboard has already initiated a Phase 3 trial in Dravet syndrome.

When it comes to the other big indication in this space, sub-indication of the space, Lennox-Gastaut syndrome, there are probably about eight approved drugs, and you have also drugs like fenfluramine there and cannabidiol. Those drugs are active also in that space. Fenfluramine got approval quite recently in 2022, so here we have an efficacy that also definitely works against those drugs at the same level, if not better. What we like to see here is more data, and also with the differentiation here that I hope will play out very much in the eyes of the prescribers and the patients and caregivers, is the broader safety profile that this drug should entail by its selective 5-HT2B agonistic effect. 5-HT2C agonistic effect and avoiding the 2B.

For tuberous sclerosis, which is a little odd, the indication in this big family, there are a couple of approved drugs. In 2020 Epidiolex again, and then a new drug that came, and mTOR inhibitor in 2018, which came through treatment of other tumour effects. And then the CDD indication has, as I mentioned, a new drug.

I think overall, the biggest potential for this is that here you don't have to really look at the various subsegments, and here you offer a therapy that actually can work across any kind of the, some of them very, very rare. And that is what we intend to do in the coming trials, that start-up of our Phase 3. Then I hand over to Charl, maybe to handle the next part of the question.

Joerg Hornstein

I'll take that first, I think, Charl, to come back to your question. I think we're talking about an attractive acquisition price, which is below, you can say, 1.5 of expected peak sales. If you compare that with precedent M&A transactions, somewhere in the range of 1 billion to 5 billion post PoC data and pre-Phase 3 data, then it's very much in line from a premium perspective, whether you

look at unaffected 52-week high or 30-day VWAP. And it is actually even more attractive if you compare it to some of the precedent rare epilepsy transactions.

But besides multiples, I think it's much more important at the same time to look at, as Johan said, the de-risked nature of the asset and the quality of the commercial case that we have been able to put together, which sits on the back of achieving a broad label, and is work out of a very diligent due diligence we have done together with Longboard, pretty much, you can say, since January of this year. It is a strong drill down into expectations we have on expected price market share launch in LoE in 41.

Charles Pitman-King — Thank you so much.

Operator — The next question comes from Xian Deng from UBS. Please go ahead.

Xian Deng — Hi. Thank you. Thank you for taking my questions. Two, please. The first one for Johan, please. On slide 12, that P-value of that Phase 2 trial, it actually crosses the threshold of 5%. Yet, the magnitude seemed to actually be very big for the active arm. Just wondering, why is that the case? Is that just multiple diseases, or is it just high variance with individual patients? And how should we translate to your expectation for the Phase 3 or your degree of confidence or Phase 3 success? That's the first question, please.

And the second one, just wondering, your level of confidence of achieving that peak sales of $1.5 to 2 billion. Because if I look at Fintepla, the consensus with several similar overlapping indications, the Fintepla consensus is actually below €1 billion. Just wondering, given your expectation's a lot higher, given the very similar mechanism, but just wondering, do you think you're confident, you think you're going to have more indications or you think you actually have a better drug, so you will have more market share? Thank you very much.

Johan Luthman — Thanks very much for that good question. If you look at the PACIFIC study, obviously it was a proof of concept study, more smaller, and it didn't include so Dravet patients, just a handful, less than a handful. The bigger population, as I mentioned before, was Lennox-Gastaut syndrome and other disease. Reasonable size of other DEEs group, but they obviously come with many different sub-indications here. I think the confidence we have, really, of going into Phase 3 is that it was consistently shown across the populations to work. Remember, this is still a fairly small proof of concept study, so P-values are not really the critical aspect here. It's really the extent of the effect and the variability you see almost at an individual level. Even in the few patients that are included from the Dravet subgroup, there was a very consistent effect. Now, one needs to look, particularly in

the Davet group, at the bigger population, and that's really what has been initiated now.

I have to say, I have a very strong confidence that this will work out very nicely across populations. Why is that? First of all, hidden in this drug is a validated mechanism, the 5-HT2C agonistic effect. While this is a super agonistic effect, so if anything, more potent. It's a very potent drug on that receptor with a remarkable selectivity. There is no in-built break in dosing here. Physicians and also in clinical trials, shouldn't be really concerned about liabilities in building the molecule. That's one aspect that I think is really very interesting with this molecule, because other drugs have a little more troubling side effects, or even REMS programs that try to avoid the problems with other side effects that could occur. Like also what has been described with, for example, fenfluramine [31:25 unclear ?] liability. It took many years for that drug to build up its dosing and go into this indication space. Here, we don't have that concern. One could go straight out and really test the drug at reasonable doses. I hope that answered your question.

Xian Deng — Yes, thank you very much, very helpful.

Operator — And the next question comes from Martin Arkhøi from SEB. Please go ahead.

Martin Arkhøi — Martin Arkhøi from SEB. Just a couple of questions. Firstly, just on your potential for initial launch in the fourth quarter of 28, would that be on the broad use, or do you need to get a single indication in the beginning and then you get add-on indications, like we are seeing, and hopefully will continue to see results?

And then just secondly, do you have any interest on other parts of the pipeline of Longboard, or is this just a single asset acquisition? And in this context, was a license in the deal or a single asset sale, was that on the table as or was it a full acquisition, which was necessary?

And then finally, to Joerg, with the additional R&D cost that you will take in, how would it impact your mid-term margin targets?

Johan Luthman — Maybe I can start and then maybe others can fill in a little bit. First of all, I think it's very important to note that the breakthrough designation that FDA has provided here is really for these unspecified [33:17 unclear ?]. That is the label one would aim for, so that would encompass Lennox-Gastaut and Dravet and tuberous sclerosis, so whatever one may have in the trial. We really are going to aim for that what you say, broader label initially. There is no slicing here, the idea is really to encompass the whole DEE population. Obviously, there are various variants of this. And the way you run the trials could lead up to various sub-indications also being labelled, or at least mentioned,

because those populations are studied in the clinical section of the label.

Other pipeline assets, yes, there is one S1P modulator that is in Phase 1. That is an asset that I would say is not any driver at all for this deal. This is a compound that is on a mechanism that has, quite frankly, also validated Gilenya and other drugs. But it's a very late comer, and this is something we didn't include in our evaluation of this deal, really. I hope that answered parts of your questions, but I think there could be also other parts that others can answer.

Charl van Zyl — I can add, Martin, to your question around what type of deal structure was available. Many of these are considered, if it's in-licensing or outright acquisition. It depends also on the seller, and in this case, it was an outright acquisition, that was really the deal structure on the table. Joerg, you want to comment?

Joerg Hornstein — I'm happy to comment on the mid-term targets. I think we feel comfortable to be able to handle this within the existing bottom line range or margin targets we have given. R&D costs are going to increase, but it's also not something new. We've seen that also this year, and that's also in line with our long-term guidance, so that should be clear.

Martin Arkhøi — Can I just have a follow on to Joerg, maybe? The peak sales estimate of US $1.5 to 2 billion, how is that regionally split, just broadly?

Joerg Hornstein — I think it's very fair to say that the US has more than a supermajority in this case.

Martin Arkhøi — Thank you and congratulations.

Joerg Hornstein — Thank you.

Operator — And the next question comes from Manos Mastorakis from Deutsche Bank. Please go ahead.

Manos Mastorakis — Hello. Thank you very much. Looking at Longboard's history and prior ownership, is there anything you can share about royalties, any royalties owed to other partners in the past?

And second question would be on general confidence you have in the approval of this deal going ahead, the antitrust approvals, if you can comment on at this point. Thank you.

Charl van Zyl — Manos, it was quite difficult to get your question. It was not a very clear line. I think your question was around prior ownership and royalty commitments. We don't see any of those of concern for us in terms of our deal structure. I couldn't get the second part of your question very well. Could you maybe repeat, if possible?

Manos Mastorakis — Yes. Just in terms of the confidence in the deal going ahead. Any

antitrust approvals pending? Just how we should think about that. Thank you.

Charl van Zyl — Thank you. I think your question is around antitrust, if I understood correctly. Currently our working assumption is by the fourth quarter of this year we should expect clearance.

Manos Mastorakis — Thank you.

Operator — The next question comes from Marc Goodman from Leerink Partners. Please go ahead.

Marc Goodman — Hi, this is Madhu on the line for Marc. We were just wondering, could you talk about the potential for the full DEE label outside of the US? Maybe what you know the EMA's view of this is, since you're going after the full label directly in the US.

And then the second question is, you alluded to the pipeline in the product, are there any indications beyond epilepsy where this mechanism could make sense? And given the superior selectivity and potentially better safety of this type of asset, we were just wondering if there's any indications in your mind, beyond the DEEs that are already highlighted? Thank you.

Johan Luthman — Those are two questions for me. Let me try with the last question first. I think this is a pretty unique mechanism for seizure conditions. We have not considered any other indications. Of course, there are conditions that come with seizures. Famous is, for example, Alzheimer's disease. You have seizures at some stage, so one could perceive maybe other indications, but they will still be some type of antiseizure medication. We're not going outside the antiseizure medication space with this mechanism, to my knowledge. Things can happen in the science field and you have to remember, this is a very old serotonin mechanism, really, if you think about it. But we don't expect anything else.

When it comes to the DEE indication, which is really an interesting and I think quite exciting opportunity now presented by the breakthrough designation. We are aware about Longboard having had some conversations outside the US, but they obviously, as a fairly small enterprise located in the US, been focusing on the US regulatory interactions first. But there have been some initial conversations also with, for example, Europe, and we understand that so far it's been reasonable, encouraging conversations. But we really need to get under the hood with this and really try to pursue our own avenue in the regulatory interactions with Europe and the Asian major markets to really understand the potential.

I think this is really great, I like the comment, I think this is a very great opening by the FDA, because this really follows where the different organisations in the epilepsy space are working. The International League for Epilepsy has really appointed to the

broader category, and I think the FDA seems very responsive to that kind of new label.

Marc Goodman — Thank you.

Operator — Ladies and gentlemen, as a reminder, anyone who wishes to ask a question may press star and one at this time. And the next question comes from Carsten Lønborg Madsen from Danske Bank. Please go ahead.

Carsten Lønborg Madsen — Thank you very much. I just had one question. Maybe you could outline a little bit about the Phase 3 trial design and whether this single Phase 3 trial is enough to get you to this USD 1.5 to 2 billion in peak sales that you are hoping for, or whether you need to add more trials over the years? Also, maybe in order for us to understand a little bit more whether this DEE indication can be captured in just one single trial.

Johan Luthman — I can start. The peak sale part maybe someone else can comment on that, but let me comment on the Phase 3 designs here a little bit. The initiated Phase 3 programme here actually is constructed with two different trials. There is one trial that is looking at ready by itself, and then another trial that's just about to start up, that looks at Lennox–Gastaut and other DEEs, so more a bundled, basket type of trial. There will be two trials within the DEE universe that will be run. This is probably more for practical reasons, etc., and how you enrol and what kind of a balance you like to have between different types of the courses of DEE.

But the overall intent here is that this will be bundled together according to International League Against Epilepsy definition of DEE that emerged in 2017. It will fulfil what we see within the DEE space. Obviously, there are literally hundreds, if not thousands of causes of DEE, but the trial is really trying to capture the major parts of the causes for DEE from the different buckets that I talked about, acquired, syndromal or genetic. The intent is really to have a design that encompass all and de-risk to get into all those indications. If that would not be the case, there is still a very strong mechanism of action, so one can even slice the cake in different ways moving forward.

In terms of peak sales, etc., I think someone else should comment on this.

Charl van Zyl — Maria, please, go ahead.

Maria Alfaiate — It links a little bit to the previous question as well. The global market for DEEs was valued at roughly US $7 billion in 2023, and we expect it to jump to roughly 11.4 billion by 2033. This is an annual growth of 5%. This is indeed an area where we could have a significant impact. I don't know if you want to supplement, Charl.

Charl van Zyl — Just to add for clarification for Carsten, our current peak sales potential that we have addressed today is dependent on us achieving that broad label, just to be very clear on that.

Carsten Lønborg Madsen — Makes sense, thank you.

Operator — And we do have one follow up question from Charles Pitman-King from Barclays. Please go ahead.

Charles Pitman-King — Thanks very much for taking the follow up. Just to double check, in terms of this aim to get the broad label, obviously there are other assets approved in some of these DEEs. What's been preventing them from achieving this broad label? Is this something that you and Longboard have been pioneering? And just what is the view of the regulator around this trial set up? Thank you.

Johan Luthman — That's a good question, I have to say. I don't sit in the heads of other people that's been looking at this stage, but I have, in my past career, worked on rufinamide, one of the early Lennox-Gastaut drugs. I think the main reason for this is, quite frankly, that this has been an evolving field, and we get much, much better definitions of the different subtypes, but also DEE as an entity by itself. It's quite recent, as I said, that we really defined the developmental and epileptic encephalopathies, 2017. I think most programmes didn't really have that kind of classification to work with when they started up.

Would they be able to move into this space? I think when you have other indications, then it's still harder, because then you have to really start those specific populations to add them into it. Here we have a programme that adds for that new definition in a broader sense, from the beginning, so that creates a better opportunity to really get that broader label. We don't talk so much about this in the industry, but there is a lot of off-label use and various indications here. I think what the world should hopefully look forward to here is the characterised on-label and verified working drug on the DEE population according to the modern criteria. I hope that answers the question, because I think it's a really important question.

Charles Pitman-King — Thank you so much.

Operator — And the next question comes from Shan Hama from Jefferies. Please go ahead.

Shan Hama — Two for me, please. Firstly how will bexicaserin fit into the current commercial infrastructure, given the prior epilepsy franchise is off pattern? And then also, is there any scope for earlier commercial launch, so prior to 4Q 28? Thank you.

Maria Alfaiate — As we have mentioned before, this asset is fully aligned with our ambition to become a significant player in the neuro-rare space.

And, of course, you know of our own internal asset, [46:47 unclear ?]. We are considering different types of synergies with commercial footprint with regards to the way we approach these neuro-rare indications. I cannot give you too much detail at this stage.

With regards to an earlier launch, we need to monitor how the trial is going. Having breakthrough designation for these DEEs is a sign of interest from the FDA, but breakthrough designation does not mean necessarily that we will conclude the trial earlier than expected. It's just a situation that we need to look into, as with any other event driven trial. I don't know if you want to supplement, Johan.

Johan Luthman

I would love to have an early commercial launch, but you need to generate the data, and you need to get the patients into the trial. Trials, I should say, because they are separated into two trials here. I think it's really very hard to estimate that at this early stage. These populations are really, really challenging populations. Remember, they are young, young children, many of them. They are born with encephalopathies that develop into seizures or born with both, running in parallel. Basically, co-morbidities. They have cognitive and developmental problems, so for caregivers it's hard also sometimes to participate in trials. But we hope that the encouraging initial data here will trigger patients to come into the trials. But in terms of reaching the DEE population, or actually any of those populations, I think one needs to run the trial for a couple of years.

Operator

Ladies and gentlemen, this was the last question. I would now like to turn the conference back over to Charl van Zyl for any closing remarks.

Charl van Zyl

Again, thank you so much for joining the call today. A very important moment for Lundbeck in our focused innovative strategy, and very pleased to be able to announce this important transformative acquisition for us going forward. And we look forward to engaging with you more in our Capital Markets event that will be next week, 23rd October. Looking forward to further questions that you may have at that point. Thanks again for joining today.