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ATH434 vers un essai de phase 2 dans l'AMS

Geoffrey Kempler, président-directeur général d'Alterity Therapeutics Limited (ASX: ATH), fait le point sur le principal composé de sa société, ATH434 de pour l'atrophie multi-systématisée, sa double stratégie en Europe et aux États-Unis et ses perspectives d'essai de phase 2. Il répond aux questions de Rachael Jones:

Geoffrey Kempler: Notre molécule phare ATH434 est capable de gérer la toxicité d'une protéine dans le cerveau appelée α-synucléine, qui conduit aux dommages associés à la maladie de Parkinson, ainsi qu'aux maladies parkinsoniennes, telles que l'atrophie multi-systématisée.
L'AMS est une maladie neurodégénérative rare et très invalidante pour laquelle il n'existe pas de traitements modificateurs de la maladie, même s'il existe des traitements qui peuvent soulager certains des symptômes.

Notre molécule principale a terminé avec succès la première phase de développement. Nous sommes en mesure d'acheminer notre médicament sur le site que nous essayons de cibler pour la maladie, et cela comprend ***le franchissement de la barrière hémato-encéphalique***, ce qui n'est pas une mince affaire, mais c'est quelque chose pour lequel nous sommes spécialisés depuis plusieurs années. Et nous pouvons y arriver avec de bonnes concentrations. En fait, des concentrations suffisantes d'après nos études sur les animaux, quant à leur efficacité.

Nous avons pu faire appel aux autorités réglementaires en Amérique et en Europe. Ils nous ont donné ce qu'on appelle le statut de maladie orpheline, ce qui nous donne des privilèges spéciaux, notamment en matière de protection intellectuelle, pour nous permettre de poursuivre dans ce sens.

Nous avons déjà commencé une étude avec des patients atteints d'atrophie multi-systématisée à l'Université Vanderbilt en Amérique. Il s'agit d'une étude d'histoire naturelle pour vraiment nous aider à déterminer les paramètres que nous allons utiliser dans notre essai de phase 2.

Rachael Jones: Et que pouvez-vous me dire sur le financement?

Geoffrey Kempler: Nous avons récemment pu obtenir un financement supplémentaire de 35 millions de dollars, provenant de fonds spécialisés en Australie, en Amérique et en Europe. En plus de nous apporter les fonds, ce qui est un gros problème - cela nous donne un bilan solide - mais, tout aussi important, cela représente un imprimatur d'organisations qui peuvent vraiment avoir un bon aperçu de nos données et évaluer leur potentiel de réussite.

Rachael Jones: Et que pouvez-vous nous dire sur votre récente approbation de brevet américain?

Geoffrey Kempler: Ll nous donne une très longue protection par brevet autour des concepts que nous avons développés depuis des décennies maintenant. Et nous sommes vraiment des experts dans la compréhension de ces protéines dans notre cerveau qui servent également à la santé, et peuvent devenir vraiment toxiques pour nous en cas de mauvaise santé et de pathologie et souvent associées au vieillissement.

Ainsi, ce nouveau brevet nous donne en fait une large opportunité commerciale sur une longue période pour répondre à certains des besoins médicaux non satisfaits les plus difficiles. Nous avons l'équipe, et nous avons l'expertise pour relever ce type de défi.

Rachael Jones: Et à une question plus générale maintenant, de nombreuses entreprises étudient des candidats-médicaments pour le traitement des maladies neurodégénératives. Où en sommes-nous et à quoi ressemblera la prochaine décennie pour les patients ?

Geoffrey Kempler: Les maladies neurodégénératives sont vraiment un formidable défi pour les personnes qui ont le savoir-faire scientifique et les compétences de gestion pour y faire face. Donc, même s'il n'y a pas eu beaucoup de succès dans le passé, nous venons de sortir d'une période très difficile, par exemple dans la maladie d'Alzheimer pour laquelle beaucoup d'argent, beaucoup de temps, beaucoup d'entreprises se sont investis et nous n'avons toujours pas eu d'approbation depuis très longtemps.

Mais nous avons entre nos mains, tout ce que **nous venons d'apprendre sur le rôle des métaux dans le cerveau, comme le fer labile,** et notre capacité à vraiment comprendre la science, à nous impliquer dans l'arrêt de certains des événements toxiques. Nous sommes en fait très enthousiastes à l'idée que les prochaines années vont commencer à montrer de réels progrès pour ces patients.
Ils ont été - excusez le jeu de mots - des patients très patients attendant que la science et la médecine rattrapent les maladies, mais nos apprentissages ont été très profonds au cours de ces dernières décennies, et nous avons pu attirer une équipe de direction qui a obtenu trois approbations de médicaments dans le passé, et je pense que c'est le genre d'expertise qui me donne la certitude que nous devrions être optimistes quant à l'avenir.

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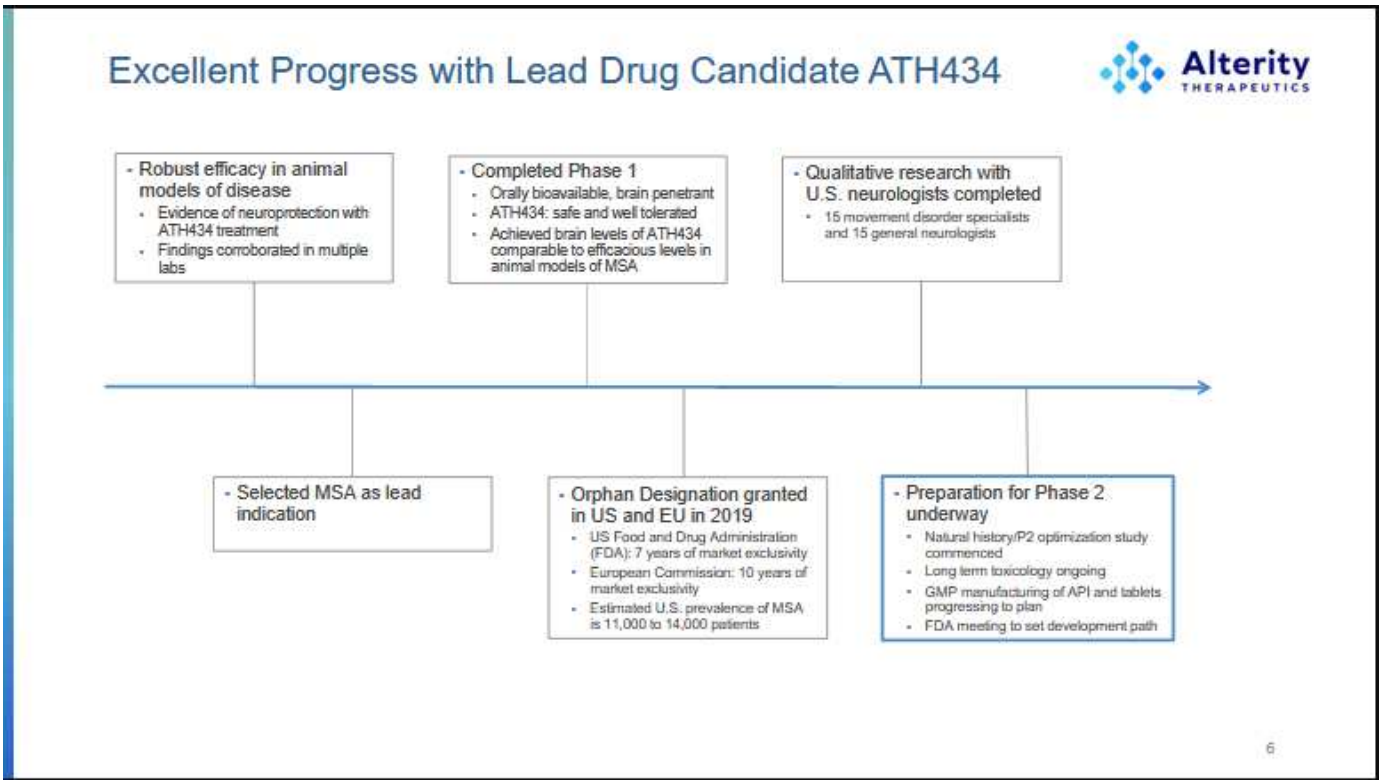
Geoffrey Kempler, président-directeur général d'Alterity Therapeutics Limited (ASX: ATH), présente un aperçu de la société. Il évoque les troubles parkinsoniens, les progrès réalisés avec le principal candidat médicament ATH434 de la société, l'étude d'histoire naturelle bioMUSE et la conception de l'essai de phase 2.

Notre principal composé ATH434, qui a terminé avec succès un essai clinique de phase 1, a déjà la désignation de médicament orphelin aux États-Unis et en Europe, et avance vers un essai de phase 2.
(...)
Au cours des dernières semaines, nous n'avons également bénéficié du soutien de nos investisseurs avertis en Australie, aux États-Unis et en Europe. Et ils nous ont soutenus avec une collecte de fonds sursouscrite, en fait, de 35 millions de dollars qui vient de s'achever. Nous avons commencé notre étude d'histoire naturelle sur l'atrophie multi-systématisée au Vanderbilt University Medical Center en Amérique, dans le Tennessee, c'est l'étude bioMUSE.

Notre principal composé, ATH434, cible une protéine du cerveau, cette protéine est appelée α-synucléine.

Nous sommes allés à la FDA à plus d'une occasion et nous avons été très encouragés par la réunion que nous avons eue avec eux cette année (...). Et nous avons eu de très fortes réactions aux données de la phase 1, qui peut-être même plus fortes que nous ne l'aurions anticipé. Et je pense que c'était pour deux raisons.

Premièrement, nous démontrerons que nous pourrions faire passer nos médicaments à travers la barrière hémato-encéphalique. C'est donc une spécialité de faire franchir cette barrière aux médicaments. Et nous sommes également en mesure de démontrer que nous pourrions atteindre la cible à des concentrations sur lesquelles nous sommes optimistes. D'autres agences en plus de la FDA nous ont parlé, y compris les autorités réglementaires qui délivrent le statut de médicament orphelin. Nous avons fait coup double. Une fois avec la Commission européenne, ainsi qu'avec les États-Unis. Les États-Unis ne sont pas sur cette diapositive parce que nous l'avons annoncé l'année dernière. Et nous avons donc été très heureux de toutes ces réalisations cette année, malgré le COVID.



Donc, comme je l'ai mentionné, nous avons affaire à des troubles parkinsoniens.
Nous avons parlé à des spécialistes des troubles du mouvement, y compris des spécialistes de l'AMS. Comme je l'ai dit, **nous aurions pu opter pour une variété de pathologies, mais nous avons choisi l'atrophie multi-systématisée comme celle que nous pensons être la meilleure pour être approuvée. J'ai mentionné que nous avons fait approuver la désignation de médicament orphelin** et que nous sommes en bonne voie pour commencer notre essai de phase 2 l'année prochaine. Et je vais vous expliquer certaines des étapes que nous avons franchies pour y parvenir.

bioMUSE Natural History Study

Alterity THERAPEUTICS

- Design: Observational (no treatment)
- Objective: De-risk Phase 2 study
  - Identify biomarker(s) suitable for endpoint in treatment study
  - Evaluate the change in biomarkers and clinical manifestations in patients with early MSA to track disease progression
- Population: Early MSA patients similar to Phase 2 population
- Observation period: 12 months
- Initial cohort: 10
- Biomarkers
  - MRI: Iron content, neuromelanin, oxidative stress, regional blood flow/metabolism
  - Protein: neurofilament light protein (CSF, plasma), Aggregating α-synuclein (CSF), phos-α-synuclein (skin)
  - Wearable movement sensors
- Clinical Endpoints
  - Clinical: Motor exam, function/ADL inventory, global assessments of severity and change (clinician, patient)
  - Functional: Timed Up and Go, 2 min Walk Test

Voici le process qui a déjà commencé. C'est au Vanderbilt University Medical Center dans le Tennessee, en Amérique. Son objectif est d'examiner un groupe de patients atteints d'atrophie multi-systématisée À ce stade, ils ne reçoivent pas le médicament, nous les observons simplement. Et vous pouvez voir à partir du deuxième point que nous identifierons les biomarqueurs que nous rechercherons dans un essai de phase 2 en double aveugle.

Et vous remarquerez sous les biomarqueurs une référence à la teneur en fer. C'est du fer dans le cerveau. Le fer est un métal. Vous êtes né avec. Une fois que cette barrière hémato-encéphalique protectrice se ferme après quelques mois lorsque vous êtes un enfant, un bébé, en fait, c'est votre complément de fer pendant un certain temps. Et c'est lorsque le fer commence à se comporter mal plus tard dans la vie que vous pouvez obtenir ces protéines qui sont généralement bonnes avant de devenir toxiques. C'est donc l'une des choses que nous allons mesurer, ainsi que ces critères cliniques.

Phase 2 Study Design

Alterity THERAPEUTICS

- Design: Randomized, double-blind, placebo controlled
- Objectives
  - Assess target engagement and preliminary efficacy of ATH434
  - Evaluate safety and tolerability of ATH434
- Population: Early MSA patients (parkinsonian variant) with motor symptoms ≤ 3 years
- Sample size: 60
- Treatment: 6 months duration
  - ATH434 high dose
  - ATH434 low dose
  - Placebo
- Biomarkers
  - MRI: Iron content, neuromelanin, oxidative stress, regional blood flow/metabolism
  - Protein: neurofilament light protein (CSF, plasma), Aggregating α-synuclein (CSF), phos-α-synuclein (skin)
  - Wearable movement sensors
- Clinical Endpoints
  - Clinical: Motor exam, function/ADL inventory, global assessments of severity and change (clinician, patient)
  - Functional: Timed Up and Go, 2 min Walk Test
- Safety Endpoints: AEs, clinical laboratory parameters, 12-lead ECGs

L'essai de phase 2 qui suivra l'étude naturelle que je viens de mentionner sera un essai randomisé, en double aveugle, contrôlé par placebo. Son objectif principal est de voir si le médicament fonctionne. Et nous allons maximiser nos chances de succès en nous assurant de choisir les meilleurs paramètres pour tester cela. Actuellement, nous prévoyons 60 patients pendant six mois. Ce sera en Europe et en Amérique. Vous pouvez voir que nous allons avoir deux doses ainsi qu'un placebo.

Après des recherches de très haut niveau sur le marché avec de vrais prescripteurs, des médecins qui rédigeront des scripts, vous pouvez voir les ventes projetées jusqu'à 725 millions de dollars. Je soulignerai que c'est en dollars américains, et ce n'est qu'en Amérique, et ce n'est que pour l'atrophie multi-systématisée. Il est clair que nous le commercialiserons dans le monde entier, et selon la façon dont le

médicament fonctionne, s'il traite l'atrophie multi-systématisée et qu'il est approuvé pour cela, il est très probable que les médecins envisageront son utilité dans d'autres troubles parkinsoniens, y compris la maladie de Parkinson elle-même. Nous sommes donc très à l'aise de présenter cela comme une estimation très prudente des ventes de notre médicament uniquement aux États-Unis et uniquement pour cette indication.

Alterity Therapeutics Limited (ASX:ATH) Chairman and CEO Geoffrey Kempler provides an update on the company's lead compound ATH434 for Multiple System Atrophy, its dual strategy in Europe and the US and its Phase 2 plans.

Rachael Jones: Hello. I'm Rachael Jones for the Finance News Network. Joining me from Alterity Therapeutics (ASX:ATH) is CEO and Chairman Geoffrey Kempler. Geoffrey, welcome back to FNN.

Geoffrey Kempler: Thank you very much. I'm happy to be here and good morning.

Rachael Jones: Good to see you. Now Alterity Therapeutics is tackling neurodegenerative disease with a focus on Multiple System Atrophy. Can you tell us more about this?

Geoffrey Kempler: Our lead molecule ATH434 is able to deal with the toxicity of a protein in the brain called α-synuclein, that leads to the damage associated with Parkinson's disease, as well as the Parkinsonian diseases, such as Multiple System Atrophy.

And so Multiple System Atrophy is a rare and highly debilitating neurodegenerative disease, and there are no disease-modifying treatments for this unfortunate disease, and there is no cure, although there are some treatments that can help with some of the symptoms.

Our lead molecule has completed phase one. It's been very successful. It's been presented at various conferences. We're very pleased with that. We're able to get our drug to the site that we're trying to target for the disease, and that includes getting across the blood-brain barrier, which is no mean feat, but it's something that we're specialised in doing for many years. And we're able to get there in good concentrations. In fact, concentrations that are sufficient based on our animal studies, for efficacy.

So if we can see that happening with patients, human patients, then that's going to be very, very exciting. And, as part of that enthusiasm, we've been able to enlist the regulatory authorities in both America and in Europe. They've given us what's called orphan disease status, and that gives us some special privileges, particularly around intellectual protection to allow us to pursue this.

So we're very pleased about all of that. And we've already also started a study with Multiple System Atrophy patients at Vanderbilt University in America, and that's a natural history study to really help us work out the end points that we're going to be using in our Phase Two. We're doing them in conjunction

with the meetings that we're having at the FDA.

Rachael Jones: And what can you tell me about funding?

Geoffrey Kempler: Of course, it's really exciting that recently we were able to secure an additional $35 million worth of funding, and it came from specialist funds in Australia, in America and in Europe. Apart from bringing the funds to us, which is a big deal -- it gives us a strong balance sheet – but, as importantly, it represents an imprimatur of organisations that can really get into having a good look at our data and assessing its potential for success.

Rachael Jones: And what can you tell us about your recent US patent approval?

Geoffrey Kempler: That was very interesting, because we've been working on that, and sometimes that's the silent achievement, as I call it. And what it does is it gives us very long patent protection around the concepts that we've developed over decades now. And we really are experts in understanding these proteins in our brain that serve as well in health, and can become really toxic to us in ill health and pathology and often associated with aging.

So, this new patent actually gives us a wide opportunity for tremendous commercial opportunity over a long period of time to tackle some of the most difficult unmet medical needs. And we have the team, and we have the expertise to gleefully take on that type of challenge.

Rachael Jones: And to a more general question now, many companies are investigating drug candidates for the treatment of neurodegenerative diseases. How far have we come, and what does the next decade look like for patients?

Geoffrey Kempler: Neurodegenerative diseases are really a wonderful challenge for people who have got the scientific know-how and the management skills to address them. So, even though there hasn't been a lot of success in the past, and for those who follow the space, we've just come off a very challenging period, for example, in Alzheimer's disease, where a lot of money, a lot of time, a lot of companies get a lot of focus to the issue around that disease, and we still haven't had approvals for a very long time.

But, in our hands, because we've just learned so much about the role of metals in the brain, such as labile iron, and our ability to really understand the science, to get involved with stopping some of the toxic events of that, we're actually very enthusiastic that the next few years are going to start to show some real progress for these patients. They've been -- excuse the pun -- very patient patients waiting for science and medicine to catch up with diseases, but our learnings are very deep over these past decades, and we've been able to attract a management team that's really had three drug approvals in the past, and I think that's the sort of expertise that gives me the confidence that we should be optimistic about the future.

Rachael Jones: Geoffrey Kempler, thanks for the update.

Geoffrey Kempler: And thank you very much.

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Alterity Therapeutics Limited (ASX:ATH) Chairman and CEO Geoffrey Kempler presents an overview of the company, discussing Parkinsonian disorders, progress with the company's lead drug candidate ATH434, the bioMUSE natural history study, and Phase 2 trial design.

Good afternoon to everybody, my name is Geoffrey Kempler, I'm the CEO and chairman and founder of Alterity Therapeutics. We're listed on both the Australian stock Exchange, as well as on the NASDAQ. And as just mentioned, we're developing treatments for neurodegenerative diseases. Our lead compound, that I'll talk about, ATH434, has successfully completed a Phase 1 clinical trial, already has orphan drug designation in both the US and in Europe, and is advancing toward a Phase 2 trial. I've worked in the biopharmaceutical industry for several decades now, and I've been involved with several different companies, but I've never been more encouraged or confident about Alterity than I am today, which is why I'm very happy to have the opportunity to tell you our story.

So next slide, please.

We'll move past the safe harbour program, which you'll be used to. Our purpose had been mentioned, but we really are there to try to create alternative futures for people living with these diseases that we target. These diseases have a tremendous debilitating impact on people's lives. You'll probably be familiar with the big ones like Alzheimer's and Parkinson's disease. I'll be talking about a special type of Parkinsonian disease today, but these are shocking outcomes for patients. We really want to have to disrupt that, and we have every reason to be confident that we can.

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So it's been a terrific year for us, and as terrible as COVID has been, it's actually given us an opportunity to really focus on what we planned for this year anyway, which was largely a planning period. So the impact of the disease overall, of COVID overall, has not been too big. It hasn't been nil of course. But we've had some good news recently, the US patent office gave us approval for a big new portfolio of molecules. It's a really big deal. It's why the marked responded so quickly to it and so strongly to it. And it's because basically it gives us the opportunity to really blow open our commercial opportunities across multiple disease targets over time. These patents give you several decades of protection, so they're very valuable.

We've also had the benefit in the last few weeks only of the support of our sophisticated investors in Australia and in the US and in Europe. And they've supported us with an oversubscribed fundraising, in fact, of $35 million that just recently closed. We've started our multiple system atrophy natural history study at the Vanderbilt University Medical Center in America, in Tennessee, it's called the bioMUSE study, I'll comment on that in this presentation. Our lead compound 434, ATH434 targets a protein in the brain, that protein is called α-synuclein. This is not a science presentation, but suffices to say that there are proteins in the brain that serve us very well when we're young and when we're healthy, and like many things, things start to go wrong either with disease or you can get age related diseases, and that includes neurodegenerative diseases. So what happens is that these proteins can start to, rather than be our best friends, can start to misbehave and become toxic to our bodies instead of useful to our bodies. I'll explain a bit about how that happens.

We've been to the FDA on more than one occasion and we've been very encouraged by this year's meeting that we had with them during COVID. It was meant to be a face-to-face meeting, but it became

just Zoom face to face, but we're able to go through our development pathway to get their support for what we're trying to do, and that was very important for us as well. We've also had a chance to represent our Phase 1 data at some conferences, which has been very useful. And we had some very strong reactions to Phase 1 data, which perhaps even stronger than we would have anticipated. And I think it was for two reasons. One is that we will demonstrate that we could get our drugs across the blood brain barrier.

That is not a tiny achievement. The brain is a very privileged and protected part of our bodies. We have a big skull on top to protect it from falling rocks, but we also have membranes inside to protect it from any of the wrong chemicals getting into it. So it's a specialty to get drugs across that barrier. And we're also able to demonstrate that we could get it to the target in concentrations that we're optimistic about. Other agencies besides the FDA have spoken to us, including the regulatory authorities that issue orphaned disease status. We've had two shots at this, we've been successful both times. Once with the European commission, as well as with the US. US is not on this slide because we announced that last year. And so we've been very pleased about all of those achievements this year, despite COVID.

So next slide please.

So as I mentioned, we're dealing with Parkinsonian disorders. The word Parkinsonian of course puts us into the camp of Parkinson's diseases, which I'm sure our listeners would mainly associate with movement disorders. And there are some specialty subsets of this. If I was to explain it in non-scientific terms, that would be a problem with this protein, but it's not just limited to one small part of the brain, but you can get it in multiple parts of the brain, hence multiple system atrophy, because it can affect different parts of the brain all negatively, all with shocking impacts on the patients. And so our goal is to be able to really address these major disabilities.

Next slide please.

So this slide may look a little bit busy, so I apologise for that. But drug development desk doesn't happen in one hit. It is actually a process and we've made excellent process this year and last year. In fact, since I last presented to this forum. I think very excitingly, we've got some very strong, robust efficacy in animals. As you'd know that in science, you begin in the lab, you go to animal models, and then eventually you go to humans. But there's animal models and there's animal models. And these are good models. We've done it in more than one type of animal model. And we've got a lot of confidence that we should be optimistic, that this will translate into humans.

And I think particularly when we look at that second box that we've completed Phase 1, which as we all know is really about safety, but we're able to escalate that so beyond safety, we could actually see that we crossed the blood brain barrier and that we got to the two concentrations that gave us some enthusiasm. And these are the sorts of things that drug developers look for along the way so they know that they've got increasing confidence of success.

We've also taken our drug out to speak to experts in the field so they can understand the mechanism of action. We've spoken to movement disorders specialists, including specialists in MSA, multiple system atrophy, as well as speaking with general neurologists. I'll speak about it a bit more later, but it gives us confidence in the usage of the drug and the breadth of usage of the drug as well, which will give us confidence behind the numbers that we're projecting as revenue. As I said, we've got a variety of things we could have gone for, but we've selected multiple system atrophy as the one that we think we're at the best shot of getting approved. I've mentioned that we've had the orphan designation approved and we're well underway to get our Phase 2 trial started next year. And I'll explain some of the steps that

we've done to get there.

Next slide please.

So this is, in fact, the trial that's already started. It's at the Vanderbilt University Medical Center in Tennessee, in America. Its objective is to actually look at a group of multiple system atrophy patients. At this stage they're not getting the drug, we're just observing them. And you can see from the second bullet point that we'll be identifying biomarkers that will become the main thing that we'll be looking for in a treatment Phase 2 trial, which will be a full cover blind study. The FDA is interested in the way we're approaching this, which is why we've had meetings with them so that we can really study a bit of the natural history of this to pick the end points that we think will give us the greatest chance of getting an approval.

And you'll notice under biomarkers, I'm not going to go through all of this clearly, but you'll notice under biomarkers, it refers to iron content. This is iron in the brain. Iron is a metal. You're born with it. Once that protective blood-brain barrier closes after a few months when you're a child, a baby, in fact, that's your compliment of iron for awhile. And it's when iron starts to misbehave later in life that you can get these proteins that are the good guys, usually, becoming toxic. So that's one of the things that we'll be measuring as well as these clinical end points as well. As I said, this is not a deep scientific presentation, but we're here for any further follow up questions for any scientists on the phone or anyone who wants more detail.

Next slide please.

So this is the Phase 2 trial that will come on the heels of the natural study that I just mentioned. It is a randomised, double blind placebo controlled trial. It's really a trial, once again, to build on the efficacy, but primarily its objective is to see if the drug works. And we're going to maximise our chance to success by making sure we picked the best end points to actually test that. Currently we're planning for 60 patients for six months. It'll be in Europe and America. You can see that we're going to have two doses as well as placebo. And once again, all the end points that we'll be picking from to go into that trial.

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So I was insinuating this, but now I'm very pleased to say that after some very high level research in the market with actual prescribers, doctors who will be writing scripts, you can see the projected sales there of up to $725 million. I'll emphasise this is in US dollars, and it's only in America, and it's only for multiple system atrophy. Clearly we will be marketing it globally, and because of the way that the drug works, if it treats multiple system atrophy and gets approved for that, it's highly likely based on the feedback from the physicians that they're going to have a look at its usefulness in other Parkinsonian disorders, including Parkinson's disease itself. So we're very comfortable putting this up as a highly conservative estimate of peak sales for our drug just in the US and just for this indication.

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So this is a slide that I'm the proudest of in the sense that it took a long time to achieve, to really get a crack team together. And the beauty about introducing my Chief Medical Officer, David Stamler, is I'm introducing a man who's actually had three FDA approvals for brain diseases. The last was in Huntington disease. That company where he was doing this was Auspex, it was sold for US$3.5 billion as you can see there. We didn't just succeed in bringing David to our company, he actually brought the

key players along with him. So we have a team that has done this before several times. It's not an easy area, neuroscience, but it's very doable in the right hands. So I'm very pleased with being able to share this information with you.

Next slide, please.

So in fact, my last slide, just to recap the things that I've said, that it's an unmet medical need for a major category of diseases, even though the first one that we picked is multiple system atrophy. We've received the imprimatur of orphan disease status both from Europe and America, and we have peak sales have explained that they are more than enough to justify an investment, but certainly quite conservative in the way we've presented that. A very successful development team that's being welcomed into discussion with the FDA, which is important. The drug is advancing well. It's in the trial at moment in the natural history study at Vanderbilt in America. It's had its Phase 1. I've mentioned the animal model there.

That novel mechanism, we can speak for an hour adapt that term novel mechanism targeting, that would be the science talk. But I think what matters when you heard things like oxidative stress talked about in the world, we're actually doing things in a very unique way. We're really addressing the root cause of these diseases. We've built up a very large level of expertise over many years through our contacts at Harvard University, where one of our founding labs was, and at the University of Melbourne. And now Vanderbilt University is another group that are helping us along the way as well. We'll be able to report data about the efficacy of the drug, fingers crossed for that, in the second half of 2022.

Because of these new patents that have just been approved, we have a strong pipeline of potential to really blow open commercial opportunities over the longer term. And because of the fund raising that we've just completed, I'm very excited to be able to say that we've got a strong balance sheet, which is important for any CEO to be able to say. Unfortunately because of the virtual nature of this presentation I can't take Q and A now, but my contact details will be available and I'm very, very happy to... in fact, I hope you can ask me lots of questions and we look forward to answering them. Clive, thank you to you and thank you to all your listeners.