Pharming Group N.V. 23rd Annual Needham Virtual Healthcare Conference - Presentation

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PARTICIPANTS

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Serge Belanger - Analyst, Needham & Company

Serge Belanger - Analyst, Needham & Company:

Hi, good morning. Welcome to Needham's 23rd Annual Healthcare Conference. I'm Serge Belanger, one of the healthcare analysts at Needham. For our next session here, we're happy to have the Pharming Group. We have the company's President and CEO, Sijmen de Vries with us, who is going to tell us about Pharming.

So, I'll hand it over to Sijmen for his presentation.

Sijmen de Vries, MD – Chief Executive Officer:

Thank you very much, Serge. Ladies and gentlemen, good morning or good afternoon. I'm happy to take you through the Pharming story, but before I do that, I would like to point you to the next slide where you see, of course, that this presentation will contain some forward-looking statements which are based upon our certain beliefs and plans, of course, which may significantly differ, obviously.

So, having said that, I'd like to take you to the next one. So, what are we doing in Pharming? We're building a leading global rare disease company. And this is the three pillars where we build ourselves on. So we first, on the left-hand side, of course, have our product that is in the market in the U.S. and rest of the world as well, approved for the acute – treatment of acute hereditary angioedema attacks. This is really however, a U.S. focused market. And you see there that we are generating very nice, positive cash flows from which we can actually finance all our current plans that we have in our hands.

And you saw that we had some very good results in 2023. RUCONEST®, by the way, was approved in 2014 and launched late 2014. It's been in the market for a while and you still see that the product continues to grow. So, we have a very special place in the treatment of hereditary angioedema attacks. Despite the fact, of course, many treatment possibilities have arisen over the years. Then, in the middle, you see the successful launch of Joenja®, leniolisib reported to be in-licensed from Novartis in 2019, to treat a rare disease called APDS, activated phosphoinositide 3-delta kinase syndrome, a very rare immunology disorder. And I'll come back to that later of course.

It was launched in April, right after the FDA approval. We got the products immediately in the hands of the patients and got immediate reimbursement and had already secured more than $18 million of revenue in 2023. And it's currently under a lot of regulatory reviews, as you can see here. I'll come to that later.

And we have a pediatric trial and Japan clinical trial as well, ongoing. And as it is a rare, ultra-rare disease, we have a very strong focus on patient finding. I will talk about all these topics later on during the conversation. And on the right-hand side, you see then the ongoing pipeline development. First and foremost, we have a second indication for leniolisib for PIDs with immune dysregulation defined, from which we have obtained FDA guidance on the clinical development program. And we're about to start Phase 2 in that indication.

And then last but not least, we are very active because we have this commercial infrastructure in the U.S., in Europe, and building it up outside of Europe as well, to actually in-license or acquire clinical stage opportunities in, for instance, hematology, immunology, respiratology and gastroenterology. We're very active in hunting rare assets.

You see our total revenue guidance for 2024 is between US$280 million and US$295 million. We will continue to grow the company going forward on the basis of RUCONEST® and Joenja®. Next slide, please.

And as you see here, the current pipeline depicted as RUCONEST® and Joenja®, obviously in the market, and they only said under regulatory review, the pediatric trials. And the label for Joenja® is 12 years and up so part of the pediatrics already incorporated. And then of course, the second indication for leniolisib is also depicted here, the PIDs with immune dysregulation. And last, not least, we have an early-stage program, gene therapy for hereditary angioedema, which is in preclinical development, together with Orchard Therapeutics. Next slide, please.

Let's just talk a little bit about RUCONEST®. And here, you see the complex mechanism of hereditary angioedema. But the bottom line is very simple. Patients with hereditary angioedema lack working or lack the production of a proper functioning C1 inhibitor. C1 inhibitor works on all those three pathways that you see here. However, there's also possibilities in dealing with the most symptomatic pathway that is in the middle, the kallikrein-independent pathway.

And a number of competing products have arisen over the years. But they all suffer from the same problem, is that although they have improved the therapy significantly and have improved especially convenience, because these kinds of products could actually be delivered both subcutaneous or orally, whereas RUCONEST® is a slow IV injection that actually patients do at home. So once they're trained is not that difficult at all.

But these are of course more convenient, these therapies, but they all lack from the same problem, that is breakthrough attacks, whereas RUCONEST® is blocking, as you can see, the C1 inhibitor that is everywhere in all the pathways and does not suffer from that. You see this on the next slide, you see that RUCONEST® actually does not suffer from these breakthrough attacks.

But you can see, you can't get any closer than 100% efficacy, as you can see on this slide with RUCONEST®. That is why RUCONEST® actually has a very special place in the market. First of all, we serve that patient population that suffers from hereditary angioedema in a very frequent way, so they have very frequent attacks and they cannot get by on these other products, and therefore they rely on RUCONEST®. And they have been relying on RUCONEST® for many years. And increasingly, because that other mechanism of action requires breakthrough medication, we see

the use of RUCONEST® as breakthrough medication for prophylactic therapies, for instance, that are on the market either in form of subcutaneous or in the form of orals, where breakthrough medication is a necessity and where the different mode of action for RUCONEST® provides the patients with a very reliable product to actually, have as a backup as and when they have a breakthrough attack.

And that explains why RUCONEST® has it found its own place in the market, why RUCONEST® still continues to grow after all these years, and while RUCONEST® takes a very special place also, where none of the other bradykinin and kallikrein inhibitors can't come because of the very high frequency of attacks that these patients have. Like I said before, RUCONEST® is not a convenient product like orals, but RUCONEST® has efficacy, and patients are trained and supported all the time by us to continue to be able to self-inject themselves in the privacy of their own home, as and when they get or they feel an attack coming up.

And then you see on the next slide that after all these years in the market, RUCONEST® has this special place. And more and more physicians continue to discover the uniqueness of RUCONEST®, and more and more patients continue to use RUCONEST®. So, we are optimistic going forward that continuing to serve this very special patient population and continue to be that unique product, that actually is a breakthrough medication with a different mode of action.

That RUCONEST® will continue to support our business for the foreseeable future going forward, despite the fact that regulatory exclusivity runs out in 2026, which is not very meaningful, because RUCONEST® is a very complex product and can only be produced with the use of transgenic animals, which is basically our production platform. And to actually start building a production platform for a product that's relatively small will take forever. And therefore, we see absolutely no competition on the horizon with regards to the C1 inhibitor that RUCONEST® represents.

So, this is all about RUCONEST®. Let's now switch to the next part of the presentation, APDS and Joenja®, which is the engine that will continue to grow the company significantly going forward. And we just started entering that market. This is an ultra-rare disease. This is actually discovered only 10 years ago, and according to the literature, it should be about 1.5 patients per million of population. So, you see on the right-hand side, the small print there in the bottom. If you take the markets where we are planning to commercialize, there should be about 2,000 patients that we could discover to treat for this disease.

And we have identified already more than 840 of those patients in those markets where we are planning to commercialize. And it is a difficult disease in a way because it has varying symptomatology. But once discovered it is actually a downhill path for the patient that suffers from it. It's a very simple genetic defect. It actually is a hyperactive PI3Kδ pathway. And the good news is also standard immunology panels have this genetic mutation in it, so it is a commercially available genetic test where you can get 100% the diagnosis confirmed.

And I should note that where we talk about patients that we have discovered, we're talking about patients that have been confirmed with such a genetic test and are really therefore potentially eligible for Joenja® treatment once, the product is approved in both geography and for their age group. And currently we have of course, a label that is 12 years and older.

Now APDS, let's look at the next slide. APDS is a disease where the immune system doesn't function. And you can see here, if you look at all the facets of life that basically these young patients, especially young, it's a very young patient population, cannot live a normal life because of their failing immune system. And if we translate it into more symptomatology, on the next slide, you see that it starts all with severe and recurrent infections, lymphoproliferation. If these young adults or young children actually are lucky, they have huge lymph nodes in their neck. So something can be seen from the outside that something is wrong there.

But swollen livers, swollen spleens, you can't see that until you start investigating a continued enteropathy, because you have big lymph nodules blocking your gastric tract can also not be very easily identified. However, it is a continuing slow downhill for these patients. And leading to autoimmunity, bronchiectasis at a young age and then last but not least, very high mortality associated with the lymphoma that these patients will fall into in the end.

And it's all about the fact that PI3 kinase is hyperactive because of this genetic mutation and actually makes that the immune system is running into overdrive, continuing to produce excess immune cells, but the excess immune cells are not functional and therefore you get all this lymphadenopathy and all the other heaps of non-functioning immune cells, whereas the immune system doesn't function.

So how does Joenja® leniolisib work in this respect? Well, it is pretty straightforward. You see that on the next two slides. It is really an immune modulator that targets the root cause of APDS. That is, Joenja® normalizes the PI3Kδ delta pathway to a normal level. And therefore, there is a balance again in the immune system and the immune system parameters start returning to normal quite quickly and therefore the symptoms start dissipating quite quickly as well. So Joenja® is really a disease modifying therapy for APDS and the first and only one that's actually on the market as we speak or in development as we speak.

How did we get to the product? It is also a unique product because it was the first PI3Kδ inhibitor that was approved on the randomized placebo-controlled trial. And it met both of the endpoints, but it also demonstrated significant improvement in the secondary parameters of the study and very important because PI3Kδ inhibitors do not necessarily have a very good reputation safety wise. We also found that there were no different side effects than placebo in this trial, and that's of course an important element. And we're talking about long-term treatment for an especially young population that otherwise will fall into the downward spiral of APDS.

Even better, we have very long follow-up data already available, up to seven- or eight-years treatment of individual patients. And we see that during the long-term follow up, almost I would say all patients stayed on therapy. So, we have already patients for up to seven to eight years on therapy. The symptoms continue to improve over time when Joenja® is used. And the other thing is, the treatment continues to be as well tolerated as in the beginning. So in other words, we have here an efficacious disease modifying therapy for this genetic defect. And we have also a treatment that also has a very good tolerability profile over time with a lot of follow-on data.

So how did we do, bringing it to the market? On the next slide, you see the execution. We had the product in the market, as I said, almost immediately after FDA approval, within days. We had reimbursement within two or three weeks. And we already have, as you can see, by the end of 2023, we had 92 patients enrolled in the U.S., 81 on paid therapy. And this is out of – at that point in time – just over 200 patients that were positively identified by genetic testing in the U.S., of which about 75% are directly eligible because the other ones are below 12. So out of the 150 patients that are immediately eligible, we already have identified 92.

We do a lot of work, finding these patients and we of course do a lot of work in making sure that they get access to the therapy in the U.S. And it generated, as you can see, already more than $18 million of revenue in the first year. And there's several ways how we actually find those new patients, because that is always the challenge with ultra-rare diseases, and I'll come to that a little bit later.

But it has an important aspect of, for instance, genetic family testing and the so-called variants of uncertain significance, which we find when we have testing results. And I can tell you already, far more patients have a VUS outcome of a test than that we find APDS patients. And you see that reflected here in these numbers. We have already identified, by the end of 2023, more than 1,100 patients with VUS outcomes, compared to well over 200 patients that we have now that are confirmed for APDS. In other words, we have to do a lot of work going forward to clarify these VUS' and to validate these VUS'. And I'll come back to that in a second, how we go about that.

So let's just first look, before we go there, about the regulatory status beyond the FDA, and you see that on the next slide. We are waiting, we are in the final stages of the process with the European authority. We're waiting for their opinion on the dossier. In Japan, we have completed a small clinical trial and we are discussing now with PMDA. And we expect to start, probably submitting the dossier to the PMDA either late this year or beginning of next year.

We submitted to the UK on the March 12, 2024. And the UK now has several recognition procedures. This one was based on the FDA approval that we have. It is, we believe, about 100 days review cycle in the UK. So we can expect some regulatory action later on in the UK as well. Then we have regulatory reviews going on in Canada, Australia, Israel, where we expect regulatory action later on during the year.

And then, as I was already alluding to, we have 75% of the patients that are immediately eligible for therapy, but 25% are below 12, so they have to wait for the pediatric study outcomes. The majority of those pediatric patients will fall under the bracket four to 11 years old. That enrollment is just this morning confirmed, completed. So we expect to see some results and be able to submit that probably somewhere within, I would say three to four quarters from now to the FDA and EMA. And then we have a pediatric study for one to six years old, which is the small minority of these patients that is actually enrolling as planned. I think the pediatric study from four to 11 is about 75% or 80% of the pediatric patients.

And then last but not least, we have expanded access and named patient programs. We have about probably close to 100 patients at this point in time that are either getting the drug through an expanded access or named patient programs, in some cases paid named patient programs. And you

will see in the first quarter results some modest revenues coming from those paid named patient programs that are outside of the U.S.

And then last but not least, we are working on and in the final stage of preparation to start a Phase II trial for the secondary indication PIDs with immune dysregulation. Come back to a little bit later.

Let's just look at the now at the patient finding strategy. And there's three pillars basically speaking there. There's medical awareness, of course, education. It's a disease that was only discovered 10 years ago. And now, of course, we already have disease modifying therapy, so we're very active in actually, you know, giving a lot of medical education there, both in the markets and at congresses. Of course, we have a sponsored genetic testing program, navigateAPDS, where we give also genetic counseling. And we're working with these genetic testing companies and doing our own program, but also buying results from other databases that we have available.

And then we have, on the right-hand side, family testing. And family testing is in the U.S. because we're talking about the U.S. market here, where healthcare is pretty decentralized that we have here a lot of work to do and we did not find it easy to go through the treating physician. But we have now our genetic counselors are reaching out to the patients that we currently have on therapy. And because it's an autosomal dominant mutation, from those patients that we currently already have, there will be family members available that have suffered from the same disease and not aware of it yet and may become available for Joenja® treatment in the near future.

As of today, I think we only have in one or two cases more than one family member identified. So, there's a lot of work and a lot of growth potential for that. And I say that in the U.S., because it's a decentralized healthcare, we only have just over 200 patients. But we already know that the patients do exist in, for instance, in countries where healthcare is much more centralized. And I name a few of those, Australia, France, UK, Denmark, Netherlands, Switzerland. Those are a few of those markets where a lot more of these patients already have been identified. And in fact, they're well beyond one per million already identified in those markets which coincide with about 500 patients in the U.S. So the patients are there, there's a lot of work to do now to find them, but there will be coming patients available all the time because of all the activities that we do.

Next slide, and that's a very important one with regards to patient finding, that is the VUS. Remember, we have about 1,100 VUS patients at this point in time that we have identified. Now, the, these will not, of course, turn all into APDS patients, but we are having a few initiatives here going on the left-hand side, the variant curation. We found a few of those patients via the variant curation methods. We're doing functional testing as we speak. So we have set up two labs at this point in time, and we're actually getting small batches of patients processed through that. It has to go all individuals. So patients, we need to find blood samples from those patients and send them to that lab, test and retest and confirm it. And once we have that, then that specific submutation will be then added to the database, the public database, ClinVar.

And in the future, not only these patients will be helped and will be automatically classified as APDS patient, but also the future patients that come with that specific submutation will be classified as APDS. So in other words, APDS is a new disease. The description is very narrow at this point in time, and the description, will be broadening by actually validating those VUSs.

Now, this is of course, a numbers game where we are processing individual patients, but we have also now got a combinatorial, and this is actually done in other genes as well, and it's called multiplexed assays of variant effect, or MAVE. And that experiment is about to run and we expect at the end of the year to have results from that. And that will actually clarify all of the U.S. in one go. So, in other words, what you will see this year is we have patients that are currently eligible for Joenja® in U.S. We will find small batches of individual patients from their functional testing and variant curation.

And at the end of 2024, the MAVE experiment will come to conclusion about all of the VUSs. And that will be a significant source for growth in 2025 in the U.S. market. Because, as I said, we have 1,100 of those patients available at this point in time and counting. And we are seeing that a certain percentage of those patients will be confirmed as having APDS. So watch this space in this respect. We will keep the market updated, of course, on progress of the initial batches of functional testing during the year, which will be, as I said, relatively small numbers. And of course, the big MAVE experiment will come towards the end of the year.

But the good news is there's a continuous source for new patient growth in the U.S. market, which is very decentralized. And once we get approvals in other markets, of course, where healthcare is much more centralized and much more patients are available, that the patient finding efforts will be a lot easier than in the U.S. And of course, the work that is done on the VUSs will be in the international databases and therefore will benefit patients all over the world that suffer from those submutations that have that are currently classified as VUS. That's all about APDS at this point in time.

I would like to now quickly switch to the PIDs with immune dysregulation. There are a broad group of disorders and they are already known to stimulate, to overstimulate the PI3 kinase pathway. So whereas APDS is not specifically known and described as mutations, but we're working on describing that definition of the disease. Here we have a disease that is much more prescribed and that have actually is based upon certain defined mutations that are well known. And you see the next slide here, you see the familiar picture coming up because it's exactly the same symptomatology.

We're talking here about disturbances in the immune system, again, because of the hyperactive PI3 kinase delta pathway and the immune dysregulation that is happening there. And you see exactly the same symptomatology as in APDS, exactly the same downhill. And the point is that there is nothing available, again, basically only some symptomatic treatments that are not approved are available here to manage the downhill spiral of these patients. And we're talking about, for instance, the ALPS-FAS, the CTLA4 and the PTEN mutations. And we expect that there's about more than three times as many of these patients. That's about five per million available and suffering from these mutations that can benefit in the future from Joenja®.

So we're very excited about being able to start a second indication, Phase 2 clinical trial in the near future. You see that on the next slide. What I just said about the different mutations that are well known at this point in time, and have a prevalence of about more than three times APDS. So, you can see that this product has very significant commercial potential going forward, not only based

on APDS, but also, in addition to that, very, very significant potential on the basis of PIDs with immune dysregulation. And as I said on the next slide, we are in the final stages of starting 12 patients open label Phase II at the NIH. And the NIH was the center that initiated the APDS trials for the leniolisib as well.

So we're very happy to continue to work with NIH at this point in time. You see here what we're doing. We're doing the dose findings study here with the tablets here of leniolisib and the 70 milligram tablets is the current dose for leniolisib. And you see here that we are working towards picking the best dose regimen for Phase III treatment for this indication. And we will, of course, keep the market updated as and when first patients go into this trial, and further progress is booked.

So finally, let's look at the financials and outlook. You can see the revenue is growing significantly on the basis of continued growth in RUCONEST®. And of course, the more than US$18 million of sales of Joenja® booked in 2023. Gross profits significantly increased. In both years we had some other income in 2022 and 2023. OpEx, of course, is significantly upwards given the launch of Joenja® in the United States, and of course, given the preparations for launch in the other geographies for leniolisib. Of course, that resulted in an operating profit that was slightly negative in 2023, and also a net profit that was slightly negative.

But we have, of course, as already mentioned before, significant amounts of cash, and we have $215 million in the bank at the end of 2023. So we can easily support the further development of the growth of the company. And that is typically from the next slide where you see that Pharming, once we got the commercialization rights in the U.S. for RUCONEST® back in December 2016, we never looked back and not only made RUCONEST® into a US$225 plus million product, but also start now building on top of that the Joenja® franchise with the first result of US$18 million of this year. I told you just in the previous part of the presentation, I explained to you that we expect that Joenja® is going to be a long trajectory of gradual growth every time from different sources of patients where you can add, which can be added to the Joenja® franchise because Joenja® is of course a chronic treatment for these patients. And then you see the next slide here, as I was talking about the OpEx, of course increasing over time.

Having said that, as in the 4Q 2023 OpEx there were a few one offs, we do not expect that OpEx is going up that much anymore this year. In fact, if you look at the year 4Q 2023, I think this will be higher than what we currently expect for OpEx during the year on a quarterly basis. But of course, you can see here the considerable investments in marketing and sales for Joenja® and also the G&A. I think there was some one offs in the G&A in incorporated.

Then let's move to the next one. We look at the revenue guidance. You see here that revenue guidance is significantly depending on not only the continued low single digit growth of RUCONEST®, but also on the Joenja® growth during the year and this is our guidance for now. For the year we expect the continued growth between 14% and 20% of total revenues for the company.

And then we have the final slide of the presentation, the outlook. First of all, the total revenue growth I talked about the continued efforts of finding patients in the U.S. by means of family testing, the VUS validation efforts and of course subsequently converting these patients that we currently

have eligible or that will become eligible to the paid therapy. And as you have seen, we're quite successful in the first nine months on the market. Then of course the ex-U.S. You will see from Q1 onwards some, albeit modest, revenues from ex-U.S. named patient program and other early access programs in some of the key global markets.

The completion of the clinical trials for approval in Japan and the pediatric expansion later on during the year, the regulatory action from all the regulatory reviews that we have ongoing. And of course we will start that Phase II trial. We're in the final stages of preparing for that. We have guided that we expect this trial to start in this quarter.

And last but not least, we have the continued focus on in-licensing and of or acquiring clinical stage opportunities in those rare diseases which can fit into our scalable, very scalable commercialization operations in both the U.S. and outside of the U.S.

And thereby we have the ambition to make ourselves a leading global rare disease company. And I hope I explained to you how we are well on our way to do that. I think that's completes the presentation for today. And I would now like to open the floor for some questions, because Serge, I think we still have a few minutes for some questions, right?

Serge Belanger - Analyst, Needham & Company:
Yeah, absolutely, we do. I'll start off, I guess, one on RUCONEST® or a couple on RUCONEST®. I guess, first how much of the $227 million is from the U.S.?

Sijmen de Vries, MD – Chief Executive Officer:
98%.

Serge Belanger - Analyst, Needham & Company:
98, okay. And then in the HAE space, there's been tons of activity on the prophylactic side. Looks like we're finally going to see a new product on the acute side. So, just curious how you think of the future of RUCONEST® with this product.

Sijmen de Vries, MD – Chief Executive Officer:
Yeah, I think, as I said, I tried to elude in my RUCONEST® part of the presentation that we serve a very special part of that population. They have a very high frequency of attacks and they heavily rely on RUCONEST® because they have failed every other therapy.

And if you look at the profile of the other therapies, the bradykinin/kallikrein inhibition you see a consistent profile, and I believe you see that as well in the new oral that may come to the market if approved, that you have about. In 30% to 40% of cases, you need second dosing or rescue therapy right. And I think essential here is if you really have high frequency attacks and you rely on RUCONEST®, you know, it works because you've seen the numbers on RUCONEST®.

We believe there's a very high hurdle for those patients to even try, because you can only get one product reimbursed, of course, to even try that product. And therefore, we believe that given the fact that patients that are on the RUCONEST® don't have the sort of freedom of choice to use RUCONEST® because it's convenient, but patients that use RUCONEST® is because they need it, not because they can choose for something else. And whereas a big number of patients are suffering

from far less frequent treatment, far less frequent attacks, either because they have prophylaxis or they use acute-only and they help themselves now with, for instance, a product like icatibant, where they do, you know, these subcutaneous injections that are very, very painful, but are not very efficacious, because they also need to redose in about 30% or 40% of efficacious, those patients will have a far less high hurdle, far lower hurdle to actually switch to a very easy tablets that has about the same efficacy profile.

So therefore, we believe that the RUCONEST® franchise is a relatively standalone thing that serves as very special segment of the patients. And given that patients always have to make a choice for one therapy that can only be reimbursed, one oral, one acute therapy, we think is a very high hurdle.

You see an example of that, for instance in, where patients are trying to switch from the TAKHZYRO monoclonal antibody to the ORLADEYO products, like also the oral. And where if you look at the reports, BioCryst are having a problem with getting the patients reimbursed because they do not necessarily want to get out of their TAKHZYRO because they know that works and they have a relatively high hurdle to actually switch over to something that is more convenient. But they're not quite sure about how it works.

So I think we are quite optimistic about the fact that the RUCONEST® franchise will not be significantly affected by these oral products that will come to the market. I hope, I explained it a little bit.

Serge Belanger - Analyst, Needham & Company:
Yeah, absolutely. So I assume there wasn't much impact when FIRAZYR went generic a few years ago. This gives you kind of a preview of what could happen?

Sijmen de Vries, MD – Chief Executive Officer:
Not at all. Absolute zero. Because everybody that's on RUCONEST® has already failed FIRAZYR.

Serge Belanger - Analyst, Needham & Company:
Yeah. Okay. And then on Joenja®, as you seek the label expansion to PID, maybe just highlight, would these patients be much easier to identify or are they already identified?

Sijmen de Vries, MD – Chief Executive Officer:
They are already identified because they have this ALPS-FAS, PTEN and CTLA-4 mutations. So, they are already identified. So not only are there more than three times as many patients, but they are already identified. So that will be much easier because by the time this comes to the market, we will also have clarified a lot about APDS, right? Because if you think about, for instance, the numbers of, we have well over 200 patients now in the U.S. identified, of which 25% pediatrics, they will be served when the majority of them will be able to be served when that first pediatric trial comes to fruition. And the other ones, of course, the VUSs, and that's 1,100 and counting will also be clarified somewhere next year and will come to the market next year.

So we expect this year that we have small numbers of patients added to the patients that are there because of the fact that we do continuous genetic testing, also because of the family testing that we do and the small batches of VUS clarifications that we will do. But next year there will be a big

batch of patients coming from VUS. So that's why you will see there's a continuous growth in Joenja®, but it's going to take time because it's an ultra-rare disease. But we know the patients are there because, in those markets, what I just explained, we have far beyond one per million patients identified in France, we have more than 70 patients identified on a population of 60 million.

If you look at the U.S. population, that will be 500 patients that we have in the U.S. Right. So, they are there. That's good.

Serge Belanger - Analyst, Needham & Company:
Well, I think we're running out of time. So…

Sijmen de Vries, MD – Chief Executive Officer:
Yeah.

Serge Belanger - Analyst, Needham & Company:
Wrapping up here. I want to thank you for spending time with us this morning and giving us an overview of Pharming. Appreciate it.

Sijmen de Vries, MD – Chief Executive Officer:
Thank you, Serge. Thank you very much. See you next time. Bye-bye.

[END OF TRANSCRIPT]