Pharming Group N.V. H1 2022 Analyst Call

August 4, 2022

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Operator:
Hello, everybody, and welcome to the Pharming's first half of 2022 results call. My name is Sam and I'll be coordinating your call today. If you'd like to ask a question during the presentation, you may do so by pressing star followed by 1 on your telephone keypad.

I will now hand you over to your host, Sijmen de Vries, the CEO of Pharming, to begin. Sijmen, please go ahead.

Sijmen de Vries – Chief Executive Officer:
Thank you very much, Sam. Good morning or good afternoon, ladies and gentlemen. I'm very pleased to bring you the first half results for 2022 today.

And before I do that, I would like to draw your attention to slide number 2, the forward-looking statement slide. Because this presentation may contain forward-looking statements. And as you know, forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based upon our current beliefs, expectations, and assumptions regarding the future of our business, future plans, strategies, our development plans, our clinical results, and other future conditions. So please take note of that.

And then I would like to move onto the next slide. And I will be presenting today the results, together with my two colleagues, Dr. Anurag Relan, our Chief Medical Officer, and Jeroen Wakkerman, our Chief Financial Officer.

So, let's move to the first bit and take a look at the strategic and operational highlights. And as you have seen today -- and that is on slide number 5, you can see that -- we have formulated some strategic objectives which are slightly different than what you were used to over the past years. Because we've done a total review of our business during the first half of this year. So, we're really focusing -- and that's nothing new here -- on building sustainable business by focusing on the RUCONEST® sales and maximizing these.

Furthermore, we're focused on marketing approval or launch and commercialization of leniolisib in key markets like the US, the UK, and the European area.

And last but not least, we're looking at ongoing pipeline development and management of rare disease assets. And that means that -- and you can see that on the next slide, number 6 -- that we are now really focusing our business to become a business that is focused on being a sustainable business, stable business that is focused on rare diseases.

And on the left-hand side, you see the most important pillar that hasn't changed at all. The engine of our business continues to be RUCONEST®. And RUCONEST® is and will be providing the positive cash flows that will help fund all the leniolisib development plans and all the pipeline development plans that we currently have in our portfolio. And we do that by -- as said before -- by fully focusing on the

maximization of commercialization of RUCONEST® in all major international markets with our own sales forces.

And on the next -- in the middle of the slide, you see the middle pillar, and that is the successful commercialization of leniolisib and the lifecycle management of future indications. And leniolisib is going to be introduced for its first indication, subject, of course, to regulatory approval. This is a new disease, APDS. And Dr. Anurag Relan will talk to you about that a little bit more in detail later on. And it is a rare, primary immune deficiency. And we believe, according to the literature that is, there is about 1.5 in 1 million of the population that is suffering from this disease, which means that if you estimate that, you will come to around 1350 patients in the US, Europe, and Japan. And we have already, without any systematic searching activity so far, identified more than 400 potential patients, and we keep finding them on a regular basis before we have really started systematically searching for these patients. And to give you one example, in an informal registry in France, we have identified some 60 potential patients in France. Which means that already -- and that's, of course, very important when you go into a rare disease that's recently discovered -- that's already one in -- that means that we have already one in a million identified. So, we expect therefore that, you know, at least some 1000 patients. If you add them all up together for the US, Europe, and Japan, could well be identified. And that is, like I said, without any systematic searching. And there might well be more because it's a new disease again.

In addition to that, we have discovered that, and that is the good work of Novartis from which we in-licensed the product, they have done extensive research collaborations in looking at other possible opportunities for leniolisib. And we are determined, and we are making up our minds at the moment which one would be the most favorable one to develop going forward. And we will be providing you with more news in the near future hopefully about which new additional development program for leniolisib we will be starting.

And then last but not least on the right-hand side, we are, and we will continue to be hunting for new assets in the market. New assets that we are able to launch within the coming say three years from the moment of acquisition, so-called late-stage clinical -- assets in late stage of clinical development through in-licensing or merger & acquisition opportunities. And then, of course, the early stage of our pipeline will continue to be developed, namely, OTL-105, our ex-vivo hematopoietic stem cell gene therapy candidate for hereditary angioedema. And last but not least, the current development of our recombinant alpha-glucosidase enzyme replacement therapy for Pompe disease.

So, let's look at some of the strategic highlights in the leniolisib programs on slide number 7. So, we've very pleased today to basically report to you that we remain on track for the commercial approval of leniolisib in the US, UK, and Europe. And in the USA, you've seen in the press release that we recently filed the NDA with the FDA on the 29th of July. We also have received -- and that is very important, especially when you are dealing with a new disease -- that we have received the ICD-10 classification for APDS. That's, of course, very important because it's a new disease. And if you are able to actually describe the disease, it means that patients can be classified as such, and that you can actually start discussing with insurance companies for instance about the reimbursement of such products in -- if leniolisib -- once leniolisib comes to market. So very helpful and very important that we have actually achieved this milestone in the United States already.

And we believe that we remain on track at this point in time for the anticipated commercial approval by the FDA in Q1 2023 because, as you well know, of course, subject to the FDA granting us the accelerated review, it means that within 60 days after 29th of July, the FDA will come back with a letter confirming

the status and the acceptance for review. And if the accelerated review is granted, then six months after that, the so-called PDUFA date is due, which means that it will be by the end of March. Which means that we are on track to hopefully get the approval to enter the U.S. market in Q1 of next year.

And on the right-hand side, you see the progress we have made in United Kingdom and the European Union. During the first half of this year, very early onwards, we received the positive response from the European authority on the Pediatric Investigation Plan. Very important, of course, because it is a disease that also has a lot of pediatric patients. And although we already have the adolescents from 12 and onwards covered in our current -- in our current regulatory file, it is of course important to also start pediatric trials for those children from one onwards as soon as possible.

On top of that, the U.K. authority granted us the Promising Innovative Medicine designation for the treatment of APDS for children in one year of age -- from one year of age. And that is, of course, the similar type of agreement of approval that the Europeans gave us for the UK.

Then we were very pleased, of course, that as announced earlier this week, that the EMA granted us the accelerated assessment for our current file. And as you have seen in the press release, we're aiming to actually bring the file to the EMA in October of this year. So, we remain on track there with the filings for EMA and the U.K. authority in the second half of 2022.

Now let's move a little bit further towards back in the pipeline and the early-stage compounds. A few words about those. With regards to OTL-105 -- on slide number 8 you can see that -- we make -- we are making significant progress together with our partner Orchard Therapeutics who are responsible for this part of the collaboration in enhancing the expression levels of the lentiviral vector. And that will give us sufficient C1-inhibitor expression in the -- in the stem cells. And we are now testing these in preclinical disease models. And we look forward to providing further updates as we move towards preparing a so-called IND filing, which is other words, a technical word for, you know, the approval to start human clinical trials.

And on the right-hand side, Pompe. We continue to work on a next-generation alpha-glucosidase therapy from our own transgenic platform for the treatment of Pompe. And we're currently engaged in some preclinical studies, where we will seek for differentiating features versus the current standard of care that is on the market for Pompe. And as soon as the results will become available, we will update the market on this.

And then as we move to slide number 9, about the programs we are discontinuing. Both of the programs, Acute Kidney Injury and Pre-eclampsia. With regards to Pre-eclampsia, we had to conclude that discontinuing further investment and development is the best way forward, which is, we think, very unfortunate. But it has to do with the combination of the difficulty in getting clinical trials going and a very lengthy and costly development -- very lengthy and very costly development plans that one has to make for a search indication.

And the same thing goes for Acute Kidney Injury. We have decided to de-prioritize the large-scale production therefore of C1-inhibitor for the -- from the transgenic cattle herd because that is not necessary for hereditary angioedema. We have more than sufficient production capacity in our rabbit-transgenic model for hereditary angioedema. Because the matter is de-prioritized, of course, the herd will still be maintained because we're looking for strategic options to actually see if someone wants to in-license this compound or take over this asset from us. And that means that also the Phase IIb clinical trial

in AKI that's currently running in Switzerland will continue while we consider the strategic options that we are creating as we speak. And, of course, we will update the market in the future as and when news becomes available about such strategic options that may become available.

And then I'm coming to the end of the operational highlights here on slide number 10. With regards to RUCONEST®, we're very pleased that we were able to book almost US$97 million of sales in the first half of 2022. In line with the guidance that we gave, a single digit increase in sales for 2022 versus 2021. And we're very pleased that this is supported by an underlying positive trend of what we talked about before, an ever-increasing number of physicians prescribing RUCONEST®, and an increasing number of patients using RUCONEST®.

So, we see that there is a continued need for safe and reliable acute treatment options for hereditary angioedema. Despite the fact, of course, that the market is moving -- has moved towards prophylaxis. We know that all prophylaxis treatments suffer for more or less from breakthrough attacks. And safe and reliable acute treatment options remain -- options remains necessary. What you can see here, of course, is that as usual, the market is -- the main market driving the RUCONEST® sales continues to be the United States. And that is, of course, you know, a fact in hereditary angioedema, not only for us, but for everybody in hereditary angioedema. And it means that RUCONEST® can continue to develop, can continue to give us the stable revenues which will allow us to allocate resources to leniolisib with a view of accelerating future growth by leniolisib sales.

And we continue to give guidance, last but not least, for the rest of the year for single digit growth versus 2021 for RUCONEST® sales. And it's important to note that RUCONEST® supports therefore the possibility, and that's important -- why leniolisib is so important. It will support the fact that we are morphing ourselves from a one-product company that is depending on mainly one geography towards a two-product company that is depending on multiple geographies, namely, United States, Europe, and Japan. And as I said, I think a very significant step forward, again, a significant transformational process in the middle of which the company is currently.

So, thank you very much. This is the first bit. And I now hand over to my colleague, Dr. Anurag Relan, to give you a bit more insight into APDS and leniolisib. Over to you, Anurag.

Anurag Relan – Chief Medical Officer:
Thank you, Sijmen. So, what I'd like to do today is quickly review some of the clinical features of APDS, walk you through some of the data that we've shared earlier, and some of our plans with that data, and then talk a little bit about the future with leniolisib.

So, as you know, APDS is a rare serious primary immune deficiency that affects both B and T cell development. And it's caused by variance in the genes that encode this subunit of the PIK3 delta enzyme complex. As a result of those variants, these patients with APDS have two key features. And we'll talk about those features in terms of what that causes in terms of their clinical aspects of the disease, but also what it causes and what we looked at specifically in the clinical trials.

So, the first feature is lymphoproliferation. And this is again because of the abnormal development of these B and T cells. And what that means, lymphoproliferation, is swelling of the lymph nodes, so lymphadenopathy is, you see enlarged spleens and livers, and you can also see what's called lymphoid hyperplasia in different parts of the mucosa of the airways as well as in the GI tract. That in and of itself is problematic. But it becomes even more serious when that becomes what we call malignant and that

can lead to something called various types of lymphomas, and you see the list of lymphomas that can develop in these patients. And we do know that a number of these patients develop lymphoma after years of this lymphoproliferation going on unchecked. At the same time that there's lymphoproliferation, we also have the problem with immune deficiency. And immune deficiency leads to infections. And as a consequence of the infections, you see a lot of the same issues that you might expect in terms of pneumonia. But on top of that, because of the lymphoproliferation, this confluence of infections and lymphoproliferations causes serious problems again in the GI tract, causes liver issues. And at the same time, there is an issue with autoimmunity. So, there's various parts of this condition where the B and T cells are not working properly and don't develop properly, don't mature properly, that leads to a number of serious problems.

And on slide 13, what we can see is the results from the double-blind placebo-controlled study that we reported earlier this year. And specifically, we see that leniolisib reduced lymphadenopathy. And again, lymphadenopathy was one of the hallmarks of this disease where we see this unchecked lymphoproliferation in these patients. And we see a statistically significant result in the co-primary endpoint there in terms of the size of the lymph nodes in these patients relative to placebo.

And on the right side, you can see there, on the individual patient basis, again, you see the improvement in any of those patients on the left side in dark blue, who were treated with leniolisib for three months, versus the patients on placebo who did not have a similar improvement.

The other co-primary endpoint is on slide 14, where we can see the improvement in the percentage of naïve B cells. Naïve B cells are important because these are B cells that have developed properly and matured properly, and as a result can fight infections that the body will encounter. And you see again, a statistically significant result on the left in terms of the patients treated with leniolisib versus those patients treated with placebo. And importantly, and you can see on the right panel, is that this starts very quickly. The patients with leniolisib, this proportion of naïve B cells increases rapidly and is sustained over the course of this three-month period, versus the patients on placebo don't have that similar increase.

Again, you say, well, what's the relevance of this? The relevance of this is again that these patients' B cells now are functioning properly as opposed to -- functioning and developing properly so that they can fight infections. And you saw from the earlier slide the consequence of having those infections on a repeated basis.

On slide 15, we can see that in general leniolisib was safe and well tolerated over this three-month period. You can see the grade of adverse events that were reported in leniolisib patients versus placebo patients. And you see that they're very similar in terms of severity. There were no deaths reported in the study. There were no adverse events that led to discontinuation of study treatment. And there were no serious adverse events that were related to the study treatment. And in general, the incidences of serious adverse events were lower in the leniolisib-treated patients than those treated with placebo.

And then lastly, what we have on slide 16 are some results from the long-term use of leniolisib. These data here are the data from the initial cohort of six patients and these patients now have actually been on therapy for several years. This is the data from the first two years, and you see that IgM levels in these patients in general are increased at baseline when they begin treatment with leniolisib, you start to see improvements and normalization of their IgM levels. And then when in some cases you can see in the dash line where patients were not able to continue therapy, you start to see their IgM levels go back

up and then when they resume therapy, you start to see those levels go back down again. So, we now have data actually going on, obviously on these patients going out several years, well beyond two years, up to six years in some patients. And on top of that, we have it from a broader group of patients, from those who were in the initial double-blind placebo-controlled study who continued in the extension study. And we anticipate being able to share that data later this year at various scientific and medical conferences to show similar results in improvements in the function and development of the immune system over longer periods of time, as well as in a larger group of patients, to show that over time leniolisib is well tolerated.

And I think, again, that you might say, well, what's the consequence of this IgM levels come down? Well, these patients' IgM levels are increased because their B-cells are not transitioning properly, or plasma cells are not transitioned properly to produce IgG. And that's why their IgM levels are high. And interestingly enough, or not surprisingly, as their IgM levels come down, we also see that these patients are able to stop or decrease the use of immunoglobulin supplementation. So, this is -- this would be therapies such as IVIG and this reflects normalization of their B cell function. I think overall what we see is a significant improvement in these patients' immune system development over the short term that is sustained over longer periods of time when treated with leniolisib, a therapy that seems to be quite well-tolerated. And we look forward to -- on slide 17, now you see our plans with leniolisib.

We filed an NDA, the new drug application, with the FDA just last week, and we anticipate further filings in Europe and in the UK later this year. And as Sijmen mentioned, APDS is a condition that affects children, and we have children enrolled as young as age 12 in the clinical trial that has been completed, but we also anticipate to start pediatric studies this year in the younger children, which I think is going to be important to be able to change the course of this disease over a longer period of time. You also heard Sijmen mention the anticipated regulatory milestones for next year, but we're also planning to start a clinical study in Japan because again, there are patients there that have been identified with APDS that have limited treatment options and we think this will be an important therapy to be able to offer to those patients too. So quite a bit of things happening over the past half year as well as coming up over the next 1 to 2 years with leniolisib. And I look forward to updating you more on that as we move forward. With that, I'm going to turn it over to my colleague Jeroen Wakkerman, our CFO review the financial highlights.

Jeroen Wakkerman – Chief Financial Officer:

Thank you very much, Anurag. Please turn over to page 19, operator. So, we had a good first half of 2022, and that is reflected in a number of financial KPI's. Our revenues went up 4% compared to the first half in 2021. Our net profit increased by one third compared to last year. We had positive cash flows, although offset by exchange rate effects and we did an important transaction in the first half of the year. We reduced our stake in BioConnection, our manufacturing partner. And in that transaction, we received a one-off cash payment of US$7.5 million and we recognized a gain of US$12.8 million. And I will go through the details of that transaction later in the presentation.

Moving to slide 20 and the financial highlights of Q2 2022, revenues went up from US$49.7 million to US$50.1 million. So that's an increase of 1%. Gross profit, US$46.1 million, which is an increase of 2.4% versus last year. So, a good development in gross profit. Operating profit had a spectacular increase from US$10.9 million to US$17.8 million. And that is, amongst others, driven by the BioConnection transaction and net profit was US$15.7 million increase of almost US$10 million versus the same period last year.

In the first half of 2022 and the financial highlights of that period. So, the total revenues went up by 4%. And as mentioned by Sijmen, it was supported by more doctors prescribing RUCONEST® and serving more patients. The gross profit increased in line with the revenue even slightly better to US$87.9 million, and that means a gross margin of 91% and the operating profit increased by 20% to US$20.6 million, and that includes an increase in OpEx, more details later, and offset by the gain on the disposal of the BioConnection shares. And the net profit for the first half year also increased by 33% to US$19.2 million.

On the next slide, a bit more detail on what happens in terms of the profit. So, the profit before tax increased in the first half of 2021 from US$20 million to US$23.8 million. You will see when the slide comes up, the drivers of this growth in profit before tax. First, the underlying business, the gross profit increased by US$4.1 million because of the increase in revenue and also because of the higher gross margin. We spent more on R&D in the periods and in total US$5.1 million more than last year. And the two key drivers of that was on the first hand, leniolisib. As we announced earlier, we are increasing our spend on leniolisib. This is, among others, the manufacturing preparation, but also US$1 million more on OTL-105, the product that we are developing together with Orchard Therapeutics.

We had an increased expenditure on G&A. That was mainly related to phasing. And we had an increased spending on marketing and sales. And here again, the key driver for this increase is leniolisib. And think about the activities to find patients. So, the 6.3 out of the 7.8 is because of leniolisib, and the remainder is basically in more travel costs that our people spend visiting more doctors than we could last year from the from the backlash of COVID still at the time.

Financial results US$1.2 million up and the 12.7 other is mainly the BioConnection that transaction with the profit of 12.8 million U.S. dollars. So overall profit before tax for the first half of 2022 were US$23.8 million.

Then moving to slide 23, a development of the cash flow. The cash flow was fairly stable, went down slightly from US$191.9 million at the beginning of this year to US$190 million at the end of Q2. And we generated US$4.6 million from operating activities. That is the normal operating cash flow, but also some increase in working capital, especially in inventories. The net cash flow from investing activities was mainly from the cash that we received for BioConnection, as I mentioned before, US$7.5 million and we had US$1.6 million of normal CapEx.

And on the financing cash flow, the US$3.3 million negative, that was the usual interest on loans and lease payments and what have you. And the negative exchange rate effect in the cash of US$9.2 million was basically from the cash that we have in a Euro functional currency. So, with that, the cash and cash equivalents ended up at US$190 million. And that is a good war chest for either buying more licenses or to spend on M&A activities.

Then a little bit more detail on the next slide on the BioConnection transaction. Obviously, it had a very positive financial impact. And what was this deal about? Well, we bought the stake in BioConnection in April 2019 for an amount of US$4.1 million, and that represented 43.85% of the shares in BioConnection. In April 2022, so three years later, we did several transactions. First, all the transactions were sold and that was followed by a partial reinvestment of 22.98% in BioConnection, and we received a US$7.5 million cash payment. So, if you look at the blocks at the bottom of the slide, you see at the end of Q1 2022, the value on the balance sheet that we have for BioConnection was valued at the net equity value. It was just ordinary shares, US$6.6 million. In the transaction, we kept part of the BioConnection holding

and that is calculated at the bottom, our share versus the original US$6.6 million that is now US$3.5 million. So that is still being valued. The ordinary shares at equity value.

Then the value of the pref shares is the fair market value was US$8.4 million and we received US$7.5 million in cash. So, the total value represented in the transaction was US$19.4 million, and as the initial value was US$6.6 million, the gain on the disposal was US$12.8 million, which is non-taxable. So overall, a very positive transaction on BioConnection. We keep related to BioConnection. We are still a minority shareholder, and we'll support future growth, but we're very happy with this transaction overall. And with that, I would like to hand over back to Sijmen.

Sijmen de Vries - CEO:
Thank you very much, Jeroen. And yes, then we have come to the end of this part of the presentation -- of the end of the meeting by looking at slide number 25, the outlook of the remainder. As I was stating before, we continue to guide for single digit growth in group revenues from RUCONEST® sales for the remainder of 2022. However, there could be quarterly fluctuations also as a result of COVID still being a potential issue. We remain, as stated before, we remain on track with the regulatory filings to EMA and the UK authority in the second half of 2022. As stated, and we plan to bring it to the EMA in October. Commercial approval for leniolisib is subject, of course, to the positive outcome of the FDA review and the granting of the priority review is envisaged to take place at the end of Q1 23, with an anticipated launch of commercialization of the US starting soon thereafter in the next quarter.

And then as we stated before, we continue to allocate significant resources towards the anticipated launch and commercialization of leniolisib. And last but not least, investment on and continued focus on potential acquisitions and licensing of those new late-stage development opportunities and assets in rare diseases is a very important -- and remains a very important part of our activities and our focus.

And with that, I would like to continue this presentation part of the meeting and handover back to the operator to answer any questions that you may have. Thank you for your attention.

Operator:
Thank you. If you'd like to ask a question, please press star followed by one on your telephone keypad now. If you change your mind, please press star followed by two. When preparing to ask your question, please ensure your line is unmuted locally. Our first question comes from Joe Pantginis from H.C. Wainwright. Joe, your line is now open. Please go ahead.

Joe Pantginis – H.C. Wainwright:
Hey, guys. Good morning and good afternoon. Thanks for taking the question. So, with regards to the decisions for Acute Kidney and Pre-eclampsia, I was just curious how meaningful are the maintenance costs for the cattle herd? Because I can totally understand why you need to have that for potential pipeline expansion. But I just wanted to have a sense of the cost.

Sijmen de Vries – CEO:
Yeah. The good news is, Joe cattle, we don't have -- we don't need that many cows to actually produce significant amount of C1 inhibitor to support those bigger indications also. And of course, whilst the program is still in clinical trials, it is a relatively minor amount of cattle. So, the costs are not -- to maintain that cattle herd are not at all that significant. Hence, of course, you know, and that is, of course, because, you know, if you want to sell an asset, then you keep it intact as possible. Hence why it was not a very difficult decision to maintain the herd such that, you know, you can offer not only that Phase IIb

clinical program, but also the herd that actually can sustain that program in in the long term. I hope that answers your question.

Joe Pantginis – H.C. Wainwright:
No, it certainly does. And then just switching to leniolisib. It was, I think, very important news that you guys were assigned a diagnosis code for APDS. So, I was just curious, have you, before that even happened, can you describe any levels of conversations that you've had with any of your U.S. carriers and what you're planning now to be able to ensure the most efficient launch and potential reimbursement through carriers?

Sijmen de Vries – CEO:
Yeah. Yeah, I can tell you a little bit about that. Yes, we have, of course, started to discuss this. And as you rightfully point out, having an ICD-10 code is not an easy task to get for a new disease. They don't give these things out very lightly, especially for rare diseases. So, we were very pleased that we both got that recognition that APDS is a rare and severe disease and hence needs and ICD-10 code. And of course, with that in hand and we are now preparing and actually have over the coming time to have these discussions with those carriers to make sure that as and when the product becomes available, it is readily -- it can be readily not only the patients are classified, but also the carriers can move quickly in terms of reimbursing the product. So yes, we are very much working on that. And I can tell you also that we received, generally, a very receptive audience in that respect.

Joe Pantginis – H.C. Wainwright:
No, that's helpful. And then just quickly, I guess, as Anurag alluded to in his prepared comments with regard to the pediatric program, I believe he mentioned that the program would be starting this year. Any other details with regard to sort of the size and potential timing to be able to get that supplement into the FDA?

Sijmen de Vries – CEO:
Anurag, could you take the question, please?

Anurag Relan – CMO:
Sure. Hi, Joe. So, yes, we are planning two clinical trials to be able to treat children. And the first study would go down to the ages of -- as young as children as young as age four. And the second study would go down to children as young as age one. And in both studies, we're trying to start as quickly as possible, including at least one of them this year in terms of treating the first patient. The size of the studies, these are, again, studies that are -- their size in line with the rarity of the condition. So, they're not large studies and we haven't given any guidance in terms of when we anticipated completing those studies, but as we move toward getting those first patients, then we'll be able to give you more look into the future in terms of when those studies will be completed, as well as when we'll be able to file supplemental to gain approval for the younger population.

Joe Pantginis – H.C. Wainwright:
Still helpful color. And thank you, guys.

Sijmen de Vries – CEO:
Thanks, Joe.

Operator:
Our next question come from Hartaj Singh from Oppenheimer and Co. Hartaj, your line is now open. Please go ahead.

Hartaj Singh – Oppenheimer & Co:
Great. Thank you for the question. I just have two quick questions and really nice update and congratulations on getting ready to file leniolisib in the United States. One question is on leniolisib. You know, Anurag, Sijmen, Jeroen you're doing research on what would be appropriate comps, you know, on a pricing perspective. Can you give us any color there or insights? Also, your pharmacoeconomic modeling, you know that you probably have for leniolisib. Is that offering any insights also as to how you think about this product and how to price it? And then secondly, on RUCONEST®, you know, it's becoming increasingly competitive in the field with a lot of new market entrants. Sijmen, are you thinking about lifecycle management for RUCONEST® going forward in the near term? Thank you for the question.

Sijmen de Vries – CEO:
Okay. Maybe I start with the second question first and in that case, Hartaj. With regards to RUCONEST®, there is no additional lifecycle management and lifecycle management projects planned nor in progress. RUCONEST®, as we stated, continues to fill the unmet need, especially for those patients that are severely affected by hereditary angioedema, which are not sufficiently or not helped by any of the other products, including prophylactic therapies. That is has been the sort of mainstay of our patient population in the past and continues to be an important part of that, despite the fact, of course, that there's been much better therapeutic options for prophylaxis on the market.

Having said that, what we now see as well is that is a continuing trend where we also see an ever increasing number in patients coming in to RUCONEST® and prescribers are using RUCONEST® is the fact that with the shift in the paradigm as a treatment paradigm for prophylaxis shifting over the last few years away from C1 inhibitor towards bradykinin kallikrein inhibitor, and it has become very clear or becoming more and more clear that, you know, choosing a C1 inhibitor as breakthrough therapy is a rational choice, and that is the underlying trend that we see. And therefore, we continue to believe that as long as there is bradykinin kallikrein inhibitors and that is the only thing that's being developed as we speak. Also, the new future products, we continue to believe that there is a significant opportunity remaining. RUCONEST® is the only C1-esterase inhibitor on the market for acute treatment, hence why we decided that -- and that is a matter of the natural way how C1 inhibitor functions, the biological half-life is determined, you know, you need to dose once or twice a week with these kinds of products if you want to go into prophylactic therapy. It means that you cannot be competing on the convenience with the C1 inhibitor. Hence why it doesn't make any sense to continue to do that in a market that's driven mainly by convenience. So, the strong spot that we have is remains our strong spot; and therefore, we have concluded that that's the best way forward to continue to manage RUCONEST®.

With regards to leniolisib, yes, of course we are doing a lot of work with regards to pharmacoeconomics and the value actually leniolisib can bring to patients and to the healthcare system in general, because as you will understand from the complexity and the severity of the disease, these patients consume rather large amounts of healthcare resources and also have a rather diminished quality of life, of course, because they spend a lot of time, you know, if they are lucky that they get diagnosed, they spend a lot of time actually in hospitals at various type of clinics.

So basically speaking, yes, we're doing that. And, you know, we have, of course, not yet decided on pricing for the compound because we are in the middle of that. But we are determined to basically, you know, price this kind of product in a typical way for this kind of rare disease compounds. And of course, we will further update the market as and when the product becomes available in the market. I hope that answers your question, Hartaj.

Hartaj Singh – Oppenheimer & Co:
Yeah, that's great, Sijmen. Thank you so much. And thanks, Anurag and Jeroen.

Sijmen de Vries – CEO:
Thank you.

Operator:
Our next question comes from Simon Scholes of First Berlin. Simon, your line is now open. Please go ahead.

Simon Scholes – First Berlin:
Yes. Hello. Thanks for taking my questions. I've just got two. I'm looking, you have 59 marketing and sales personnel overall at the end of last year. I was just wondering how many you expect to have by the end of this year and how many you might have by the middle of next year by the time leniolisib is launched? And then secondly, you've also been alluding to possible capital market access to finance future acquisitions. I was wondering if you can comment on the likelihood of that, of any future capital market financing will be non-dilutive.

Sijmen de Vries - CEO:
Okay. There's the first question, Simon. We just hired or in the process of hiring an additional 25 people, colleagues in the United States here to actually go start a more systematic patient identification possibilities and for disease education. Those colleagues will be turning into a sales force in -- after the product has been approved. That's -- there would be no additional changes in that. And if you think about the expansion for the European commercial presence, I would say that we're sort of planning a lot less in that respect. But I would say that the combined is probably below 10 initially for the coming time in, let's say looking at 2022 and 2023.

Simon Scholes – First Berlin:
Okay.

Sijmen de Vries – CEO:
With regards to your question about, you know, acquisitions and capital market access, yes, we believe that we have access to significant amounts of non-dilutive capital. Given our balance sheet and given our commercial performance, we do not only believe that, we know that. And, you know, as and when we find interesting M&A opportunities, those will possibly also be financed, of course, with partly, this kind of non-dilutive financing. On the other hand, it depends, of course, on the size of such a transaction. And we have, of course, taken the NASDAQ listing because of the fact that we have a currency in hand with the NASDAQ shares, which is well recognized in the US, of course, and which we also think can serve to, you know, pay for this acquisition and also change the shareholder base as a result of that and drive a lot more liquidity towards the NASDAQ market. So that also remains, of course, a distinct possibility. And it depends, of course, on what kind of transaction we do.

With regards to the likelihood of that, yeah, that's a good question. It's of course, relevant only when it's 10%, I can tell you that on a regular basis, we have evaluations and we have due diligence ongoing, and we have further, even further discussions with potential parties, because it's a very interesting time, to put it mildly, to be in the market. Now, of course, with a lot of the industry suffering from the current drought, shall we say, of the capital markets for the biotech industry in general. Hence, we are in a not unfavorable position, despite, of course, being hurt ourselves in terms of market capitalization. But still, we are in a not unfavorable situation, we feel. And that's really, you know, we have increased even our activities to look for in-licensing/M&A opportunities. So longwinded answer I apologize but --.

Simon Scholes – First Berlin:
Yeah, that was very interesting. Thanks very much.

Operator:
As a reminder, if you like to ask a question today, please press star followed by one on your telephone keypad now. Our next question comes from the line of Jacob Mekhael from Kempen. Jacob, our line is now open. Please go ahead.

Jacob Mekhael – Kempen:
Hi there and thanks for taking my question. I've just got two today. The first one is what are the factors that drove your decision to park Acute Kidney Injury and have you already had conversations regarding licensing of the assets? And my second question is how soon after approval can we expect sales of leniolisib to ramp up in the US and EU?

Sijmen de Vries – CEO:
Yeah, the audio was not very clear, but I think you're asking me a question about if we already had discussions with regard to the AKI, you know. Is that right?

Jacob Mekhael – Kempen:
Yeah.

Sijmen de Vries – CEO:
The answer is no. No, we recently took that decision and we have not yet entered into any discussions. We have some potential targets in our minds, but we still need to approach those, and we will do that as soon as possible, obviously.

Secondly, Jacob, with regards to the sales, let's -- assuming this PDUFA date of the end of March. Typical for industry, typical industry practice is that in the United States, obviously you have to -- you cannot import your drug before you have a positive PDUFA result from the FDA. So, it means that there's a number of logistical matters that have to work. And you also, of course, have to, you know, prepare a few other things. But I would say typical for the industry would be that somewhere, you know, within two months, I would say from the PDUFA dates, you should see the first sales. And we have every intention, of course, to stay within these kind of industry standards going forward. We're working very hard to preparing ourselves for such entry of the commercial sales of leniolisib. I hope that answers your question.

Jacob Mekhael – Kempen:
Certainly does. Thank you.

Sijmen de Vries – CEO:
Pleasure.

Operator:
There are no further questions, so I'll hand back to Sijmen for any closing remarks.

Sijmen de Vries – CEO:
Thank you very much for attending our conference here of the first half results. I would like to remind you that we are finding the company in a very important point in its time, in a big transformation from being a one product, one geography company toward that multiple product and multiple geography company to build a sustainable, commercial and profitable business. And for the shorter term, we, of course, continue to give the single digit growth guidance for our revenues and the regulatory filings, as we discussed that we are on track with and we are anticipating the commercial approval, subject of course to the FDA granting the priority review and positive outcome, in Q1 23.

And we continue to significantly invest in the preparations for the launch of leniolisib. And last but not least, we, because we are -- have the capability to leverage our commercialization apparatus both in the US and in Europe with more rare disease products, we continue to hunt aggressively to get additional in-licensing opportunities like the leniolisib that we can launch within three years from the acquisition or the in-licensing and/or the M&A transactions of such assets that we can launch within that window of three years from now approximately.

Thank you very much for your attention and we look forward to updating you on the next occasion with our results. Thank you very much. Goodbye.

Operator:
This concludes today's call. Thank you for joining. You may now disconnect your lines.

[end of transcript]