2021 preliminary results transcript

Siggi Olafsson:
We are very pleased to talk to you today, both from a personal point of view of seeing people face to face for the first time in two years, but secondly to talk about the great results that we have in 2021. I'm not going to go through the results. I think you saw the press release, and we have the presentation this morning. A strong growth in all three businesses in 2021. A lot of new launches, many business development deals. Challenging environments still in the U.S., but overall, I think the performance was really, really good in all three businesses, and a strong guidance for 2022. So, with that, I was just going to open it up for question and answer. Maybe we start in the room here. Then, of course, we go online a little bit later on when we are running out of questions in the room. So, who wants to start? Yeah.

Male Speaker:
Just one second. If you [inaudible] they could use the microphone. They don't need to [inaudible] introduce yourself to people on the line.

Emily Field:
Emily Field from Barclays. Maybe just to start, you know, the deflationary environment in generics. I believe you're talking about low double digit inflation for 2022. So, the factors driving that, you know, if you expect that to persist or kind of what you think is a more normalized environment for generic price deflation?

Siggi Olafsson:
Yeah. So, what we saw in 2021, we saw gradual worsening of the pricing environment. And you see that on the slides we put up this morning, that 2020 was particularly good year, in a way. We have the price erosion of around 4 percent for the [unintelligible] business in 2020. We got it to 6 to 8 percent or mid-to-high single digit last year, pricing. And our pricing came out just about 8 percent for the full year in 2021, maybe eight and a half, so just about 8 percent. So, but we saw that throughout the year that there has been, the focus of the customers has been the security of supply in 2020. So, there were very few tenders or auctions happening in 2020. So, I sometimes say there was like a pent-up demand from the customers of tendering out the portfolio, so we've got so many tenders coming in. In the first half that impacted then the second half in terms of pricing. So that's how it started.

I think, also, maybe some of our peers have inventory issues because there were less volume in the market in during COVID due to less diagnosis. We are back to normal volume in the market, as we showed in our slides. So we have the feeling that at least some of our peers have inventory issues, and therefore pushed down the price a little bit in the market. In terms for how long will this last, you never know, but I believe -- and I've been doing this now for just over 20 years -- the pricing in the U.S. is cyclical. It really is cyclical.

And, you know, I've been very close to the market in the U.S. since 2010, and you can see that you usually have maximum two challenging years, and then you usually have three very -- three to four very decent years. We had '16 and '17, which was challenging years from pricing. We had '18, '19 and '20 quite good years. We had the chains of the storm a little bit in '21, and we are forecasting low double digit pricing for '22 based on the tenders that we see and expectation in the market.

So, I'm still optimistic on the market. This is cyclical, and I hope -- I'm hoping, also, like, if there's any extra inventory of our competitors, that will flush through, hopefully, in the first half of the year. So, I'm optimistic about the market, but clearly we are in a different environment today than 24 months ago, for example. Somebody has to [inaudible] --

Pete Verdult:
Pete Verdult, Citi. Three questions. [unintelligible] myself. PANDAs. Today we were talking about PANDAs -- change in FDA regulations where drugs that were approved pre-'84 and are being converted to a sort of 505(b)(2), so that could have implications for generic companies in terms of post-marketing surveillance or potential litigation. So, I think they're saying they might have to withdraw at least 30 products, potentially, from the market, and some of them are on the shortage list. And I think there are two that stand out the Hikma Dexamethasone and Digoxin. So, just wondered if that was on your radar or not.

And then, specifically to Hikma, on the generics outlook, I mean, the margin is pretty impressive. You always said 20 percent is good, and you're guiding 25 -- or let's say 24 to 25. Is that all just product mix, or [unintelligible] it's just because you're not spending as much. Just wanted to get a sense there, because it does feel that you're finally conceding that the revenue outlets for things like Advair and Vascepa, for example, might not be as big as people hoped.

And then, lastly, on the buyback. I mean, in the past, you said, look, it's a bit like giving a kid -- candy to a kid, you have the short-term impact. What is the signaling or thought behind doing the buyback now? Is it just to help prop up the earnings outlook, or how should we interpret that buyback? Thank you.

Siggi Olafsson:
Do you want to start on the buyback, Khalid?

Khalid Nabilsi:
Yes, I'll start on the buyback. I think, in terms of our capital allocation priorities since capital market in 2018, we have four priorities. One is investing in organic goals, M&A, BD acquisition, and this has not changed. Today, our balance sheet is very strong, and we have very low leverage, even within our industry. We have the flexibility, so a buyback of 300 million, up to 300 million, is not going to affect our ability to pursue further acquisition. And you saw during this year we had a couple of, like, signed some licensing deal, acquired a few products, we did Custopharm. So, it's not going to have an impact on our financial flexibility.

So, it's in a way that the board and the management, we believe that the market is not reflecting the intrinsic value of the -- of the company and, therefore, maybe a share buyback just shows that we believe in the prospects of the company and the future.

Pete Verdult:
[unintelligible]. How quickly is it going to sell?

Khalid Nabilsi:
It's going to -- it's going to -- we are going to do it over before the end of this year, so it's going to spread over the -- during this year.

Siggi Olafsson:
One the -- on the older ADAs approved prior to 1984, as you said, Pete, in your question, it's only affecting two products for us which are relatively small. I think also to keep in mind is I don't think the FDA wants us to take these products off the market, because there will be a shortage on the market, especially on these two products that we have. Digoxin is a lifesaving drug, but I think most of the applications are very old in the market, and it would be very bad for the market. And the second thing on Dexamethasone, it's very important especially now during COVID, but it's a relatively small product outside of COVID season.

So, I -- we keep an eye on it. I'm not sure it will be as drastic as Teva is painting it, but you know, out of the 85, 86 products we have in generics, it's only two of them that we are monitoring at the moment. And for Digoxin, I doubt if it will come through. We are ready for it, but --

Female Speaker:
[inaudible] don't think it [inaudible] market.

Siggi Olaffson:
No, no. So, the question is basically if the bio study is older, but we need to check, but I don't think that Digoxin is at risk. Dexamethasone might be at risk, but we need to look into that. In terms of the -- in terms of the generic market. So, remember when I joined four years and four days ago, the company, I basically set out my ultimate goal in five years' time would be to have a gross margin in the mid-forties and the net operating profits in the twenties. We have achieved that. Even in a year where we are guiding to a double-digit price erosion similar to what we saw in 2017, we are guiding to net operating profits 24 to 25 percent. And that highlights to you what we have done to this business. This is not the same business. We -- I will remind you of the numbers in 2017, our net operating profit was 3.6 percent and our gross margin was 36 percent. So, now we are guiding 23 to -- 24 to 25 percent net operating profit in that similar pricing environment as we are focusing. So, totally different business.

In terms of investment, we are continuing with the investment. So, it's not, we are getting to this level by cutting the R&D or cutting the sales. We are launching big specialty products. We hope we will bring Ryaltris to the market sometime around middle of this year. We have the approval in hand, but the supply is not available yet from Glenmark. Glenmark is responsible for the supply for us, so our best estimation is probably soon in third quarter that we'd be ready. So, we will miss the main allergy season, so -- but we need to start to build a sales force. We are expanding our promotion of Kloxxado.

So, really, it's not cost cutting. It's control of the cost, of course, I think you saw that the gross margin for the generics in 2021 has never been higher. We showed the 47 percent gross margin, and show me any peers that don't have injectables with like-to-like comparison. This is really amazing result, and it's about the work the team has done over the last four years. So, I feel, you know, I have maintained -- I have never committed to say it's going to be in the mid-twenties, but I think this business, even in tough years like this, this business should continue to deliver a net operating profit in the twenties. I'm very confident about that.

Thibault:
Thibault from Morgan Stanley. So, my first question, on the -- on the generic Xyrem. So, I think it's, according to the guidance, launched in the middle of the year. Just, if you could give us a little bit color on what you're expecting in terms of market share uptake, timing of official launch, and, I guess, the kind of mid to long-term outlook for the generic in terms of if there's a longer stay value than usual generics on that?

Siggi Olafsson:
Yeah.

Thibault:
Just, also, on Kloxxado you could maybe give us a little bit of color on the early trends of the launch. What did you try and compared to what you were expecting before launch of the strategy you explained to us in the past months and quarters? And maybe, just to finish on the biosimilar. So, some of the biosimilar agreements you've made, are there any trials ongoing in China? And just, if you could tell us more about your confidence of obtaining

FDA approval with these trials. When we saw what recently happened with Eli Lilly and [unintelligible] drug recently was the [unintelligible] was not -- doesn't seem to be ready to approve, actually run that biologics based on a study conducted exclusively in China.

Siggi Olafsson:
Yeah. So, let me start on your last question around the biosimilar. So, last year we signed two biosimilar deals, with Bio-Thera on ustekinumab and with Gedeon Richter on denosumab. Both really good companies, very impressive development. In terms of Gedeon Richter, they are doing a global trial. I'm not even sure they have a site in China. In terms of Bio-Thera, they have patients in China, but they're running the trial in six different countries, so it will not be solely based on Chinese population. The phase three study, for sure. Overall, we read the guidance from the FDA, and this issue came up around Eli Lilly analysis of their innovative products. I don't think it affects the biosimilars per se, but no matter what, we are running a global trial for both products, so we don't think that will be an issue for neither development. But, you know, you keep an eye on it, but I think it's a specialty product issue, but you know, I'm more confident, of course, by having a global trial be behind the development work for these. Your first question, if you could just repeat it?

Male Speaker:
[inaudible] --

Siggi Olafsson:
Let me take the Kloxxado while you're looking the other one up.

Thibault:
Xyrem, Xyrem.

Siggi Olafsson:
No let me do Xyrem. So, Xyrem -- we, obviously, we have no guarantee when it's launched. We are saying mid -- around mid-year, it could be a little bit into the second half of the year, of course, but our best estimation is around mid-year. So, it's difficult to give the exact timing. Xyrem, or sodium oxybate, is a specialty product in a closed system. So, we have seen that the branded companies tend to retain a significant market here when you come into the market. And the best example is Advair. Today, I think GSK in fourth quarter was 52 percent market share.

So, our expectation is that the brand will maintain some markets here due to the closed system and so few payers around this product, because if only one payer decides to stay with Jazz, that could mean 60 percent of the patients. So, this is -- this is a very different situation. When you're modeling it, you need to think about that. We obviously don't know, and we will know it when we -- when we launch the product, but that is what we have seen as an action. We're keeping an eye on it. But remember that we included in the guidance that the timing of the launch is difficult to say because that is based on the decline of Xyrem. So, I'm not going to help you to model this in too much details, but you have to recognize that if an acceleration takes place, the volume has declined quite significantly.

On top of that, that the brand might keep some of the -- some of the market. But we are ready to go. The good thing is this is an authorized generic, so we will get the supply from Jazz whenever this is reached -- this level. And we also have access to the REMS program, so we are ready to move whenever the calculation tells us that we can have an accelerated approval. We feel it's going to be, as I said, around mid-year, but let's -- we haven't even seen the sales numbers in January yet.

So, it's monitoring how the -- how the same is going because it's not like you can pick up a Xyrem in IQVIA as I'm sure, you know. In terms of Kloxxado, we are very pleased with the

feedback on Kloxxado. So, we are working now in two-folds, with the communities where we are going to different states in the U.S. and buying into their police departments and get it on their register. We have had the good feedback, because the feedback, especially from the emergency workers and police departments, they like to have a higher doses instead of having to give two doses of four milligram, because that is two things they have to have on their belt.

We -- you know, but there is a pensive cycle in the states. So, it takes a little bit of time. Remember we only launched this at the end of August of last year, but we are really pleased with that. On the prescription thing, they are starting to come. You can see that there's slowly, every week, there's more and more. There's a growth in the prescription, still relatively low, but we also got one of the major pharmacy chains in the U.S. to keep it in stock as an emergency medicines in their pharmacies. So, that is -- that is a big win for us. So, it takes time for -- as per expectation or little bit better. It is a good thing.

Maybe the follow-up question, has the generic version of Narcan impacted our sales? It really hasn't, because the generic's solely focused on the prescription market. Generics wouldn't go into the communities. You need a totally different sales force, and it's costly, so the impact of the generic four milligram, which Teva introduced to the market on the 18th, really hasn't impacted our sales as we -- as we expected.

Christian Glennie:
Christian Glennie from Stifel. Just to follow up then, I guess, on a couple of products. You know, we're expected to step up last year at some point, generic Advair, generic Vascepa, which generic Advair ran eight percent, Vascepa 12 to 14, I think. What is the expectation then? I mean, have you got supply sorted on Vascepa? What's the expectation with both products as it relates, obviously, to your guidance for the generics overall for --

Siggi Olafsson:
Yeah. So, if I take both products -- so, in terms of Icosapent, the challenge here is we got the third player in the market that's now actively marketing at the moment, so Apotex introduced by the end of last year as a new entrance to the market. We don't know if Teva is coming or not. They have approval in hand, but they haven't launched the product. So, at the same time, there's still a shortage in -- of supply in the market.

If you look at IQVIA for fourth quarter, you still see that Amarin remains about 80 percent. Apotex is still at zero because they just launched by the end December, so they don't register yet, but they are active in the market in early this year. I think we came up 14 percent and Dr Reddy's at six. So, you can still see that there is a shortage everywhere in the market. We are working everywhere to increase our supply. I think, for the time being, we expect increase a little bit through the year.

But the step-up in increase would mean, to our expectation, would mean a big step-up, would mean that the FDA has to be inspected some sites for us and maybe for the others. So, that's the reason, because the queue at the FDA to get the quality inspection for foreign plants is very long at the moment, and this is not the priority. So, there could be some time until you see a big step up in the generics with a significant API supply in the market. So, three-player market is quite competitive, but only about 20 percent of last year, probably a little bit more now, in terms of business.

In terms of generic Advair, the Teva got approval in December. They haven't launched yet. But I read the analyst notes as you did about them, so they are expecting to launch soon, whatever soon means. In the market, obviously, Mylan and Prasco. In terms of others that could come in, to keep an eye on, I think Lannett in their -- in their press release on their second quarter earnings, they said they're expecting a letter from the FDA in February. And

there's not many days left of February, so let's see what the letter says. And then, Cipla has indicated that they're waiting for feedback on their decision, see responses from the FDA. So, it is -- there are more companies thinking around it.

In terms of our markets share, so we, I think, in fourth quarter, on average, we had about 20 percent of the generic market. So, ten percent of the total market, if you count it like that, you know, roughly. We, I think we will see still an increase, because it's been a gradual increase to that. We have plenty of supply. We don't have any shortage of supply. We have manufacturing lines. We probably could supply nearly the whole market if it would be needed. But, overall, it is going to be more, significantly more, competitive product in 2022 than it was in 2021.

Male Speaker:
Do you think Advair will grow this year, in '21?

Siggi Olafsson:
I don't guide on revenue on individual products. It depends also on when Teva comes and if Cipla comes or anyone else, but you know, so there's so many things outside of our control that can affect it.

Paul Cuddon:
Hi, Siggi, it's Paul Cuddon from Numis. Just pivoting to the injectables business. I'm just wondering if you could provide a bit of a overview of the pricing environment, kind of around the world within injectables, and the margins taking a bit of a step down next year, to what extent is that sort of cautious assumption reflecting, maybe the contract manufacturing, and where might that leads in the next few years. And then just generally, on your customer service proposition, closest to the hospitals. I mean, is anybody starting to kind of match that to your levels?

Siggi Olafsson:
Yeah, so good question. So, overall, the injectable business did extremely well in '21. And the reason I say that is that the comparator in 2020 is very tough, because we were selling, especially in the first half of 2020, so much of the COVID related treatments. So, the comparison, remember mid-year, we were not growing in the U.S. and on full-year basis, our U.S. business grew four percent, which is very significant because we had a strong comparator in 2020.

In terms of our U.S. business, it is doing very well. We launched 15 products in 2021. We continue to gain market share, so we became number two in the market. We overtook Fresenius in terms of volume in the U.S. market. So, Pfizer is still the biggest, but we became number two.

In terms of our service level, they are really second to none. We have been really, really good in dealing with that. In terms of the margin -- so I think in '21 we did 37.6, so 37 point -- 37.6 net operating profit, which is a really strong profit. You have to always keep in mind that U.S. has the highest profit, and MENA and Europe, have a lower profit. And both MENA and Europe are growing faster than the U.S., so there will be a little bit dilution, always, on the net operating profit. There's more dollars at the end of the day, but the faster I grow in Europe and MENA versus the U.S. market, there will be a little bit of dilution in the business.

In terms of '22, we are excited about that in terms of the new launches we expect to be in the similar numbers as previously, ten to 15 new launches for the U.S. injectables. The growth in Europe will continue. We expect to have our first revenues in France, and with the small acquisition we did in Canada of Teligent Canada, bankruptcy of the assets of Teligent Canada, gave us a little bit of platform to launch our own products. We have registered nine

products already in Canada, but we have not launched it because if you launch only with nine products, you are loss-making. So, we wanted to sit on our hands until we have a big enough portfolio to offer.

In MENA, we will continue on the biosimilars getting more approval, and that will really drive the growth of injectables in MENA in '22. Especially on Herzuma and Rituximab, you know, we are getting the approvals through in more and more countries every year, and still Remsima is performing very well. So, in terms of the profit, I've always maintained that you should think about the injectables, 35 is the base. We always hope to do a little bit better than that, you know, shortages in the market usually mean you do a little bit better. You, can't build in shortages this into your forecast, you know, that would be, you know -- because for example, Fresenius, even though they have challenges at their Melrose Park plant, it really hasn't benefited anyone because they have done a good job in managing that quite well. So, overall very excited about the injectables.

We will -- we have the first sale of our compounding, so compounding, we kicked that off. We have now a manufacturing plant that is fully running with validated processes. The challenges are that you need to license in every state in the U.S., so we are just starting so we have between five and 10 states at the moment. So, we expect that, as we come through the year, some of the states require us to have the FDA to visit before, so then we need to wait for the FDA to visit. So, this is why in '22, don't expect a big contribution from this. This will be the start here, and hopefully mid-year, the -- my thinking is I can give you more of a focus of long-term what this business can do. We will see more of the market. We will have better information from the hospitals. But this is the kickoff that we see in '22.

Khalid Nabilsi:
Just adding to that, back to the margins, in 2021, there was some impact in the injectable margin coming from fx, so if you exclude that -- and there's an appendix, some explanation about the hyperinflationary impact which affected the injectable board, the margin would be higher, like 38.9 percent in constant currency. So, slightly higher than 2020, as well.

Male Speaker:
[inaudible] Just, yes. We focus a lot on generic price deflation and things like that. So, and a lot of investors will ask me, what it like for injectables [unintelligible] and --

Siggi Olafsson:
And so -- so we are still remaining that it's a low to mid single digit. We are not seeing the pricing impact there, because I've always said and maintain that the service level that we have and the relationship and how we have been able to step into when others have not been able to deliver, has, a little bit, helped us to maintain pricing better on the injectable side than on the non-injectable side on the U.S. generic. So, I'm much more positive on the injectable pricing environment in the U.S. than maybe on the non-injectables.

Male Speaker:
Thank you.

Male Speaker:
[inaudible]

Siggi Olafsson:
Yeah. So, operator, if you open the line for questions online?

Operator:
Sure. Thank you. Ladies and gentlemen, 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 to withdraw your question. If you're streaming from a web browser, kindly press the flag icon on your web browser to ask a question. When preparing to ask your question, please ensure your phone is unmuted locally.

Male Speaker:
We have a question.

Operator:
We now have our first question from Max Hermann from Stifel. Please, go ahead.

Max Hermann:
Great. Thanks very much for taking my question. It was just, really, a follow-up on the injectables again, on the pricing. Just because we've seen this week from Fresenius commentary about, you know, tougher pricing environment in their injectables business. And I know you said your customer relationships mean you don't expect a change from your previous guidance. So, I just want to try and understand, you know, are these -- are their relationships not as strong, or what is the difference that they're seeing a change in the market? So, I just wanted to understand why you're not seeing that change.

Siggi Olafsson:
Yeah. So, the issue is between Fresenius and Hikma, the key difference is the portfolio that we have. So, our portfolio, we have over 120 products, but all of our products are relatively small. So, we -- when we get a competition on a single molecule, that doesn't affect us nearly as much as when Fresenius. Fresenius has at least five very, very big products in the hundreds of millions in revenue. So, when they get the competition or new entrance on these bigger molecules, they obviously are reflected in more price erosion that you see in the market. So, the buildup of the portfolio, I think Fresenius has a really good relationship with the customers. I don't think there's a big difference there, but it's really the buildup of the portfolio, why we are recording a little bit different numbers of how we see the pricing in the market. Therefore, us having a much -- a very large portfolio, but really no blockbusters to talk about in, you know, I would love to have their blockbusters, but also at the same time in the test pricing environment, it is better to have smaller products, and a lot of them.

Max Hermann:
Okay. And then, just a final, last question was just on Custopharm. Can you -- I may have missed this, but can you update us in terms of the completion and what the process is at the moment in terms of the regulatory review where [inaudible] --

Siggi Olafsson:
Yeah. So, yeah. So, by the way, Custopharm is not included in the injectable guidance. You know, obviously, we don't know the exact numbers today, so -- and we don't know exactly when we close, so it wouldn't be right to try to guide for those numbers. In terms of when this transaction closed, it's based -- at the same time, as we said, when we announced, so we expect it by mid-year, hopefully the second quarter of this year. We are working closely with the FTC. You know, nothing is quick in this process, but really, there's no outstanding issues. We are very comfortable on the transaction itself, and we expect that to happen in second quarter.

Max Hermann:
Great. Thanks, guys.

Operator:
Thank you. We now have our next question from James Vane-Tempest from Jefferies. Please proceed with your question.

James Vane-Tempest:
Yes, hi. Thanks for taking my questions. Just starting with injectables, and apologies if I missed it, but can you give us a little bit of clarity around the 35 to 37 percent margin? And is this based on regional mix or is it more based on new launches? Just to give us a flavor of that. I'm just looking at '21. Despite, you know, European and MENA growing really, really well, which we know are low margin, you know, you're still in the middle of your guidance. So, I mean, is the underlying, you know, U.S. margins going up just given the growth it has delivered and where you came over the full year?

And then, the second question is just on Custopharm. I appreciate it's still to close, you're not guiding specifically, but just as a scenario to help us, if it was the close, say, the middle of the year, can you give us a sense in terms of what, you know, the contribution would be to the business? Thank you.

Siggi Olafsson:
So, on the -- on the margin itself, it is, overall, it's still a strong margin. In terms of the 35 to 37, it has to do with the regional mix, a little bit, you know, differentiation. There is increase in the cost of transportation. There's a little bit of increase in cost of manufacturing that we are dealing with in this business, because you have to remember for the U.S., half the volume that we sell in the U.S. is coming from Portugal. So, there is a tiny bit of increase in that cost, but you really cannot push that to the customers. It's nowhere near that some of our peers are seeing, because we have a good control, but that's part of it. Part of it is that the biosimilars in MENA are growing the fastest, and biosimilars, because we are sharing the profits with Celltrion, naturally has a lower profitability. And then, part of that is also, you know, how the contract manufacturing comes in overall.

But overall, there's no big change in the -- in the business that means that the profitability is going way down. It's small things here and there. The regional, little bit of increase in transportation costs, and then more sales of the -- of the partnership drugs, which means naturally impacting our operating profits. Second question, if you'll remind me --

James Vane-Tempest:
Custopharm.

Siggi Olafsson:
Custopharm, yes. So, Custopharm -- so, the FTC doesn't allow me even to visit them, so I really don't know what their budget is for 2022. So, that's why I'm very blindsided. Remember when we announced the transaction, we said that a rough estimate of their revenue for full year 2021 was 80 million. And that's really all I have. I have no update on that per se because we need to treat each other as competitor until the transaction closes, but that's three -- I'd say in a way, James, the only indication I can give you is what we announced when the transaction was announced in September.

James Vane-Tempest:
Thank you.

Male Speaker:
One more.

Siggi Olafsson:
One more on line?

Operator:
Thank you. We now have our next question from Nicholas Fowler from Barclays. Please proceed with your question.

Nicholas Fowler:
Hi there. Thanks so much for taking my question. Just, I had a quick question on the R&D. I know that it's difficult for you to guide towards revenue, specifically on the individual products and business lines, but just thinking about what guidance looks like for 2022, some of the brokers have been explaining that they expect R&D overall to increase. How do you kind of see R&D and also the allocation across the regions as well? So, we should expect to see probably MENA and Europe with the greatest allocations of R&D?

Siggi Olafsson:
Yeah. So, R&D is roughly -- we don't guide on R&D, by the way, but what we have been delivering through the -- since I joined the company, at least -- it's approximately six percent of revenue on R&D. Could be a little bit less or a little bit more, but that's really the, what has come out over the last few years. I can't guide you on '22. In terms of where the most money is being spent, we spend, when you look at the numbers, we spend a little bit more, we spent more on generics and injectables than we do in MENA. And the simple reason for that is so big portion of our pipeline in MENA is also business development, so we do our own development, but also we compensate or basically mix the two together, where we have specialty products in the pipeline, which is done by our partners. So, around -- we have delivered around six percent of global revenue, more on generics and injectables versus MENA, but that's really how far I can take you in terms of the allocation of the R&D.

Nicholas Fowler:
Okay. Thank you.

Pete Verdult:
Pete Verdult, Citi, just two questions, maybe, for Khalid on cashflow. Pretty strong, just --

Siggi Olafsson:
Pretty?

Male Speaker:
Oh, I'm sorry. [unintelligible]

[laughter]

Pete Verdult:
On a serious note, during the crisis, you made it clear that you've had higher inventories, and you -- that was putting you in good stead, but of course it's been profit growth, but is there anything meaningful change in the image levels of your holdings, receivables, payables that is helping? And then secondly, for both of you maybe, on the MENA region, just any -- can we -- I know there's hyperinflation and effects, but we put that to one side, anything you want to highlight in terms of country performance? And then more broadly, you've had this long-standing strategy of holding the cost base, delivering a better portfolio. I mean, it feels to me like it was years ago that you did for [unintelligible] Brasilia deal. When might we dream that that starts to sort of translate into a -- like the time before when it's in margins, maybe, just finally getting off that bottom around 20 percent?

Siggi Olafsson:
You want to answer?

Khalid Nabilsi:
Yeah, in terms of cashflow, it -- there was a focus from the -- from the beginning of the year, all the management team, on how we want to manage inventory levels. Because if you look into 2020 versus 2019, it went up. And we had, actually, a project that we've done with all

the segments and involves many of the supply chain, purchasing team, finance, to look into how we are going to optimize our inventory level. And you can see this drove our inventory down and really drives the increase in our operating cash flow. It's one side. It's not just the cash flow, as well as receivable, now we have much more control over our receivables. We put in place certain controls that, when countries can sell, different levels of authorization, and control and mechanics to the credit limit, which helps as well, controlling the receivable balances in a way.

So, all of these helped with the targets that we are setting to the end -- to the regions as well, and how they are going to achieve the cashflow targets, helped to improve our cashflow. And we've been working on this since sometime, not just in this year, and we've been delivering year on year on our cashflow. So, it's nothing, I would say, specific other than the inventory, but it's much more control and bringing the inventory into a more normalized level.

Siggi Olafsson:
Yeah. And also, I think, on inventory, we are very selective what we keep more inventory of, you know, because of delay in transportation and things like that, there came a shortage of rubber stoppers for our injectable business. And then you say, get more rubber stoppers, you know, so, it's not like finance takes everything down. You can see that our inventory '21 there's a little bit more than 2019, but lower than 2020. Isn't that right?

Khalid Nabilsi:
Yes, 2020 is --

Siggi Olafsson:
2020 was very high because the pandemic was going on, and we [unintelligible]. It was better to have more inventory than less. So, there was an opportunity to fix that method in '21. In terms of MENA, the country I'll call-out which did it amazingly in '21 but also in '20 was Algeria. Algeria now, is our star market in MENA. So well executed on all fronts. They introduced a new oncology plant. We've got eight products from a brand new plant to the market. And the beauty in Algeria is you are alone. If you manufacture locally, then others cannot import it. So, you -- I think we grew Algeria 42 percent, if I remember correctly. So, very strong growth, but we also grew in Egypt, you know, not at the same level, and these are tier one markets. In Saudi Arabia, Saudi Arabia is still a very strong market, but what's happened in 2021, was the government restructured the governmental tenders, so there was a delay in the tender. So, we -- the tender part of the business didn't perform, maybe, as well, but I'm saying that the timing for me --

Khalid Nabilsi:
[inaudible]

Siggi Olafsson:
So, there was six or seven different tenders in Saudi Arabia for different parts, different hospitals, different regions. So, they now have one central tender for the whole country, and by doing that, there is a delay in the -- in the -- in the tendering business that's happening. So, it will benefit us going forward, but the retail side of the business in Saudi did very, very well. This was encouraging. Jordan did well, probably the best performance in Jordan that we have seen, at least since I joined the company. So, we feel really good about the MENA in terms of profitability. So, if you take out the hyperinflation, they delivered the low twenties as a profitability, the hyperinflation, I'm sure you saw it. I -- it took me forever to, I think, to understand why it's done like this, but the hyperinflation obviously increased our revenue, but decreased the profitability. So, the branded business delivered, in constant currency, low twenties profitability, which is where it has been, to your question, in terms of where -- when we can raise us into the 23, 24 percent, we don't know. But you know, as you can see, it is no matter how we deliver on the business, it seems to be eaten up by fx and our

hyperinflation accounting and things like that. So, that's my biggest thing. We launched the Gedeon Richter product, Vraylar, in the first country end of last year. It takes a long time to register products in MENA, up to three years approval time in many of the markets, especially for specialty drugs they don't recognize.

So, you know, we are hopeful. You know, the ultimate goal is we want to be just over 50 products branded generics, just under 50 produced specialty drugs. But also, you have to keep in mind is when I introduce specialty drugs, I'm sharing the profit with a partner at the same time. So, hopefully there is a better, and the better is more, better utilization of my OPEX, better utilization of my sales force. Because we have a big sales fors, we have 2,000 sales reps and sales support, and they need to grow and better utilize it. It's like an overhead in the plant. The more a manufacturer, the less the overhead is impacting. It's the same, I'm thinking about, for the MENA region, but it just takes some a little bit and it takes time.

Male Speaker:
[inaudible]

Siggi Olafsson:
Even better.

[laughter]

You should see the inventory of rubber stoppers it's beautiful.

Khalid Nabilsi:
But the volumes in MENA, as well as you can see it, so the business itself is doing very well, as Siggi mentioned, there, you get bits and pieces from fx from different countries, so it's like 18 countries, each country has its own currency. So, but it's in a way we are managing and managing that. And I think this year, we targeting to improve as well.

Siggi Olafsson:
The, maybe the last point on MENA, is that -- so, I think five, six, seven years ago, between 60 and 70 percent of our sale there was antibiotics. Now, over 50 percent is chronic medications, and antibiotics is down to 20 to 30 percent of our sales, which tells you that this strategy of building in more chronic medication, relying less on the old -- the old brands are still good, they're still very valid, but the growth is more in the chronic medication because the movement is less. So, I'm really pleased with that. We showed that on the slide, but over 50 percent of our portfolio being chronic medication, it's a huge improvement of the portfolio markup that we have for the business. Any more questions online? Nothing. Any more questions in the room? Yes?

Thibault:
Thank you. Thibault from Morgan Stanley. Just two more questions.

Siggi Olafsson:
Yeah?

Thibault:
So, this one's just on the -- on the operating margins for the branded business. When you think about the kind of normalized data for 2022, will we see some sorts of negative based effects in the first half, which means that we'll probably be below this kind of normalized margin because of the [unintelligible] in the first half? That's my first question. And a second question, just from the compounding business, if you could tell us a little bit more about, you know, kind of your industry? So, who are the competitors? Kind of [unintelligible]

markets, and just kind of gives it a bit more details on the -- on what you're doing here. Thank you.

Siggi Olafsson:
Do you want to start?

Khalid Nabilsi:
On the first -- the first question, I think if you look into that H1 and H2, in a way, how much we have achieved, there's a lot of, I would say, control calls in the second half in order to manage our -- and this is like we've put a plan into how to reduce our cost and control our costs, which helped in, as well, the margins. But a big chunk of the inflationary impact took place at year-end, because it took us by surprise, to be honest with you, because the currency in Sudan was stabilizing, and suddenly the CPI index showed a different result to the stabilization of the currency. So, a big chunk of the effects took place in the second half, and therefore affected the margin. If we exclude that, you would see more of a normalized level on margin for the second half, and margin would be stronger than the first half for the branded business.

Siggi Olafsson:
So, in terms of the 503(b) business, it is a big and growing business. So, it's estimated there was FDA conference, virtual conference, last year about this business. It's estimated that the total market is between 2.3 and 4.6 billion. So, the reason nobody knows is that direct sales to the hospital, this doesn't hit any wholesalers. So, how this happened is you have a courier from your plant straight to the hospitals because it's -- made for each patient in a way. In terms of the environment, so in the U.S. today, there's 67 companies that say they're into 503(b), and they have approximately 75 manufacturing plants for this business. The biggest company is QuVa, Nephron [spelled phonetically], CAPS, caps. Those are the top three, I think, in terms of the business.

Pete Verdult:
What's the revenue they're getting.

Siggi Olafsson:
They, they are not public, so --

Pete Verdult:
We guess?

Siggi Olafsson:
I honestly don't know. I think QuVa -- no, I don't know. I think it's in the, probably in the hundreds of millions, the biggest ones. You know, it's maybe a hundred something millions, but I -- it's a pure guess from my point of view. In terms of the portfolio opportunity, it's pretty big. You know, there are different opportunities. And also, when there is a shortage in the market, what the FDA allows the compounders to do, is to compound this product for the hospitals. You know, if there's a shortage on the listed work, but the first focus is sterile to sterile compounding, where you take a drug and you make it into a bag when it's not in bag, and you mix it. What we heard, and the reason why we stepped into it is, when we met with the hospitals, the hospital pharmacists, the doctors, and the nurses, there's been -- this industry has been inundated with quality issues. And if you go online and go on the FDA website, and you look the 483 and warning letters that this industry has had, it's a long reading.

This is like all volumes of Harry Potter, you know? That you -- so, there is a long reading. And they came to us and said, this is not a reliable industry. Is there a way of utilizing the quality system you have for the pharmaceutical companies, on the SOP, this validation, the

stability testing to change this industry into something different, and really revamp it in a way that will step up, of course, the quality, but also will give the hospitals more trust in the products that come in? So, that's really where we came to this. It is that there is a need in this growing market for a high-quality supply. We have a fit and beautiful plant.

I'm really hoping, if this damn pandemic goes away, that I could invite you to see the plant. Maybe this year or early next year, because we are ready. It's running. It's estimating we will have 100 people there. In the -- in the video that went on social media, you can see a little bit of video from the plant itself where it is. But the idea behind it is a big market, we have to obviously start from zero. We have this idea, we thought about doing an M&A, you know, because it takes a long time to start from zero. But we went against that because what you take is the quality records of the companies that you're buying, and instead of starting fresh and taking maybe an extra one or two years to build up the trust, that was how we thought about it. But the thinking is it's the quality of the pharmaceutical industry you're introducing into the 503B business. If you take a microphone.

Male Speaker:
Yeah, it's just a very quick one, and I expect the answer is no, given the mix of your business, but is there any potential impacts direct or indirect from Russia-Ukraine conflict?

Siggi Olafsson:
No.

Keyur Parekh:
Keyur Parekh from Goldman Sachs. A couple of, kind of, questions for you. One is, kind of, you've announced a 300 million buyback, which is going to reflect this great cashflow you had last year, but at what level is it also reflective of, in your view, lack of inorganic growth opportunities, kind of, across the industry? One of the things, kind of, people want you to do is grow faster. So, is this 300 million in buyback kind of because you're not seeing enough growth opportunities? You can do 300 plus everything else, kind of, you want to do? That's question number one. The second is, if press reports are to be believed, kind of, that could be a different owner to one of the large generic players by the end of the year, it could be in private equity hands. How about if that was to happen? How do you think that kind of changes the competitive environment, kind of, broader industry, and what does that mean, kind of, for Hikma? And then, lastly, as you kind of enter this new market on 503B, how should we think about the margin profile for the business, kind of, over the next few years? Because you've kind of, as you said, you evaluated inorganically and then that market was -- is doing it organically off a very low base, but I presume it's going to be margin dilutive for you, kind of, in the next couple of years, but any kind of help that would be helpful? Thank you.

Siggi Olafsson:
Yeah. So, let me start on the last first. So, in terms of the margin, so clearly when you're starting and kicking off a business and you hire a hundred people to have a very little sale, there will be a little dilution to the market this year, you know? But, overall, when we are up and running and then this business is going and when we have the licenses, we wouldn't expect this to be diluted. It's basically only the startup cost that is impacting the market. Do you want to take the --

Khalid Nabilsi:
Yeah.

Siggi Olafsson:
If you start and I can --

Khalid Nabilsi:
Yeah. In terms of the shared buyback, it's -- if you look into this year, we've done -- 2021, we've done several like Custopharm, and we've done two deals on biosimilars, we have a couple of business activities, and the team's still looking into several opportunities, of course. So, a buyback of 300 million is not going to impact us in terms of doing any organic or inorganic growth -- because the firepower that we would have, it's still above a billion, a billion, or something. Even our net debt today is 0.6 times. Sure, the buyback is going to increase it to its minimum level, and it's not going to affect our ability to do bigger acquisition. So, it's just how the management believe that the market is not a really seeing the intrinsic value of the business and the value of the business and the multiples that we are trading in.

Siggi Olafsson:
So on Sandoz, I -- so, if you look at the profile of Sando versus our profile, we really are only overlapping in U.S. They are 55 percent European company, and then they're all around the world, they don't have a big business in MENA, so the U.S. business, yes, we are competing with them on the injectables and on solid orals in the U.S. I don't think it's changed in so much. There have been declining double digits in the U.S. over the last few years versus where we have been growing double digits, so they have a very different portfolio of products they're dealing with. They sold their solid oral business, they got it back, so there've been many challenges that they have been facing.

So, I don't see a new owner of Sando will fundamentally affect us. I think it will be a lot of integration that needs to take place, you know, to make this into a standalone company. So, I'm not sure if it will be operational by year end but, you know, overall, I think the impact on us is very little to nil.

Keyur Parekh:
Siggi, just following up. So that 505(b)(3), you said when you get to --

Siggi Olafsson:
503(b) --

Keyur Parekh:
-- to that kind of steady state, it will -- it won't be margin diluted. How long before you get to that steady state?

Siggi Olafsson:
So, I'm hoping that -- so, it will be -- so, it's so small this year. It's just a tiny bit market diluted this year. Next year, I'm hoping that we will already not be diluted. It's might not be accretive next year, but maybe in the third year, it could be a tiny bit accretive if the plan goes ahead as we expect. Any last questions? Very good. So, I just want to thank you all. Great to see you face to face, and thanks to the people on the phone. Hope we can see you all soon face to face again.
Thank you.

Khalid Nabilsi:
Thank you.

[end of transcript]