

Hikma Pharmaceuticals | R&D Spotlight Series - Respiratory, Nasal, Semi-Solids & Liquids | LSEG | October 20, 2026

[Intro video plays]

Moderator:

Good day, ladies and gentlemen, and welcome to the Hikma Pharmaceuticals R&D Spotlight Series, respiratory, nasal, semi-solids, and liquid session. At this time, all participants are in a listen-only mode. Later, we will conduct a question and answer session. If you wish to ask a question, we ask that you please use the raise hand function at the bottom of your Zoom screen. Instructions will also follow at the time of the Q&A. Participants can also submit questions through the webcast page using the ask a question button. I would like to remind all participants that this call is being recorded. Questions will follow after the presentation. I will now hand over to Susan Ringdal to start the presentation.

Susan Ringdal:

Good morning and good afternoon everyone, and welcome to the first of our series of spotlight events that have been designed to help the capital markets understand our R&D capabilities, our vision, and how we will deliver it. We'll cover why now is the time for Hikma to increase our R&D spend and how this investment will deliver growth and value over the medium to long term. Today, we are joined by Hafrun Fridriksdottir, who is our global head of R&D, and she'll give a group level overview of how our R&D organization is set up, and that will be followed by a deep dive into our respiratory, nasal, semi-solids and liquids platform with Chris Edlin, who heads up that platform. There are some supplementary slides that we will have available on screen and also on our website.

Before we start, I'd like to remind you that any forward-looking statements or projections made by Hikma during this call are made in good faith based on information currently available and are subject to risks and uncertainties that may cause actual results to differ materially from those projected. For further information, please see the principle risks and uncertainty section in our latest annual report. And with that, let's dive in to our first conversation with Hafrun. So Hafrun, welcome. Thank you so much for joining us today. It would be great if we could just kick off with you giving a brief introduction about your background and maybe going right up to why you decided to join Hikma.

Hafrun Fridriksdottir:

Yeah, thank you, Susan. As Susan mentioned, my name is Hafrun Fridriksdottir and I have more than 30 years of experience in the pharma business. I am a pharmacist by training and I have a PhD in physical pharmacy. Most of my career I have spent in R&D. I worked across multiple pharma companies, both small and large ones. Probably my biggest R&D organization was around 5,000 to 6,000 people. And I have been leading teams which have been developing all kinds of products, included branded product, both small molecule and also large molecules, meaning biologic, also led teams which have been developing biosimilars and of course last but not least generics.

And I probably spent most of my time in leading teams which have been developing generic formulations and that includes all kinds of formulations, both covering what we are covering today, I mean semi-solid and liquids, nasals, inhalations, injectables, both simple injectables and also

long-acting injectables. And last but not least also solid orals, both the immediate release and extent release, delayed release. So I have quite a broad experience in R&D and very happy to take over this R&D organization for Hikma a year ago.

Susan Ringdal:

Fantastic. Thanks for that, Hafrun. I think clearly we can all understand why having joined as president of Hikma Rx, we reasonably quickly put you in charge of our global R&D function. Can you just talk about what changes you've made since you took over the R&D function?

Hafrun Fridriksdottir:

Yeah, of course. Happy to do that. So as I mentioned, I took over this organization around a year ago, slightly less than a year ago. And before I took this organization over, it was basically located within the different divisions. Rx had their own R&D, MENA had their own R&D, and the Injectables had their own R&D. But we decided when I took over this organization that we would like to establish a global R&D organization which is more specialized that focused on more specialized tasks, and that's why we set it up as you can see on the screen here.

And so we have three different main platforms and the platform which we are going to talk about today is the respiratory nasal semi-solid and liquid platform, which is led by Chris Edlin, and you will hear from him as well later in the call. Majority of his team is located in Columbus, Ohio.

Then we have the solid oral platform which is led by Jaber Qasem and majority of his team is in Jordan. Then we have the Injectables platform which is led by Zdravka Knežević and big portion of her team is in Croatia, but she also has a team in Portugal, in Cherry Hill and in Jordan as well, and then smaller teams in other MENA countries. So to support those three platforms, we have the cross-functional R&D operation team and also regulatory team.

So far it has been working quite well and since we set up this organization, we have been focused on selecting more of a global product. So each and every market is involved when we are selecting product, which has been quite important for us. Of course, I mean, if there are interesting opportunities for individual markets, then we still of course develop product for those market, but we are more focused on global product than we were in the past.

Susan Ringdal:

Thank you for that. Clearly, there's been a big change in how we've been structuring the team, but we've also talked a lot about a material change in the amount that we invest in R&D. Maybe you could just quickly talk about why now is the right time for Hikma to be making this material change in the amount that we're investing in R&D.

Hafrun Fridriksdottir:

As I mentioned earlier, there is a lot of opportunities out there. There's a lot of opportunities within those product or platforms which I mentioned earlier, and we have been identifying opportunity, exciting opportunities in all three platforms. Chris will of course talk more about the semi-solid and liquid and inhalations and nasals. But for example, for the solid orals, we are more focused on first to file, first to market opportunities than maybe Hikma was in the past. And you will hear more about this later on also from Jaber when he presents the solid orals. So there's a lot of opportunities which we are going after now.

Susan Ringdal:

Yeah, it's obviously very encouraging to hear that there are so many good opportunities to go after. Perhaps you can talk a bit about how you think about returns on the spend and therefore how do you select the products that we will actually put into the pipeline?

Hafrun Fridriksdottir:

Yeah, I mean of course return on investment is of course very important for Hikma and for any other pharma company. And that's of course a big thing when we are selecting our product, we have quite a sophisticated product selection process, dedicated portfolio and product selection team. And this team, they work very, very closely with the commercial team, with legal, with finance, et cetera, and of course with R&D team as well. And we have an NPV model which we take each and every product which we select, new product which we select for development through. And we decide of course to go after product based on their value, based on the return on investment. And then we take them through product selection meetings and the executive team is part of those meetings. So it is quite a thorough process which we go through when we are selecting product.

In addition to that, as part of how the product is progressing after it has been selected, we have quite a sophisticated stage gate system, meaning that when the product comes to, for example, the next phase of development, we take it back through this NPV and IRR calculation just to make sure that the value is still there. And if the value is not there anymore because, for example, that there is a new competitor on the market, then we don't hesitate of course to cancel the product because that's a very important part of this process is to make sure that we are focused on the most valuable product and we take those forward, but we don't hesitate to cancel if that's what's needed.

Susan Ringdal:

Yeah, that makes a lot of sense. I guess obviously there's a lot of work that's going into the product selection and as we talked about a lot of investment, but ultimately we have to have some confidence that we can be successful with these projects. So could you talk a little bit about what gives you confidence in our ability to succeed, especially since we're working across a number of different pillars?

Hafrun Fridriksdottir:

Yeah, maybe I can start with talking about the strength of the organization. I strongly believe that this setup makes sure that people are more focused than maybe the team were in the past. So this is absolutely the right setup for the organization

Because the teams are more specialized, they're more focused on the individual tasks. And we have a very, very strong team and we have been strengthening that team over the last two years or so. We brought in people with a strong background and strong knowledge. Chris, for example, he joined from other respiratory organization around a year ago or so. And as I mentioned earlier, you will hear from him later on this. Then Zdravka leading the injectable teams, she took over her role just recently, but we basically took over quite a strong team with the acquisition of Xellia around a year ago as well. But that team was specialized in developing ready-to-use injectable formulations. But we have also been adding more talent to that team over the last few months, so that's going quite well. So I strongly believe that we have the right team.

In addition to that, I don't really need to talk about the solid orals because that team has a proven track record both for the MENA market and for the U.S. market, and they have been doing very well. We have also seen, I mean, of course, improvement in submissions, but that's not

necessary. It's not about submissions in the end of the day, it's about approvals and being able to launch products. So we have already seen a lot of progress and I'm very happy with the team and I have a full confidence in that they will be able to take this organization forward.

Susan Ringdal:

Fantastic. Maybe just to wrap up in your section, we obviously have three of these events planned. Today is the first one. What would you like the key takeaway to be from these sessions?

Hafrun Fridriksdottir:

I mean, when IR came up with this idea, I was very, very happy to see that because I think it is very important that investors, they know more about what the R&D team in Hikma is doing. And so that's very, very important for every pharma company to show that the R&D organization is working very well because that's of course, in the end of the day, the bread and the butter for the organization, and that's of course to support the future growth of the company. So we are not trying to tell investors what numbers they should be putting into their financial model. But of course with these sessions, I hope that investors will see that we have a strong team and we are making good progress and we are really focused on developing the right product for the markets which we are operating in.

Susan Ringdal:

Fantastic. That's very clear. Thank you very much. So now let's move over to Guy and I will let Guy introduce Chris. Thank you, Hafrun.

Guy Featherstone:

Thank you, Susan. And thanks Hafrun. Before we introduce Chris, we're just going to run a very short video which was shot at our Columbus site where Chris and his team are based. So if the operator could please run that now. Thank you.

[Video plays]

Okay, so Chris, thank you so much for joining us today. It would be great as Hafrun did, if you could start off just by introducing yourself, giving us a bit of detail on your background, and then also what drew you to join Hikma.

Chris Edlin:

Sure. Thanks Guy. So like Hafrun, I've got roughly 25 years experience in the industry. I started life as a chemist. I have a degree and a PhD in synthetic organic chemistry from the University of Durham. I picked up an MBA along the way too. I worked for several large multinational pharma companies in discovery with a big chunk of that in respiratory discovery. I also ran a startup company in South Africa for about five years. I was elected as a fellow of the Royal Society of Chemistry, plus I've got more than 40 peer reviewed publications and patents to my name too.

Prior to joining Hikma about two years ago to the day actually, I ran a respiratory CMC discovery site for another large generic organization in Ireland. What drew me to Hikma, a couple of things primarily. Firstly, their commitment to fund complex combination products. They take a long time. So having that commitment to take those through selection, R&D through to commercial, it takes that commitment and I was really impressed by that during the recruitment phase.

And secondly and most importantly, I think co-location of the R&D teams with the site of manufacture is really important. Combination products are called that for a good reason. We need

to develop them in combination not only with the R&D team, but the operations team that are going to deliver them to patients ultimately.

Guy Featherstone:

Brilliant. Thanks Chris. And we'll talk more about some of those large complex combination products in a bit. But before that, maybe for those less familiar with it, could you just explain what sits within the RNSSL platform? There are four categories within it. So how does that work and how is your team set up?

Chris Edlin:

Yeah, sure. So respiratory covers orally inhaled products like dry powdered inhalers, pressurized metered- dose inhalers, soft mist inhalers, nebulized products. In general, they're the largest markets with the highest barriers to entry. They're the ones that we're committed to developing products for.

Nasal products cover both multi and single dose sprays, and we're moving those forward using a number of regulatory pathways, and I'll talk about those a little bit later too. So the ANDA and the branded 505(b)(2) route too.

Semi-solids, creams and ointments, those programs are mainly prosecuted in sites in our MENA region.

And then finally liquids. This covers both oral solutions and suspensions, and that includes controlled substances that we execute in Columbus.

Overall, the team is organized around three functional areas. So we have a strong analytical group, a formulation and process development group, and a clinical group, and they're supported locally by device engineers, human factors scientists, and regulatory affairs that are all co-located in Columbus.

Guy Featherstone:

Great. Thanks for that, Chris. And then coming to Hikma more generally in terms of what makes Hikma stand out in this field and what capabilities do we have to justify this as a platform in its own right and make it a defensible one?

Chris Edlin:

I think we've got a demonstrable track record in developing and commercializing a number of complex combination products. So you can look to our generic Advair success story and fluticasone propionate multi-dose nasal spray that are sustained in the market. Developing these combination products, it requires a unique combination of skills across all of the functional areas in R&D, so analytical, formulation and clinical development. We need to make sure that we understand not only the drug product, but how that drug product interacts with the device too. And I think we've built a team that's capable of delivering that.

Guy Featherstone:

Amazing. And so before we dive into a few of those assets, maybe at a high level, and I know Hafrun and Susan touched on this as well, but maybe you can talk from your platform's perspective as to how you go about product selection and shaping the broader pipeline.

Chris Edlin:

Yeah, so I think Hafrun outlined how we look at that holistically as an organization, and that trickles down into my organization too. So we routinely use MPV, return on investment and IRR as a way to prioritize how we allocate resource to projects, and that's a routine part of how we operate. So we do that through frequent and regular stage gates, but not only look at the business case, but also at the probability of technical and regulatory success too. It's a dynamic process. It's kind of embedded in the way that we think and talk about programs at the leadership level in the site here.

Guy Featherstone:

Great, thank you. And so onto some products, and maybe some of the larger opportunities, one that we've spoken about recently and had some recent news on around filing is our intranasal epinephrine. So could you just talk a bit about that product itself, why it's an interesting opportunity, and then after that we can go a bit into the 505(b)(2) pathway that we used on that product.

Chris Edlin:

Yeah, sure. So we communicated externally that intranasal epinephrine's been filed and accepted for review in the U. S. The same story in the EU where we filed via the decentralized procedure. At the end of last year, we filed in the UK to the MHRA. We've also filed in Canada, Jordan, and Saudi Arabia. We're really excited about this product. We believe it has clear advantages. Unfortunately, I'm sure you'll understand this, we can't share the actual data right now whilst it's under regulatory review. We expect feedback from the FDA in the first half of 2027, but unfortunately we can't guide on exact launch dates at this time.

Guy Featherstone:

Thanks, Chris. Yeah, so I mean we obviously look forward to communicating more in that product down the line, but maybe I mentioned the 505(b)(2) pathway there, as did you. We have a generalist audience as well as pharma specialists on the line, but maybe for the more generalists, could you help explain what that pathway is? It's a U.S.-specific one, but how we've gone about developing the nasal epinephrine spray and mainly focused on the importance of that 505(b)(2) route.

Chris Edlin:

Yeah, sure. I'll do my best. So I think the traditional way of branded companies developing new chemical entities, NCEs, is to follow the NDA pathway where companies would generate all of the safety and efficacy data through the discovery preclinical and then phase one through three stages. And then the other extreme of the process is the ANDA, the abbreviated NDA process, where we, as a generics organization, demonstrate equivalence to a brand and then we rely on the safety and efficacy data that the FDA hold on file and we work using the product-specific guidances that the FDA publishes. 505(b)(2) sits between those two. Companies often repurpose routes of administration and they leverage the established safety and efficacy of the molecule. Epinephrine's a great example of that. It's been around for more than a hundred years. The safety and efficacy has been proven and well-used, and we've found a way to reformat that into a dosage form that's going to be more convenient for patients.

Guy Featherstone:

And could we leverage that 505(b)(2) pathway for other potential products in the pipeline in the future?

Chris Edlin:

Absolutely. So we have a number of activities going on in-house where we are looking to synergize with franchises that we're going to build around the epinephrine asset and also looking for adjacencies to that, but also looking to leverage the internal manufacturing capability too. So we have a strong track record in commercial and contract manufacturing for nasal products, and we're looking to utilize our expertise to develop new programs where, for example, the nasal route offers unique advantages in terms of onset of action.

Guy Featherstone:

Brilliant. That makes a lot of sense. Maybe we can now move to respiratory. So we've messaged that we're looking at Ellipta, which is the next generation of inhalers. Generic Advair has been a great success for Hikma. People will be familiar with that from us for a long time now. It took a long time to develop, but it's been a good product for us. To that end, can you talk a little bit about Ellipta and on our other respiratory projects and what's going on in that field.

Chris Edlin:

So yeah, absolutely. Excuse me again. So we've made great progress with the Ellipta program. We've selected a device partner and that relationship is working extremely well. We have formed a great team around moving that forward. We've generated not only in vitro, but human in vivo data that gives us huge confidence that it was the right choice. And we're moving forward with establishing commercial manufacturing capability in Columbus.

There's a lot of synergy with the generic Advair program, too. So for example, the first step in the process is we'll use the same equipment that we use commercially for the Advair program. For later steps, we use slightly different equipment, but the same vendors. So we have established relationships with those two, so we'll leverage that. In terms of the other dosage forms that we're looking at, we've selected external partners to work with where we don't have that capability in-house to manufacture or where it's niche or specialized device engineering requirements.

Guy Featherstone:

Right. And so you touched on a little bit there, but it's obviously clear that partnership is an important element of some of these projects. How do you decide between developing in-house, licensing a device or partnering?

Chris Edlin:

Yeah. So I think we've taken a very common sense approach to that. Where we've got capability in-house, we've leveraged and amplified that. Where we don't have that capability, we've sought established partners in the areas and built co-development programs with those people. So it's a bit of a spectrum of activities really. So with the generic Advair, it's predominantly in-house with some device expertise externally, whereas the pressurized meter dose inhalers is predominantly external through co-development activities.

Guy Featherstone:

Okay, great. And going back to, again, a topic that was raised earlier, but on returns. I mean, if you take a project like Ellipta, this is a long-term project. How do you think about return on

investment when you're making decisions today for something that'll come a long way down the line and how can we be confident in future success?

Chris Edlin:

So it's a very similar answer to before. We monitor the market, we have a robust governance procedure where we routinely check the business case, we routinely check that the MPB of the program is aligned with our expectations, and we stage gate investments so that we de-risk that for the company going forward.

Guy Featherstone:

Yeah, great. And I guess that stage gating is a key part of everything.

Chris Edlin:

Yeah.

Guy Featherstone:

Artificial intelligence, maybe just quickly touch on that. It's obviously a big topic and it'd be great to understand how you and your teams are using AI in your day-to-day.

Chris Edlin:

Yeah, so we've deployed it widely through R&D in Hikma. We see it primarily as a productivity tool. It's really freed up scientists' time to do science rather than more administrative tasks. So we've found ways to automate report generation, data aggregation and analysis. It doesn't take away the QC step of scientists doing the science and looking at the data, but it really has freed up our time. So over time, I think we'll be able to move more projects forward with the same amount of resource, process more data, that kind of thing.

Guy Featherstone:

Brilliant. Thanks for that. And I know that's the case across much of the Hikma group in terms of how we're deploying AI. So finally, we'll go to some Q&A from the audience in a moment, but before that, Chris, it would be great to hear what you feel investors and analysts should take away about your pillar from these events.

Chris Edlin:

So mainly focused on projects and people. I think we've built a balanced portfolio of high value complex products that will take a longer time to deliver, offset with some near term wins around, I guess the less complicated dosage forms. So that's one thing. The second thing is the people. I think it's essential that we build a team and a culture that is enabled to deliver, and we've spent a long time the last couple of years really building that team, and I truly believe that we've got the technical expertise to deliver these programs to patients.

Guy Featherstone:

Fantastic. Okay, thanks very much, Chris. And with that, I'm going to hand back over to the operator who will initiate the open Q&A session.

Moderator:

Thank you. We will now start the Q&A. If you wish to ask a question, please use the raise hand function at the bottom of your Zoom screen. As a reminder, participants can also submit questions through the webcast using the ask a question button. We'll pause a moment to allow the queue to form. Our first question comes from Zain Ebrahim from JP Morgan. Please unmute your line and ask your question.

Zain Ebrahim:

Hello, Zain Ebrahim, JP Morgan. Thanks for taking the question. I'll ask one, which is just on the Ellipta portfolio development, I think you mentioned filing in 2029 in terms of expected timelines. But could you just talk through maybe some of the experience with generic Advair that you had? I think that took a little bit of time to file post some of the FDA feedback, so how you've incorporated some of the experience from the development from Advair in your thinking for Ellipta.

Chris Edlin:

That's a good question. So I mean, a couple of things there. So one, starting at the AI level, so for example, we've looked at all of the deficiency responses that we received from the FDA through the Advair review process, and we've used AI to do a lessons learned exercise there so that we can incorporate a number of those learnings into our development program. So that's the first thing.

Hikma had to repeat some of the clinical trials for the Advair development program. The product specific guidance has changed now for these kinds of programs, so there isn't a requirement to do a clinical endpoint study. So the burden's changed slightly in terms of the methods to demonstrate equivalence to the brand. So it just requires a different set of technical expertise and we're well-placed to deliver on those at the moment, I think.

Zain Ebrahim:

Thanks very much.

Moderator:

Thank you. Our next question comes from Giang Nguyen from Citi. Please unmute your line and ask your question.

Giang Nguyen:

Hi guys. Giang Nguyen from Citi and thanks for taking my questions. I have two, please. I think the first one is Hafrun, thanks for providing the color around the product selection framework. I was wondering how does Hikma thinking around returns on R&D and capital discipline such as the value metrics that you mentioned, how does it differ today from a year or two ago? So that was my first questions. And then my second question is for Chris. Thanks for providing us the details around Ellipta program. Was wondering if you could provide a couple of comments around the other two programs, so that'd be Respimat and the MDI's program. Thanks.

Hafrun Fridriksdottir:

Yeah, so if I start with regards to return on investment and around the product selection, we have of course some specific limits. For example, if we are selecting a global product, what does the NPV needs to be? What does the IRR needs to be? I'm not necessarily going to exactly what those numbers are, but we will follow that of course strictly. But for example, if we are developing product for a smaller market, then we have different NPV and different IRR if we are only focused

on one or two markets. So we follow that product process quite closely. How it was done in Hikma in the past, I don't have a detailed review on that, but I think I know that at least we have a very strict process to which we follow quite closely. So, Chris?

Chris Edlin:

Yeah, so just to recap then, so the questions were on the Respimat SoftMist and the pMDI programs, correct? So Respimat, I think we are slightly delayed compared to the last time that we communicated that from a submission point of view, but we don't believe that it will materially affect the launch timings, which are still focused around patent expiry. Just to note, it is a highly complex device and there's been some technical challenges, but again, I think we've resolved most of those. But it has resulted in some delays to the submission timing. The pMDIs, we've selected two areas that are high volume from a pMDI perspective. We are still in the final stages of finalizing that contract with the third party partner.

Moderator:

Thank you. Our next question comes from Sebastien Jantet from Panmure Liberum. Please unmute your line and ask your question.

Sebastien Jantet:

Hi, thanks for taking my question. So just I guess a couple of quick questions. First of all, it's just if you're going for more global programs, does that mean we should start thinking about the R&D pipeline focusing on slightly larger products? And I guess within that, how do you manage therefore the specific risk of having a lot of eggs in one basket, so to speak?

Hafrun Fridriksdottir:

Yeah, I mean, if I can start. So I think Hikma has of course been developing global programs in the past as well. But the reason for why I talked about selection of global programs, why that is critical both for the R&D organization but also for the commercial organization is that we take all the requirements from all different countries into consideration when we start the program. The tendency was maybe a little bit to start with one market and then having maybe to repeat some of the work which was done to adjust to other markets. But now our focus is really to take into consideration the requirements from all markets when we start those programs. So that's the main difference, which I would say that what we have implemented over the last year or so.

Sebastien Jantet:

And I guess the other part of the question was just to understand then how would the concentration look? Should we be thinking about you launching a small number of large peak sale products or a larger number of small peak sale products within the portfolio?

Hafrun Fridriksdottir:

Yeah, sorry, I missed that part. No, I think it will be a mixture of both. I mean, for example, if I talk about, for example, the solid orals, which many of them are not necessarily huge products, but if we approve them for development for all markets at the same time, then clearly of course the cost of developing those programs is less. But then we have of course larger programs as mentioned for epinephrine is as an example where we have in most of the market which we are operating in. So I would say it will be mixture of both, and I don't want to lose those smaller opportunities which maybe cost less, but still give us a significant return on investment.

Sebastien Jantet:

Brilliant. Thank you very much.

Moderator:

Thank you. Our next question comes from Kane Slutzkin with Deutsche. Please unmute your line and ask your question.

Kane Slutzkin:

Thank you. Morning. Oh, afternoon. So we're seeing more generic company shifts towards more complex products. And as that's happening, I mean, are you seeing competitive intensity rise in those areas in respiratory or nasal? And given the long lead times, how do you actually assess what the competitive landscape and returns might look like by the time the product actually reaches the market? And just following on from that, is submissions the right metric that we should focus on, or should we be increasingly looking at the value or complexity of the products that are coming through the pipeline?

Chris Edlin:

Do you want me to have a go at that, Hafrun, or do you want to... So I guess the simple answer is in terms of managing expectations, we talked about the way that we govern projects and we stage gate things. So we review business cases frequently, so we make sure that we're still on the correct trajectory. In terms of whether submission is the right metric, it's probably a little easier to forecast submission rather than launch because there's always ambiguity when you file with the regulator authorities. But to try and offset that ambiguity, we are investing in improving our right first time metrics using things like AI, making sure we learn from lessons in the past to increase the robustness of our filings so that we can more accurately forecast when we're going to get approval. Does that answer your question?

Kane Slutzkin:

Yeah, sort of. Thanks.

Susan Ringdal:

Chris, maybe just going back to the first question around the competitive intensity, maybe you could, I don't know, I think maybe Advair would be a good example, but maybe you could talk a little bit about how competition has evolved on Advair, and maybe what you would take from that, thinking about or using that to think what do we anticipate in terms of the potential competition for the Ellipta products?

Chris Edlin:

I mean, I think it's very difficult to say exactly how much competition that we expect, but compared to solid orals, for example, the number of companies that are prepared to commit to the spend and timelines of these programs is significantly lower. So I think that in terms of market share, ultimately it's going to be higher than some of the, this is not the right word to use necessarily, the simpler dosage forms like solid oral dosage.

Hafrun Fridriksdottir:

If I may add a little bit about Advair, because Hikma of course launched Advair probably around five years ago or so, and so far it has been three or four competitors on the market and it took a

long time for many of our competitors to take it through the final approval. But surprisingly, actually it was two approvals this year. And I think for both those approvals, it took those companies up to 10 years to get to approval. So I mean that's of course demonstrating how complex those programs are. And also you really need to have the right experience, you need to have the right team, you need to have the right capability in the organization to be able to develop them, and of course being in the first wave of launching them. And that's something which we absolutely believe that we have in our organization in the Hikma organization today.

Susan Ringdal:

Sorry, go ahead, Chris.

Chris Edlin:

I was going to say just it's not only the skills in developing, but it's also the skills in manufacturing consistently to high quality too, which isn't easy. So we shouldn't underestimate that aspect of it too. And again, something that I think Hikma has fairly demonstrated over the last five years with Advair.

Sorry, Susan.

Susan Ringdal:

No problem. I wanted you to make that manufacturing point. I think it's a good one.

Chris Edlin:

Okay.

Moderator:

Thank you. Our next question comes from Miles Dixon with Peel Hunt. Please unmute your line and ask your question.

Miles Dixon:

Thank you. Yes. So we've heard lots on the benefits of isolating R&D. I was wondering if I'd just ask you, Hafrun, given the last, well certainly the last year, what was the biggest challenge really in implementing this new structure and approach around R&D?

And also relatedly to Susan's point about competitive intensity, you talked about identifying products and opportunities around patent expiry, et cetera, but they then cancel or can cancel, I should say. What's the frequency in which that happens and how's that changed over the last few years? Thank you.

Hafrun Fridriksdottir:

Yeah, what was the biggest challenge in establishing the new organization? It was of course, first of all, to decide did we have the right team in place and where did we need to add additional capability? And that's something which we have been working on and has been going, I would say, quite well. So I strongly believe, and I mean developing programs as we are developing is so dependent on having the right capability and right experience in place. And I strongly believe that we do have that now. So was it extremely challenging? No, I wouldn't say so, and it has been going quite well.

Now I'm trying to remember the second part of your question. How frequently does it happen that you need to cancel product because competition has changed? It happens quite frequently, to be

honest, and especially for maybe the more easier programs. And we really try to be well aware of trying to a kill program early if they need to be killed. If we see that there is an extreme competition coming in, then we try to do that as quickly as we can. It happens mainly for the programs which we are developing for the US market because that's of course where the competition is probably the highest. It does not happen very frequently for programs we are developing for the MENA markets, but it happens. I mean, I can't really give you any statistic, but it happens. And I think that's very healthy. I mean that's how things should be treated, that's how things should be done.

Miles Dixon:

Thank you. That's very helpful.

Moderator:

Thank you. Our next question comes from Beatrice Fairbairn with Berenberg. Please unmute your line and ask your question.

Beatrice Fairbairn:

Hi, thank you for taking my question. So you've highlighted enhanced cross-functional synergies and knowledge sharing across platforms, but I suppose could you give us more color on what is different now versus before the centralization of R&D?

And then I'm conscious you can't share specific data, but more generally, what are your expectations for competition in the epinephrine market when considering the nasal platform approach that you've taken? Thank you.

Hafrun Fridriksdottir:

Yeah, if I can start, Chris, then I will give it over to you.

But I think what's different now, as I think I mentioned when we started this meeting is that we have much more specialized team, team which are specialized in developing, for example, inhalation product, in nasal product. They're all sitting together and working on similar formulations. Same for injectables, they're all sitting together and working on similar formulations. So people are learning from each other. They're not trying to be experts in each and every area, but they're much more focused. And I think that's very, very beneficial and that's something which I have done in my previous organizations as well.

Synergies between the three platforms. I mean, we have, for example, one harmonized extractable leachable lab, which is supporting all the three platforms. We have harmonized nitrosamine labs which are supporting each on every platform. Regulatory team is supporting all the platforms. R&D ops is supporting all the platforms. So we have seen a lot of synergies in this setup as well.

So Chris, I'm going to give it over to you with regards to epinephrine.

Chris Edlin:

Yeah, sure. So just to note that we're not going to give commercial guidance on this call, but I guess what I'm going to say is caveated to some extent.

So it's a highly competitive space, the epinephrine market, there's established gold standards in terms of the intramuscular dosage form to deal with it, but we believe that our product is differentiated from that and others that are being developed and are close to approval. However, we can't make any claims because the product is under regulatory review at the moment. And

unfortunately, you are going to have to just wait and see for when the label is published. But the commercial team have got great plans to move this program forward. Sorry.

Moderator:

Thank you. As a reminder, if you would like to ask a question, please use a raise hand button at the bottom of your Zoom screen. We'll pause a moment to allow a queue to form. There are no further questions on the webinar. I'll now hand over to Guy Featherstone to address written questions.

Guy Featherstone:

Thank you very much. Actually, there are two questions which have been submitted, which are both on nasal epinephrine. Chris, I think you actually just covered the point. I mean, just for transparency, Victor Floc'h, BNP Paribas asking about commercial ambitions on nasal epi and competitive differentiators, and Christian at Stifel again asking about observations on the competition, the ARS products, and how that's performing.

Unless there's anything else to add, Chris, I think you covered it off just then. Sorry, I'll hand it to you.

Chris Edlin:

Maybe just one thing. I mean, just to give people some insight into how the process went with the US regulators, the FDA. So at every stage through the development of the program prior to submission and acceptance for review, the FDA saw the data that we generated, they approved protocols before we executed the next round of clinical studies, and saw the data from those. So the FDA have been along this journey with Hikma too, so I think that's highly encouraging.

Guy Featherstone:

Thank you.

Hafrun Fridriksdottir:

If you want to talk about the neffy and the competition, I mean, I don't think if it is really appropriate to address that here, but...

Guy Featherstone:

Sorry, as Chris said, we'll talk more about this product as we go through the process with the regulators and when we have more news next year.

Chris Edlin:

Yeah.

Guy Featherstone:

There are no more written questions.

Hafrun Fridriksdottir:

If I just may add on epinephrine, that we are not the first filer on nasal spray for epinephrine because neffy was of course launched probably a year ago in US and in Europe as well. But we believe that being a fast follower is actually very beneficial because hopefully they will be very

successful in building the market for the nasal spray for epinephrine, which we believe is preferred, or should be a preferred dosage form for the product moving forward.

Susan Ringdal:

Thank you, Hafrun. I think that's a great note to end on.

So on behalf of the whole Hikma team, I would like to thank everyone for joining the call today. Just a reminder that our next event will be covering the Solid Orals R&D at Hikma, and that's scheduled for Tuesday the 24th of November at 2:00 PM GMT. So thank you again. We hope you found this valuable and we look forward to seeing you all then.

Moderator:

Thank you for joining today's call. We are no longer live. Have a nice day.