Hikma Pharmaceuticals | R&D Spotlight Series - Solid Orals | 24 November 2026

Operator:

Good day, ladies and gentlemen, and welcome to the Hikma Pharmaceuticals Solid Orals Session. At this time, all participants are in listen-only mode. Later, we'll 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'll now hand over to Guy Featherstone to start the presentation.

Guy Featherstone:

Thank you, operator. Good afternoon and good morning everyone, and welcome to the second in our series of Spotlight Events aimed at helping the capital markets better understand our R&D capabilities, our vision, and how we can execute on our plans. I'm Guy Featherstone, Director of Investor Relations here at Hikma. So last month we covered our Group R&D setup, and then we had a deeper dive into our Respiratory, Nasal, Semi-Solid, and Liquids platform. Today, we're joined once again by our Chief R&D Officer, Hafrun Fridriksdottir. And we are also joined by the head of our Oral Solids platform, Jaber Qasem, who we'll be in conversation with today. The format will be the same as last time with around 20 minutes of Q&A between me and Jaber, and then we can open the call up for a short open Q&A. There are also some supplementary slides available to download on our website, and we'll be flashing those up on screen through the event too.

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 uncertainties section in Hikma's latest annual report. So with that, we'll start with a short video showcasing our Solid Orals platform. So, if we could roll the video please.

[Video plays]

Excellent. Okay, so Jaber, thank you very much for joining us today. It would be great if you could start just by giving us a quick summary of your background and then what your role at Hikma involves.

Jaber Qasem:

Thank you, Guy, and good day everyone. I'm a pharmacist by training with a PhD in pharmaceutical sciences and 26 years of pharma experience. 22 years of those I spent in the States where I have worked in a broad range of pharma organisations ranging from small startup biotech companies all the way to the large manufacturers, pharma manufacturers. I've worked in branded new chemical entity focused organisations. I've worked in 505(b)(2) focused organisations and also generics. Four and a half years ago, I was recruited by Hikma where I joined the Branded business here in MENA as the VP of R&D for MENA. And later on I was assigned the API business which we call Hikma Chemicals. And last year with Hafrun's restructure, I've been heading the Solid Orals vertical ever since.

Guy Featherstone:

Brilliant. Thank you for that, Jaber. And now maybe just for those on the line who are less familiar with it, could you explain what sits within the Solid Orals platform, which markets you develop for, and also how your team is set up?

Jaber Qasem:

Well, in terms of the core functions are still there within the solids, we have the formulation development, analytical development and clinical development. Project management, PMO sits outside in the newly created R&D operations vertical. RA or regulatory affairs is a vertical by itself supporting all technical groups. That's in terms of the functional group structure within the vertical and the new structure within

R&D. In terms of the markets we support, we support all markets where Hikma is present. We support MENA, all 18 markets within MENA, United States, Europe, and Canada. What I'm showing here is the footprint or the R&D footprint that we have. Central R&D is located in Amman, Jordan. We have two sites. General formulation development is in Bayader and the potent high containment development site is in Sahab. In addition to central R&D or the Center of Excellence we have in Amman, we have six other tech transfer R&D sites in Saudi Arabia, Egypt, Tunisia, Algeria, Morocco, and of course the United States. Two of those sites, in addition to tech transfer, they have local development capabilities whenever we deem it is more advantageous or more useful to develop it in these markets. Those are United States and Egypt.

Guy Featherstone:

Brilliant. Thanks, Jaber. So clearly a very global setup you've got. On Oral Solids in particular, I think some investors may think of Oral Solids as maybe the more commoditised part of generics. Where do you see the value and what makes this a platform for us in its own right?

Jaber Qasem:

So being commoditised is somewhat of a real perception, but I think a more accurate description is very competitive. There is the commoditised component of the solid dosage form and there is the high barrier to entry more complex component to solid dosage form. Nevertheless, the value is absolutely there. And what we are sharing with you here is the loss of exclusivity from the United States and Europe for non-injectable dosage forms over the next 15 years. And as you can see, 88% of those in the US are coming from Solid Orals and 72 are coming from Solid Orals in Europe. This amounts to about more than $250 billion over the next 15 years in the US and more than $70 billion in Europe. This is key and this is the case now and this is the case in the past. And we believe, I believe that it'll continue in the future.

And the reason behind that, I draw from my background in developing new chemical entities and the way we go to choosing dosage forms. Developing new chemical entities, the main objective is getting that new molecule approved for that particular indication. And the number one dosage form of choice is Oral Solids. The formulation development is secondary if not tertiary objective. You only deviate from Oral Solids if you couldn't deliver it, meaning you have limitation in terms of physical chemical properties where the API is not bioavailable, there's a first pass metabolism, it's not stable, or the pathogenesis of disease for that particular molecule for that particular indication dictates local delivery such as topical or inhalation. So the value is there now and it will continue in the future dictating the need for that particular vertical. Now, when we talked about commoditised and competitive, I want to address this by saying correct, it is very competitive.

Nevertheless, we believe we can compete. We have the team, we have the success track record to be competitive and extract some value from this high value vertical for Hikma.

Guy Featherstone:

Right. Yeah. That makes a lot of sense, Jaber. Thank you. So we've got the team and then how about capabilities? What capabilities do we have that make the Solid Orals platform stand out? How defensible do you see those?

Jaber Qasem:

We have a broad range of capabilities basically to allow us to develop any oral solids that we choose to tackle. We have broad range of technology. And in terms of development capabilities, we have general formulation development and manufacturing capabilities. We have potent or high containment development and manufacturing capabilities in different sites, Sahab, in the US as well, and in Egypt and other MENA markets. We have development and manufacturing capabilities of controlled substance. So that's in terms of footprint development capabilities. In terms of organisational capabilities, we're not just an R&D organisation, we are vertically integrated. We have our own API business, which I mentioned earlier, which we call Hikma Chemicals. We have a strong clinical team that allows us not to only tackle the standard healthy volunteers bioequivalent studies. We have executed patient base B studies successfully. We have done clinical endpoint bioequivalent studies and we've done phase 4 clinical studies in MENA. So we have a strong clinical team.

In addition to that, we have our own CRO that gives us a leverage and an advantage in terms of faster turnaround and low cost CRO. So that's in terms of the organization. In addition to that, and again, we have a strong cross collaboration. The know-how is not exclusive to the solid. Yes, we have strong know-how in the solid vertical, but we have as strong in the injectables and we have a strong know-how in the inhalation vertical and in chemicals. And we leverage those for products that are hard to develop, hard to formulate, and gives us an advantage and a high barrier. And I will share an example down in a little bit where we leverage those know-hows in a very competitive manner. So in summary, we have a broad range of capabilities.

None of them stand out by itself. Other organizations have API vertical integration, others have potent capability or controlled substance capability, but collectively we can serve the whole spectrum. But what I think stands out and differentiate us is the way we deploy these capabilities to benefit Hikma pipeline and our product.

Guy Featherstone:

Brilliant. Yeah. Thanks. Thanks, Jaber. We'll get to those couple of case studies actually shortly. Before that, so you said you've been running the platform for the past four years. We've seen a lot of strength in the launches that we've had in MENA driving really strong growth there, which is great to see. More recently, Hafrun has become the Chief R&D Officer. So my question is what changes have you made firstly since you joined four plus years ago, and then what changes or evolutions have taken place since Hafrun took over the global role?

Jaber Qasem:

Well, I'll give you a tip and the audience a tip. R&D is not that complex when it comes to objectives. Whatever organisation you join, it has the same objectives, pipeline and execution. You want to build the highest return investment pipeline and you want to deliver it in the most efficient, cost-effective way possible. So with these two objectives, strategies of achieving this objective change from one organisation to another, from one leader to another, but these objectives are the same. When I first joined Hikma, the first thing we've implemented is a return on investment threshold. If our objective is to have the highest return investment, we created and we implemented a threshold. And that way we ensured we are having a high value of pipeline.

And even strategic products, I always have this conversation wherever I go. If the product is strategic enough for you to advocate, it should be strategic enough for you to put a forecast next to it, not us commit capital to it. So that worked very well for us in MENA. In terms of selection as well and pipeline, we focused on high barrier to entry products that we can leverage our capabilities - products with difficult to source APIs, products with complex clinical studies, products that has IP that requires significant know-how for a workaround, and that help us build that high value pipeline.

Nevertheless, complexity is not the only value available. There are significant value for lower complexity products that we also pursue. But to pursue these, we need to go to the second component or the second objective of R&D, which is execution. Because the differentiator in these products is not technical, it is speed. And for those, we have implemented multiple performance indicators that helped us track and improve. And one of the key challenges of R&D, and again, is our life cycle between selection all the way to commercial realisation of that pipeline. We're talking about three to five years on average. And we don't need to wait five years to see if we are on the right track. We implemented many interim performance indicators such as, I'll share a few, time to first experiment, BE success rates, cycle times, lots of cycle times without getting into details. And by tracking those, I always say, if you don't track it, you cannot improve it. And over the time we were able to improve our processes, and this is what we did in the execution.

And just to give an example, when we first joined Hikma, our team over the past four years has not grown significantly. It's almost flat headcount, but our output went from three in-house development to, right now, last year we've had 13 in-house development from central R&D. So with almost flat headcount, that talks about execution.

Finally, of course, our boss is here. Hafrun, when she joined, she is a joy to work with. And two things, something we've done in the past and she helped advocate and push for, which is co-development or

development for the US. We've done development in the past, but it's always been, let's look at the pipeline and let's take this one for MENA. What Hafrun's done is structuralise this workflow. And when I talk about execution, our organisational structure is a component of improving execution. Because what we did is we formalised a workflow that helped us leverage our core structure in MENA, but more importantly, leverage our know-how in MENA. So that's a lot of components to Hafrun contribution, but to me, that's one of the main points relating to this conversation around the vertical.

And a second one, and I say it lightheartedly, her being an R&D person, we can be more aggressive, because she knows the risk reward in what we are doing. So she can support us. We want to be more aggressive in terms of pursuing especially high value products with first-to-file opportunities.

Guy Featherstone:

Brilliant. Thanks, Jaber. And then maybe a bit on Jordan. So obviously you are based in Jordan, your team's in Jordan. How does a team base mainly in Jordan develop products for the US, other highly regulated markets? And maybe what advantages do you think that gives us?

Jaber Qasem:

I'll answer this question at the risk of coming across a little bit biased, being Jordanian-American. But in all honesty, it is the right call. It's a logical one to make. But to set the stage, I'll go in three phases. First is that I'll go to the origin story of the pharma industry in Jordan, something I'm proud of being Jordanian-American.

From the get-go, the Jordan market is in the small side. From the get-go, whether it's regulators or pharma entrepreneurs like the late Mr. Samih Darwazah, they realizes the industry will be an export based industry. And therefore from inception, we adopted and we took the best and the highest standard globally, whether it's coming from the US or Europe, in the way we regulated our industry. So we are a highly stringent regulatory environment. The JFDA is, as I said, has the same standard for the most part, and sometimes it's a little bit more strict because we're taking from US and Europe. Sometime we find ourselves in the stricter version of that. So that's the industry.

Second, talking about Hikma itself, very few people know that we entered the US market in '91 and our first commercial product manufactured, developed and manufactured, in Jordan to be launched in the US took place in '96, well before any of our Indian competitors who started in the 2000s. So the concept of development in Jordan, we had a FDA site approved in Jordan in the '90s. So the concept of developing product for the US in Jordan to be launched in US has always been there, but it's never been an export model. Hikma, if you notice that we have a footprint across MENA, we believe in localisation. We believe in being good corporate citizens in any community we enter and we serve. So that's the second component.

The third is something near and dear to my heart, which is the people that we are working with. Jordan has one of the highest educated workforce out there. We're cost competitive, and there's a sense of pride working in Hikma. And the track record that we have done in Jordan, and that proves it. And by the way, most of the team that is in Jordan right now, all of them have worked for the US, have done US development, including myself. I was recruited.

And the last point, which is advertising Jordan, it's a great place to live. It's easier to recruit to. We recruited myself from the US, we recruit from Europe, and we recruit from South Asia. So it's not a hard place to recruit talent whenever we need it. We have plenty of talent here, but whenever we want to augment talent, we have no difficulty doing so. So that's why I think the decision to go to Jordan for central development is a logical, well-supported decision.

Guy Featherstone:

Amazing. Yeah, a lot there. And yeah, thanks for bringing up that.

Jaber Qasem:

I hope I wasn't too biased.

Guy Featherstone:

A little bit, maybe, but no, I think that's super interesting. And the 1996 first entry, so some 30 years ago we were bringing products into the US. I think it really demonstrates the pedigree we've got coming out of Jordan. Before we move to my next question, I also just wanted to pick up, you said it a couple of times, and I think it is an important point to pick up on is your ability and the team's ability to get first-to-market approvals, first generics as well. It's clearly a core skill of ours, one of the reasons for the strong performance. So I don't know if you've got anything more to add on there. Is it fair to say we can expect more of these kind of opportunities to come in the future globally?

Jaber Qasem:

Absolutely. This is something we're looking at. Again, first, it's very competitive. I mean, and one of the things that gets raised a lot about the Indian competitors and can we compete with India, it's a fairly legitimate question. I always say there are two parts to this question. One, can you compete in development and can you compete in manufacturing? And they're completely separate questions. The competing development, there is no advantage. Scientists are scientists. If they have the resources and the tools, they can compete with anybody regardless of their location.

Yes, in the manufacturing side, they are more competitive, but our cost structure here in Jordan is also somewhat competitive. So we're focused on first to file and first to market opportunities, and this is part of our pipeline right now. And just FYI, 60 to 70% of our filing and launches in the MENA region are first to market products.

Guy Featherstone:

Yeah, that's an amazing-

Jaber Qasem:

No promises that we will deliver that in US, but this is the reality of MENA.

Guy Featherstone:

Brilliant. The next question, I think we went into this a bit in our last session, so maybe a brief answer, but just on pipeline and in particular product selection and how you go about that, what your priorities are when you go about product selection.

Jaber Qasem:

Just like you mentioned, you guys went through it. Part of this restructure is not just the vertical, but also our work systems and our workflows. One of them is the pipeline. We standardised our process for pipeline selection the same way. The objective is the same, to have the highest return on investment selection process. The process starts similar to what Hafrun mentioned in the last session. It starts with ideation to be followed by assessment from IP, API, technical CapEx requirement to come up with a feasibility assessment, whether it's financial or technical doability. And this then later on shared with the larger team for nomination and selection. And once it's selected, it will go to product development. And we manage our pipeline through stage gates and we assess these programs and these stage gates. And if they are still feasible and financially compelling, we will continue. Rarely we have killed projects, but it is part of the process and it is the right thing to do if the feasibility changes over time.

So for the most part, we are doing the same. The only difference here is, again, with the solid, we've been doing more global programs. In the past, again, I mentioned that we've done development for the US, but it's been one or two products a year. We've had more than 13 to 15 selections so far for global programs.

Guy Featherstone:

Great, thanks. Okay, so Jaber, we'll have pharma specialists on the line today, but also quite a lot of generalists in the audience. And I always think to help tell the story, it's great to use a case study or two. And I know we've got a couple of no names based case studies to talk through. So maybe as a slide that

perhaps we can put on screen and then, Jaber, if you could just talk to these two projects, that would be great.

Jaber Qasem:

Absolutely. So we selected two case studies to highlight, product A and product B, to highlight a different aspect of the vertical within Hikma. Both are first to market within the MENA region, both have been launched in '26. Both are high barrier to entry products.

Product A, the challenge is the barriers to entry are threefold. One is it's a cyclodextrin formulation, which you'll take the API, encapsulate it into a larger molecule called cyclodextrin for the purpose of improving solubility and improving stability. We have never done this before. That was our first product. And the team were able to develop it and learn it and successfully develop the product.

Then comes the second challenge, which is lyophilisation. Solid dosage from don't know about lyophilisation. It's not a know-how we have, but we have our colleagues just across the aisle in injectables. They're experts in lyophilisation. We reach out to them, they help us develop the process and the manufacturer instead, and they help us not just only in the formulation side, in the process side, but they help us implement and put lyophilisers in the middle of a solid plant, which is a little bit of a new one.

And the third, the BE requirement is not as straightforward healthy volunteers. It was in patients, which a little bit more complex than your standard BE study. We worked the system and we developed the product and we were successful and we launched it this year. This was in-house and this product, it will be the first out-licensed product out of MENA where we have a signed deal for this product to Europe, and this would be the first in-house developed product in MENA for out-licensing. We're usually for in-licensing, but this would be the first out-license.

The second product I want to highlight... So the first one is leveraging the know-how and the capabilities conversation we had earlier with the injectables and the clinical. The second example is developed for MENA, but we also filed it in the US. The process, the original process, requires solid dispersion that uses a spray-dried process and lots of acetone, solvent-based process. And we didn't want to use solvent, so we wanted to walk away from that and used hot melt extrusion for solid dispersion. However, the challenge is hot melt extrudates tend to be on the larger side of particle size, and the milling is a challenge because the heat generated from milling mills, they halve the extrudate, so we had to devise a unique milling, cryogenic milling machine that one of one did not exist before. We worked with our Swiss vendor where we've designed it and fabricated just for Hikma and we installed it here, where we immersed the hot mill extrudate in liquid nitrogen and uses a special stainless steel grade only used in nuclear reactor cooling equipment, so we don't know that part.

So we built that machine for Hikma and we are one of one and it sits right now in Sahab, and this product and this innovative part from our team not only allowed us to get the product, but the outcome, we have a lower cost of goods manufacturing process because we are not using all these solvents and we're environmentally more friendly. This product is approved and launched in MENA this year and tentatively approved for the US with the, I think settlement date is in '29.

Guy Featherstone:

Brilliant. And I think these are great examples of showing how leveraging, as you said, our injectables know-how, our clinical experience and developing these new technologies, we can be first to market in MENA, and the out licensing as well, so congrats on that. So I think Jaber, maybe that about wraps us up, but perhaps it would be great to hear what you would like investors and our sell-side analysts to take away from this session and more broadly about the Solid Orals platform.

Jaber Qasem:

Well, in general, again, your question about the commoditised component, I think it's very telling and I just want to highlight that there is significant value in the Solid Orals as we showed by the numbers. It is competitive, but hopefully I was able to demonstrate our ability to be able to compete, our track record of success within the MENA, we will carry forward global level. The decision to go to Jordan is a logical one, it just took some leadership from Hafrun to make it, but we're proud of it and we look forward to, we take a

sense of pride to be based in Jordan developing global programs. And I think that's the key message, I hope I did not miss much. So thank you.

Guy Featherstone:

I think you covered a lot there, very clear message. So thanks Jaber. So we do have time for a few questions. If there are any questions, I think I'm just going to hand to the operator to check on that please for Q&A. Thank you.

Operator:

Thank you. We'll now start the Q&A. If you wish to ask a question, please use the raised hand function at the bottom of your Zoom screen. As a reminder, participants can also submit questions through the webcast page using the Ask a Question button. We'll pause for a moment to allow the queue to form. Our first question will come from Giang Nguyen from Citi. Please unmute your line and go ahead.

Giang Nguyen:

Hello. Thanks for taking my question and I hope you all can hear me and thanks Jaber for the presentation. I have two, please. The first one I would like to ask if you could elaborate more on your competitiveness against Indian players. You touched upon cost structure in Jordan earlier for example, but it would be great to get more colour on both the development and the manufacturing sites. And my second question is for Jaber again and Hafrun, if you're on the line. As we have been talking more about the broader momentum and upward trends in the broader injectable markets, how are you fighting R&D allocation for Solid Orals in recent times? Thank you.

Jaber Qasem:

So I'll quickly answer the first question and I'll pass it to Hafrun. The first one, I will touch base on it in terms of competitiveness. The core structure in Jordan is somewhat competitive, we're not India based like India, but we're also not like Europe or the US, to some extent we're competitive. But I mentioned also that in the R&D component, speed and ability to succeed and be first to file or first to market, is where competitiveness comes in the R&D section. Our manufacturing, we've been manufacturing for the US for a long time, we have excellent quality standing and we are also competitive now compared to Indian manufacturing. I'll let others speak to it rather than R&D, but I think I wanted to draw a distinction on the R&D side, success and speed is the key variable for competitiveness, not cost structure.

Hafrun Fridriksdottir:

Yeah, maybe if I may add to that, can you hear me guys?

Jaber Qasem:

Yes.

Hafrun Fridriksdottir:

Okay. If I may add to it as well. Of course it's just to add to what Jabar said with regards to the manufacturing, it's not all about cost. We strongly believe it's very important to produce domestically for the markets which we are in, and that's why of course why we have been building all this manufacturing capability in US, in Jordan, in many of the MENA markets, and also in Europe, so we strongly believe it is very important to be where the market is. But I think the second question was with regards to how we allocate the R&D funds between the different segment, between Solid Orals, between Injectables, between Semi-Solids and Liquids and Inhalations, and we of course, we do that based on value, we allocate the R&D fund based on the return on investment and NPV numbers, but we also are very well aware that we also need to support all those markets, all those different segments which we are trying to grow.

So it's not necessary only based on NPVs and return on investment, but we are also making sure that we allocate a decent amount of R&D funds to those different markets and different segments.

Giang Nguyen:

Thanks guys.

Operator:

Our next question will come from Victor Floc'h with BNP. Please unmute your line and go ahead.

Victor Floc'h:

Great. Thank you very much. Can you hear me well?

Guy Featherstone:

Yeah, we can.

Victor Floc'h:

Yeah, great. Thank you very much. So maybe first question on the recent R&D investment. I think you've previously indicated that the increased R&D investment will start paying off from 2028. So looking at the maturity of the overall solid pipeline today, how comfortable are you with that timeline? And my follow-up is on the split between internal development and versus licensing. Should we expect a greater proportion of future overall solid launches to be developed internally? And I was wondering if you can discuss how you decide whether to develop a product in-house or partner with another generic manufacturer, is it just down to speed to regional market or is there anything else that come into your decision? Thank you very much.

Hafrun Fridriksdottir:

Maybe we can take the first shot at this question. Jaber, you can add to it if you want to. So of course we want to make sure that we have a balanced approach between internal development and business development or co-development deals. So I mean my preference is of course to develop everything internally if we can, if we can develop it internally. I mean, even though we have a broad capability, especially in Solid Orals, we don't have all the capabilities, for example, in the injectable R&D yet, we are of course working on building up some capability, but we don't have all the capability yet. So if we have to sign a co-development deals, for example, for some of the long-acting injectables, then of course we will do so. We will of course look into what's the best for the company in each and every case, but my preference of course is to try to develop as much internally as we can because I strongly believe that's the best outcome for the company.

The return on the investment will be the highest if you develop a product and produce them internally. But we are of course, we are open to a business development deal, co-development deal, and we sign many of those for the MENA market, for the US market and for the European market, and we are very happy with all our suppliers, all our vendors, and we have a very good and strong relationship with many of our partners, and we will make sure that that will continue.

Guy Featherstone:

And I think the first part of the question was just on timing on return on investment. And I can maybe start it and maybe Hafrun, jump in. I think in terms of when we've talked about '28, '29 and onwards picking up, that's certainly more relevant for Injectables, for Respiratory, where there's more investment going in. And I think in Solid Orals it's been pretty stable throughout. I don't know, Hafrun, if you had anything to add to that.

Hafrun Fridriksdottir:

But of course, I mean, I missed that part of the question, I'm sorry for that. But of course it takes time to develop a product and independent from if it is Solid Orals, if it's Injectables, if it's an Inhalation product. And let's say on average, let's say for example, if it takes one, one and a half year to develop a Solid Oral, then of course you need to file it, it takes at least a year to take it through all the regulatory procedures, and in the end of the day, when you have it even approved, then it could be some IP which is hindering you in

launching the product as soon as you have the approval. So I would say it's very normal even for simple product that it takes up to three years from the start until the product is on the market, I think that's very, very standard and very normal.

But as Jaber mentioned earlier, we of course always want to do everything as fast as we possibly can, and that's why we are so focused on first-to-file, first-to-market opportunities.

Victor Floc'h:

Great, thank you very much.

Operator:

Thank you. Our next question will come from Sebastien Jantet with Panmure Liberum. Please unmute your line and go ahead.

Sebastien Jantet:

Good afternoon everyone. Thank you for taking my questions. Two questions if I may. Just turning to slide seven, I think you set out on there 140 active projects, 50 new filings and 40% of the portfolio in complex and differentiated. What would those numbers have looked like three years ago, would we see something very different there? And then the second question is just looking at the loss of exclusivities, and there's obviously some quite big numbers there, historically you pursued a mixture of bigger products, smaller products, how does the mix look in terms of the kind of active projects that you're working on at the moment in terms of say average peak sales of the products you're looking for?

Jaber Qasem:

So I think you're referring to the slide where we... Okay, so the numbers about three years ago, the 50 represent, the total 50-plus represent MENA five major market, US target filings, and the European filings. The European filings was, I'm not sure if I can divulge the exact numbers, but was zero then. MENA three years ago, I refer to the Jordan submissions about four years ago, it was three.

In terms of central development, right now we're standing at, last year we delivered 12, I think or 13. And this year we're also targeting 13, 14. All record numbers with almost similar headcount. For US, I don't know the number about three, four years ago, but I know the... Can I share the numbers with the US? Guy? Targets?

Guy Featherstone:

Yeah, I think that's -

Jaber Qasem:

Yeah, so last year in-house development, and I would refer to in-house development for US, the filings were three products, two from US and one from Jordan. This year our target is five and I think we're in position to deliver five and it's based on our decision whether to do six or not, and we are still debating. So this is where we are in the US for this year. And our target next year we have not finalised, but we expect significant growth compared to this year and past.

Hafrun Fridriksdottir:

May I jump in, sorry for that, but I think of course he's talking about the solid orals and of course we have number of injectable filings as well in US and in Europe as well and of course in MENA and the same for the semi-solid and liquid. So he's only referring to the solid orals.

Jaber Qasem:

And only in-house solids, not in licensed solids, not co-development, not third party manufacturer. These are in-house development oral solids.

Guy Featherstone:

And then Seb, the second part of your question was on the LOEs and the mix looking forward in terms of product sizes that we're going for.

Sebastien Jantet:

Yeah, that's right. Yep.

Guy Featherstone:

I don't know, Jaber or Hafrun.

Hafrun Fridriksdottir:

Yeah, maybe I can start. Especially for the solid orders, many of the product which we have been selecting, let's say this year, and Jaber mentioned that we have been selecting 15, 16 new global product this year. Many of them are first to market NC-1 opportunities. So we have been much, much more focused on filing or working on first to file and first to market opportunities, both for the US market, but also for... That's something which has been done in the past also for the MENA market, but that's clearly our focus. And of course those numbers which you saw on the slides are of course those are the brand values and we know of course very well that normally when the generic launches against those brand product, the price erosion in US is of course significant and that's not a surprise to anyone.

So we know that this is not necessarily value which we will be seeing when we will be launching those products. But this is just to highlight that there is a significant value in those product today as it was 10 years ago. So nothing has really changed there, that the solid oral platform is extremely important and will continue to be very important moving forward.

Sebastien Jantet:

That's really helpful. How should we think of that mix? Should we think of that mix as being a few large products and a few smaller products? I get it's all about first-to-market, but presumably there's also a mix in there because they've got to make a return and drive growth in the business.

Hafrun Fridriksdottir:

I think that’s exactly how you should think about it. It will be mixture of both small and hopefully of course larger opportunities as well. I have always believed and will continue to believe that it's very important to have multiple shots on goal. Because if you just decide to select three or four product because the brand value is really big and significant, then if you're not the first against those products, then of course the competition will be eating you up. But in many cases going after smaller products which you have fewer companies going after is as valuable and even more valuable than going after those biggest ones. So I strongly believe in having a mixture of both and I think that's the best setup and that's what we are trying to do today.

Sebastien Jantet:

Brilliant. Thank you very much.

Operator:

Thank you. As a reminder, if you wish to ask a question, you can use the raised hand function at the bottom of your Zoom screen. And for those of you who have joined us via the webcast player, you can submit written questions using the ask a question button. Our next question will come from Christian Glennie with Stifel. Please unmute your line and go ahead.

Christian Glennie:

Thanks all for taking the question. I guess just on that first-to-file, first-to-market opportunity, you talked about that 60% to 70% in MENA, but what might an equivalent proportion be for the US market maybe

today and/or maybe is there a five-year ambition for what that sort of mix of the first-to-file opportunities will be in the pipeline? And then the second one was just to pick up on what you were saying earlier, Hafrun, just are you still minded to go after those really big off-patent products where you may end up being one of 20 products in the market even if the potential opportunity is still quite large overall or are you a bit wary of those sort of opportunities? Thank you.

Jaber Qasem:

I'll take the first one about the mean and I'll let you the second one, Hafrun. In terms of the 60, 70, I was referring to real numbers of launch products, not the pipeline. The percentage was a product of the selection process that gave us the 60 to 70. We don't go out there looking for a percentage to be first-to-market. Of course, we would love all them to be first to market, but we're going after value and our ability to deliver this value. For the US, I don't think we have a preset ratio for the percentage of the first-to-market or first... But this is something we're pursuing and we're looking into and wherever the percentage might fall is irrelevant to our ability to deliver the value in the pipeline that we selected. So hopefully that answers your question. Hafrun, the second question, the second part.

Hafrun Fridriksdottir:

Yeah, maybe I can just add a little bit to this. I mean, we have been more focused on selecting NC-1 products now this year than what Hikma was in the past. And even though of course in many cases the launch dates for those products can be up to seven, eight years out, but we still believe that this is something which is important. Are we still going after those big brand products which we could in some cases see up to 15 or 20 competitors on? Yes, we are, but we are also looking for more niche opportunities, as I mentioned earlier, smaller products which maybe no one has been able to develop or not necessary product which are losing exclusivity because of patent or anything like that.

But those are product which no one has been able to develop or there are very few competitors on the market. So we are also going after those even though they are smaller opportunities. So we try to make sure that we have the right mix because at least that's something which I believe is the right way of building a pipeline is to have a right mix of opportunities, both big, both large, near term opportunities which are going off patent a little bit later because you need to find a way to build up for the future.

Christian Glennie:

That's great. Thank you.

Operator:

Well, there are no further questions, so I will hand back to Guy for the closing remarks. Thank you.

Guy Featherstone:

Thanks operator. And yeah, thank you Hafrun and Jaber for joining us on today's call and thank you to everyone who dialed in and for your questions. The third and the final event in our R&D spotlight series that will cover Injectables and is scheduled for 2:00 PM GMT on Wednesday the 16th of December. So we look forward to seeing you all then. Thank you very much.

Operator:

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