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**NOVEMBER 2025 HIKMA PHARMACEUTICALS PLC TRADING UPDATE
CALL**

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CORPORATE PARTICIPANTS

- **Riad Mishlawi** *Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director*
- **Khalid Nabils** *Hikma Pharmaceuticals PLC - Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

- **Operator**
- **Zain Ebrahim** *JPMorgan - Analyst*
- **Charlie Haywood** *BofA - Analyst*
- **Christian Glennie** *Stifel - Analyst*
- **Victor Floc'h** *BNP Paribas Exane - Analyst*
- **Beatrice Fairbairn** *Berenberg - Analyst*
- **Kane Slutzkin** *Deutsche Numis - Analyst*
- **James Vane-Tempest** *Jefferies - Analyst*
- **Seb Jantet** *Liberum - Analyst*
- **Sidhartha Modi** *Barclays - Analyst*
- **Miles Dixon** *Peel Hunt - Analyst*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to Hikma November 2025 trading update. (Operator Instructions) I will now hand over to investor relations for opening remarks. Please go ahead.

Unidentified Company Representative

Thank you. Before we start, we'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 Principal Risks and Uncertainties section in Hikma's latest annual report.

And with that, let me hand over to our CEO, Riad Mishlawi.

Riad Mishlawi *Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director*

Many thanks. Good morning, everyone, and thank you for all joining this call regarding our November trading update that we have published this morning.

Before we come to our queue of questions, I want to briefly cover a handful of key points in the update. Firstly, the business is performing well, and we are on track to meet our 2025 guidance. It is really encouraging to see all three businesses doing well.

Secondly, we know that there is a keen focus on the Injectable margins. We have always achieved industry-leading margins, and we are now confident that this will continue. But we have said this morning that we now expect the Injectable margins to be around 30% over the medium term.

I want to very clearly explain what is behind this change, particularly given that we have delivered margins above the mid-30s in recent years. There are four key reasons Bedford, R&D, partnerships, and geographical expansions.

Let me take you into each one in turn. So, first, Bedford. As a reminder, we bought this US site through the Xellia acquisition last year. While this capacity will be a welcome addition to our US operations, we have seen delays in machinery largely driven by global supply chain issues. This means that we now expect the site to be operational towards the end of 2027, with commercial production and revenue accelerating in '28. We will keep manufacturing Tyzavan as a third-party until this time.

Point number two is R&D. Our plans from 2026 onwards see a meaningful pickup in R&D spend. Today, we've announced a restructuring of the group R&D function. And we are now looking closely at R&D spend allocation and ensuring that we are positioning ourselves to succeed when it comes to the pipeline, part of this involving spending more than we had done in recent years. This is a great thing for us as the pipeline is crucial for our growth and with Hafrun running this business and the new facility in Zagreb, I'm really excited about what we can deliver in the future.

The third reason in our strategy of leveraging partnership, both in terms of commercialization and manufacturing. For example, Liraglutide, this is an important GLP-1 and has been a good contributor post launch. We partnered to launch this product which really removed all the risk on us. But with shared economics with partnership, it means that the margin will come at a lower rate. The same will be the case for our biosimilar products, important products, good contributors, but at lower margins. These are all complex products and partnerships help us bring those to the market more quickly.

The fourth point is our fantastic growth in Europe and MENA. They're excellent markets, and our confidence in them has only grown in recent months. But again, the margins here are lower than the US, still very healthy, but the outsized growth in ex-US will impact the margins.

One final point on Injectables as part of the broader restructuring, Bill Larkins has stepped down as president, and I will run it on a temporary basis until his successor is appointed.

I'm excited by what I have seen. The business has exciting prospects for future growth that can continue to deliver strong, sustainable industry-leading margins.

Finally, at a group level, we are revisiting our medium-term expectations today, primarily to reflect the shift in the Injectable margins.

Let me pass it to Khalid just to step through those details.

Khalid Nablsi *Hikma Pharmaceuticals PLC - Chief Financial Officer*

Thank you, Riad. Our 2024 through 2027 group revenue gain of 6% to 8% is now expected to be at the lower end of the range which is in line with current consensus. 2024 to 2027 group core EBIT CAGR is now expected to be 5% to 7%.

The EBIT revision is largely reflective of our revised expectation on timing of going fully operational in Bedford as well as our updated assumptions on the Injectables margin as already set out by Riad. This will be partially offset by an even better performance from Hikma Rx which is being driven by the strong base portfolio, a growing pipeline, and our CMO offering. The margin for Rx could go up to 20%.

This change to our group core EBIT guidance reflects a low single-digit percentage downgrade to consensus group core EBIT for 2026 and 2027.

Riad Mishlawi *Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director*

Great. Thank you, Khalid. I want to finish with a reminder that we are maintaining our target of reaching \$5 billion of group revenue in 2030.

This ambition is supported by our future confidence in the Injectable business and the four specific points that I had made relating to that. It also reflects our leading position in MENA with our world-class branded business. And the outlook here is fantastic as we continue to take share, launch product, sign partnerships, and ultimately deliver profitable growth.

And it also takes into account that our Rx business remains on a strong footing. Product across the base business continued to grow well, with more complex products in our respiratory and nasal spray categories underpinning our performance.

So that's the summary. Let's stop here and hand over to your questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Zain Ebrahim, J.P. Morgan.

Zain Ebrahim *JPMorgan - Analyst*

Hello. Thanks for taking my question. My first question is just on the overall for 2026. It sounds like you said low single-digit core EBIT, but the consensus is what you're thinking for the next two years. So are you expecting to see profitable growth in both 2026 and in 2027? It would be maybe the first question.

And on the second question, just in terms of Rx and the increased confidence in Rx margins over the midterm, how much of that is being driven by the updated agreement with Jazz over the Xyrem royalties and how much of that is being driven by the underlying Rx CMO?

Khalid Nablsi *Hikma Pharmaceuticals PLC - Chief Financial Officer*

Yeah. For 2026, if we look into even all the segments, we'll see a strong growth. Even for the group in general, we will see a strong growth in 2026. So all three businesses are growing. Even the Injectable business, we are lowering the margin but still going to show growth.

As I mentioned, the generic Rx is going to show a growth where margins are going close to 20%, which is a very strong growth. And this will continue in 2027.

In terms of our medium term guidance, the shift, and as I mentioned, is a low single-digit downgrade to the consensus. And it's a result of shifting execution some of the plans from one year to another. So this is what caused, like, you have some operational cost in one year, but the associated revenues will come on the following year which is 2028.

So what's driving the growth in Rx is we have a strong portfolio. The base business, we have solid products. We have a pipeline. We have the CMO business which we are going to get as well -- grow the business in '26 and '27. We have services that we are now doing for our CMO partner. So there are different, I would say, elements for growth for the generic business. And now, it's a very, I would say, healthy business providing healthy margin to the group as a whole.

Riad Mishlawi *Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director*

Yeah. Just to add to this one, I think the strategy of the Rx that we had designed a couple of years ago, we're seeing the result of that. As we had mentioned before, we had talked a lot about that, what were the strengths of the Rx and how can we capitalize on it. And one of them was can we use contract manufacturing and in this case, we had told the market that we had signed a meaningful contract manufacturing. This is coming to fruition in the very near future, as we speak, actually.

Again, we wanted to strengthen our R&D. And we had mentioned that the spend on R&D in this division has increased significantly. And in fact, from '24 to '27, we expect an increase close to 70%. And we're also looking at the base business and getting more equipment, getting more capacity just to make sure that we are responding to the demand that we have in the base business.

So every element of this business had worked out right. Every element had worked out exactly as we designed it. And this is what we're doing with the rest of the company. Each division has its own strategy and it has its own elements of what we need to do, including the Injectables and the Branded as well.

Operator

Charlie Haywood, Bank of America.

Charlie Haywood BofA - Analyst

Thanks. Charlie Haywood, Bank of America. I have two on the Injectable margins please. So just in terms of the updated outlook for the 30% midterm Injectable margins, could you help us understand, I guess, why now is the time to update the market on this outlook versus, I guess, sort of prior [looser] commentary around mid-30s. I think it's not entirely clear what has changed within your midterm versus, let's say, six months ago when you gave the midterm outlook there.

And then the second one is the cadence of Injectable margins from here, to that 30%. Is it fair to think of around the 30% levels where we should think you'll get to by 2027 and we're sort of straight line from 32%, 33% from here, to that 30% in '27? Or how should we think about the cadence of that Injectable margin development? Thank you.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Yeah. I think it's a good question. What happened in the last, I don't know, six months that would drive us to make that statement, I think several things. But the main thing about it is the Bedford facility.

Bedford facility, we're counting on it. It was happening really at the borderline of the medium term. So what was happening -- the whole action was happening in '27. That's when the facility is going to start. That's when Tyzavan was going to be transferred to. We are going to be making a lot of products there. Contract manufacturing will be expanded into this facility. So there were many things happening in 2027 that we were counting on in the past.

We had been notified by the suppliers of the machinery that that will not be possible. It would be a delay of six months. So that shifted into '28. So nothing really has changed in the plan. It's just a shift in the plan because the facility now is not going to be on in '27 which means all those benefits that we were counting on to happen in '27 will be shifting in '28. And this is why we are reiterating our 2030.

So we, although there is some softness in the margins today, we still say 2030 we will be able to get to where we need to get. And that's because we believe in the '28 beyond that when we have everything online, our strategy is starting to pay off, our spend on R&D is starting to pay off, all of the stuff that we're doing now I think we will see a big acceleration there.

Also, the other point is we really want to give the market a number that we are very, very, very confident that we can get. We want to make sure that we will do better than this number. But we want to give a number that we don't -- there's a lot of focus on these margins in the past years, the Injectable margins has always been a big focus. And that's why we want to make sure that whatever number we are going to put against it, it has to be achieved, and we have to be confident that we achieve it and never come back -- and try to do better --

Khalid Nabils Hikma Pharmaceuticals PLC - Chief Financial Officer

It's similar to what we have done with the Rx business in the past when there was some concern. And we set a floor of \$100 million to \$120 million of EBIT. And we continued executing and delivering and over-deliver on what we promised the markets. So the 30% is the floor, around 30% is the floor.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Going back to how the cadence is, I think, we just need to follow what we are guiding. 30% is what we're guarding right now. Hopefully, we can do better. But I think this is where we want to be, and this is where we feel very comfortable of achieving. But of course, we will be really looking to do better. But for now, I think we want everybody to focus on the 30%.

Charlie Haywood BofA - Analyst

Okay. Thank you.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Which is, by the way, it's still very, very high margins for this business, compared to the industry standard.

Operator

Christian Glennie, Stifel.

Christian Glennie Stifel - Analyst

Good morning, guys. Thanks for taking the question. Maybe just to follow up there specifically, just a further clarification. Are you implying that both margin cadence for both Injectables and generics Rx, is it 30% then for 2026 for Injectables margin? Or is there a sort of 30% by '27 scenario? And does the Rx margin similarly step up to 20% in 2026? Or is there sort of more a medium term progression to 20%?

Khalid Nablsi Hikma Pharmaceuticals PLC - Chief Financial Officer

Yeah. Actually, we are not giving guidance today on 2026. But I think we are happy to assume 30% margin for this business from now until 2026 on the medium term. And a similar case for the generic business, but it will accelerate and hopefully, it will expand in the following years. But again, we are not giving guidance at this stage. But we are confident in achieving the 20% in '26 for the generic business, close to 20% for the Rx business.

Christian Glennie Stifel - Analyst

Thank you. And then I guess in terms of the R&D investment as it relates to Injectables, just a bit more on that, what are some of these areas of investment? And what's the sort of potential benefit of that in terms of margin?

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

When it comes to R&D, I don't think it is specific to the Injectables. It's something that we had identified a while ago that we need to increase our spend in R&D in all divisions. So in all divisions, significantly in the Rx, for example, we have gone, as I mentioned, if you compare it to what we're planning to do, it would be an increase of 70% in the next medium term. And the Injectables will be around 50%.

So it is a significant increase. But we believe that this increase is necessary. In fact, we believe that it's overdue. I think we should have probably started spending money on R&D much more before that. But I think now, we really believe that this is something that is needed for the business, is needed to continue the margins that we have, continue to (inaudible) the growth that we have. And it's not only the spend. It's also how you're organized, how you are going to leverage the experience of others, how you are going to make sure that there is a program that is extremely rich in the company. And that's why we not only increased the spend, but also restructured all R&D.

I think now, the R&D is one unit. We will benefit from all the experiences out there. The important part is, if you remember, the acquisition of Xellia. Zelia, added a very nice center in Zagreb with 80-plus people, scientists there that are very competent. We want to build on that. So that's what prompted us to say, listen, let's just put the focus on R&D right now. Let's spend more money on R&D. Let's reorganize ourselves. Let's get people that are competent and go after complex, challenging products and not be satisfied with just going by the low-margin simple products. And that's why the shift and the spend is there.

Christian Glennie *Stifel* - Analyst

Thanks. And then maybe one quick final one on Tyzavan, just some expectations around -- obviously, you started to roll it out now, some expectations around that maybe for '26. But in terms of absolute revenue and/or the margin impact of Tyzavan, specifically, on the business? Thanks.

Riad Mishlawi *Hikma Pharmaceuticals PLC* - Chief Executive Officer, Executive Director

Well, I can't give you exact numbers. But what I can tell you is that Tyzavan is a very important product for many, many reasons. One, it is an important molecule to start with. This is something that hospitals depend on. There's probably over 40 tonnes of vancomycin that gets sold one way or another. Almost all of that gets converted from powder to liquid form before they're administered to patients.

We have a product, and it's unique in the market. It's room temperature that's stable for quite some time, 16 months. It's got all different strengths because vancomycin is administered to a ratio of body weight. So the ease of use of this product is fantastic.

It is a patented product. It's very challenging to make, and so forth. I can say a lot of things about this product. So we're very excited about it. We are excited that we will be in a market where we can have the demand that we need. We've already started with a similar product before, which is vancomycin, ready-to-use. This one is much more superior than that one. So we know the market well. We know how this market will play out.

We hope the growth will be as steep as everybody's thinking. But we're very excited. This is a great product, and we're excited about it. And we're concentrating right now on a very healthy launch that will start as we speak today.

Operator

Victor Floc'h, BNP Paribas.

Victor Floc'h *BNP Paribas Exane* - Analyst

Hey. Thanks so much for taking my question, Victor Floc'h, BNP Paribas Exane. So maybe first question on the recent announcement from Hims & Hers to launch, they are planning to launch an oral testosterone next year. So I was wondering if you could discuss whether it might further increase the competitive landscape there.

And my second question is a more bigger picture question on the back of the recent discussion from the FDA to streamline the biosimilar development and basically have the development time and cost. I was just wondering in that context, would you be able to comment on where biosimilars are going to fit in your strategic priorities? So now, you are basically working with partners, but could we expect that at some point you could move forward and become a bit more active in terms of development? Or is it like too far away for you? Thanks so much.

Riad Mishlawi *Hikma Pharmaceuticals PLC* - Chief Executive Officer, Executive Director

Can you please repeat the first one? We got the second one. I believe you're talking about the biosimilar strategy. But what was your first question?

Victor Floc'h *BNP Paribas Exane* - Analyst

First one was on Hims & Hers' plan to launch an oral testosterone next year in the US. I know that that product in the US has been quite under pressure lately. So I was wondering if whether like this new competitor might trigger more competition in 2026 for you.

Riad Mishlawi *Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director*

Let me start with the second question. I think, from the biosimilar strategy, as you know, we have two biosimilars that have been approved and the recent ones, I think. And we always knew that we will not be at the top five of those biosimilars when we launched. So our agreement with our partner considered the fact that we would have to have very competitive pricing in order for us to compete.

And I think because we had looked forward for this and we kind of predicted this, we were doing well. I think we're launching right now. We have the demand that we need. Actually, we have asked for more units from our supplier. I cannot tell you much about how this is going to pan out. But we know that we have the demand today. And we know that we have the right pricing for us to compete in. So there's not much to say about that. We had just launched one and we're planning to launch the other one in the next few months.

About the ondansetron market, as you know, ondansetron is probably the largest -- one of the largest units when it comes to units in the US. I think, if I remember correctly, it's about 70 million units. The problem with this product is that it's at very, very low price. I think it's in the \$0.20s, \$0.25, \$0.26, \$0.27 right now. Competition is coming mainly from China, I think, Chinese companies, through an agent, they're selling a lot in the US.

We used to make a lot of this product, but we decided to make it more of a capacity filler rather than the primary product in our portfolio. So it is an interesting product. It's something that we do well because we also make the raw materials. So we're backward integrated. We're also forward integrated. We can make a lot of it easily in our integrated lines. But still, the pricing has gone down to a level where we only look at it as more of a capacity filler rather than a strategic product.

Operator

Beatrice Fairbairn, Berenberg.

Beatrice Fairbairn *Berenberg - Analyst*

Hi. Thank you for taking my questions. I had a few questions, if that's alright. So firstly, would you possibly be able to quantify how much of the Injectable margins guidance expectations was related to Bedford versus product and geographic mix as well as setting out what you're seeing in MENA and European injectables markets. And then secondly, could you just clarify the timeline for bringing the other Xellia products in-house once the Bedford site is online and kind of what your expectations are there? Thank you.

Riad Mishlawi *Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director*

You want to take the first one?

Khalid Nabils *Hikma Pharmaceuticals PLC - Chief Financial Officer*

Yeah. It's highlighted in Riad's note. It's part mainly the Bedford costs that are bringing the margins down, especially for 2027. As we said, it's shifting. But there are several reasons. Increasing in R&D. We mentioned earlier this year that we have competition on some products like calcitonin and testosterone. The Liraglutide, we're seeing more competition on it. But this is a part of the business. And as we said, we are setting the margin around 30% as a floor. So we are not breaking it down between MENA or the geographic mix. Both are growing. We are investing as well in these markets.

So if you look now, we have operation and plants in Morocco, in Algeria, and we are building one in Saudi Arabia. These as well are incurring some costs. So it's a geographic mix. It's bringing the margins down, but we are investing for the future. So it's all investment related. And we are very confident of this business that will continue to deliver in higher than the industry standards margin.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Let me just add to this a couple of things. I think when it comes to the Injectables, the injectables had always been very much dependent on manufacturing. Capacity is very, very important. Manufacturing complex injectables was very important and historically, we had all invested in difficult-to-make products. And that sustained a very good growth for a long time.

So when you are impacted with capacity, your plants are impacted severely. And in this is exactly the situation in this case. We were depending on adding this capacity of (inaudible) online because we had a lot of products that needed to be transferred to a new capacity, especially, when we're talking about a product like the vancomycin that we're talking about. So when this gets delayed, the whole shift gets delayed. But the cost continues. Your facilities, you need to hire the people, you need to get your quality systems going, you need to get your IT system. There's a lot that you have to do to prepare for validating the facility and get it going. And all of that cost has to be prepared ahead of time.

But when you have costs falling in one year and the benefit falling in another year, it shows a big difference. And this is our case here. We're going from '27, which is our limit of the medium term, to '28. And we're stopping on '27. So it shows that big gap there. But really, this big gap is that we are incurring a lot of costs without benefit in return. You'll see this benefit very much in '28.

When we'll be having the Xellia products transferred? Again, Tyzavan is our most important product, and we are in the process of transferring that. It doesn't mean that we'll be ready. Of course, there's steps for it. So you transfer the methods, you transfer the manufacturing, you have to file to the FDA for approval. So all these steps we'll take. We started with those steps. And we think that we should be able to transfer the most important product in '26.

There are other products, there are smaller products, but we are all going to be working on the transfer in '26. In fact, we have about 40-plus batches of transfer products that will be made in the facility in the next, I would say, 10 months. So we are using that time to do the transfers, to do a lot of R&D, while we are waiting for the rest of the equipment to come in and validate the facility and become commercialized.

Operator

Kane Slutzkin, Deutsche Bank.

Kane Slutzkin Deutsche Numis - Analyst

Morning, guys. Just a quick clarification on the guidance. I mean, you said you're not giving guidance for '26. I'm just wondering the low single-digit cut you were referring to, I guess, in '27, just to confirm, that includes you getting close to 20% in margins in Rx? That's the first one.

And then just quickly on post '27, I mean, I don't want to look too long-term, but you have said you're still comfortable in your long-term. I'm just wondering, the mix in Injectables, the mix story, the R&D story, I guess, that's here to stay. But the Bedford piece is what you're calling out as the main driver. So assuming this is just pushing out the plan, I mean, do you see sort of long-term potential to get your margins back up to where they were? Or is it more a case of let's get the short to medium term guidance on spot now and deal with that at a later date?

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Well, we hope so. I think there is a -- we're doing a lot today to get us back to a healthy margin. But I think, before we promise something that we can't get, we have to ensure something that we can sustain, ensure the number that the market can depend on. And our goal is to beat that number. Our goal is to accelerate this beyond that.

There is a lot that is happening in growth in MENA and in Europe. We like it, but again, it's taken away from those very, very high margins. But as we go on and grow the US market as well and get into interesting products and get our R&D to start delivering, I think we will have very, very healthy -- hopefully, we can get to much higher than 30%.

But for now, I think we're going to stick to the 30%. We're going to promise that, and we're going to try to beat it every year. But there's no need for us to get to the 29%, 30%. We know that in 2030, we are going to say that \$5 billion seems to be very achievable with this business. But exactly how and when and all of this, I think we'll leave it to when the time gets closer. Did I answer your question --

Kane Slutzkin *Deutsche Numis* - Analyst

Yeah. That's perfect. Just sort of a clarification, you're talking about low single-digit cut. Does that include the potential to get to 20% in Rx? I assume that does.

Riad Mishlawi *Hikma Pharmaceuticals PLC* - Chief Executive Officer, Executive Director

Yes, it does.

Kane Slutzkin *Deutsche Numis* - Analyst

Okay. Perfect. And let me, just last one, is there anything to call out on the competition you had for your two products in Injectables? Anything that's sort of worsened? Or is it sort of just normal course of business, as you say?

Riad Mishlawi *Hikma Pharmaceuticals PLC* - Chief Executive Officer, Executive Director

No. I mean, it was a big hit. It all happened. It was a perfect storm for us happening all in the same year. And this is one of the reasons why we had to decrease our margins in August. But it's behind us now. We just have to manage it. This is the type of business headwinds that come every now and then, and we'd have to deal with it. So it's behind us right now, and we're just dealing with it as we go.

Kane Slutzkin *Deutsche Numis* - Analyst

Okay. Thanks a lot, guys.

Operator

James Vane-Tempest, Jefferies.

James Vane-Tempest *Jefferies* - Analyst

Hi. Thanks for taking my questions. Two if I can on Injectables. I'll just come back for one on the generics business. So when we think about 2025, many people are concerned, at least, thinking about the second half margin on Injectables. I know you're not giving detailed numbers by quarter, but I'm just wondering if you could comment on the weighting of Q3 and Q4 and how dependent that is on the final quarter.

And then my second question is just on Injectables margins. Riad, you gave sort of 4 points. I guess I'm curious firstly on R&D, the step-up you're highlighting and why that's different to what you outlined in detail over the Capital Markets Day, so less than six months ago.

And also I was actually wondering if there's a possible fifth reason which is potential pressure on the base business. You've mentioned previously China, some other competitors. I was just wondering, when we think about that longer-term margin, whether you're now assuming more aggressive competition in your base business? And then I'll come back for US and generics. Thank you.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Let's start with the last one. So competition is part of this business. You need to be aware of it, you need to deal with it, and you need to be ahead of it. So yes, we do have pressures. Yes, we do have price erosions. This comes and goes.

But we have strengths too. We do have the muscles and the strengths. We manufacture very efficiently. We have large facilities. Our supply chain is simple. It is mainly made in the US, so supply chain is much shorter. We can respond to the dynamics in the market much better than any company 4,000 or 5,000 miles away from there. We are in the market, we play in the market, we understand the market, and we try to predict what happens to the market. This is the name of the game. This is what you have to do to defend yourself against the competition. But competition is not going to go away. And that's basically what happens with the competition.

Your second question was about margins.

Khalid Nablsi Hikma Pharmaceuticals PLC - Chief Financial Officer

And in terms of the margins for 2025, if you look into it on a group level, it's relatively flat half to half. But as we said, Injectables, it's going to be H2-weighted because of the timing of the CMO business, incremental benefits coming from new launches. So it's the same message that we had in the past. Branded, as we said, it will be H1-weighted, similar to 2024, but maybe not the same extent. And same case for the Rx. So no change to our messaging in 2025.

James Vane-Tempest Jefferies - Analyst

The question was more is it more Q4-weighted than Q3. Just to understand the bridge to essentially hit your guidance. Are you able to kind of comment in terms of whether the timing of deliveries is more Q4?

Khalid Nablsi Hikma Pharmaceuticals PLC - Chief Financial Officer

We have many launches that will come in Q4 which we announced. Like today, you saw we announced a biosimilar, Tyzavan. We are preparing for the launch. It will come. So this will contribute as well to the profitability. The business has been like month by month accelerating and top line growth whether across the three regions, whether US, MENA, and Europe. So we are seeing increased level of sales. So some launches will come as well like in this month, November. So we are executing, and this is why we looked into every single product. And we are confident on delivering on what we promised the market.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Yeah. I think, we talk about Tyzavan enough, but we are launching it in the third -- the fourth quarter. So you would imagine this quarter would be stronger than other quarters since you add an interesting product to it. We also are adding some products that we were out of for a while that we're waiting for some regulatory answer and we are re-launching it, like lorazepam. So it is a progression. As you add more product to your portfolio, of course, you will get stronger. So a lot of it is happening in the fourth quarter.

James Vane-Tempest Jefferies - Analyst

Thank you. And then my follow-up question on the US Rx business, again a clarification question. Earlier in the call, you mentioned the segment margins would be getting closer to 20% in 2026 and this would continue into 2027. So I was just wondering whether this is entirely driven by the new royalty payable to Jazz. And I guess if you're saying it should probably continue into 2027, I imagine this assumes that the sodium oxybate business is relatively stable given the options you have.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

I don't think that this is the biggest contributor. I think there are a lot of things that contribute to the growth of this business. I think the contract manufacturing business will be going well at that time. Our base business, we had added some lines. We had increased our supply. There's a lot of demand on some of the liquid products that we have. Advair is doing very well. We have a few small products that we're launching. I mean, I think there's a lot of good factors that contributes to that growth. Of course, also, Jazz and the agreement and the sodium oxybate is a contributor. But I wouldn't think that this is that meaningful.

James Vane-Tempest Jefferies - Analyst

Thank you.

Khalid Nabils Hikma Pharmaceuticals PLC - Chief Financial Officer

And just to add to what Riad just mentioned, even 2027, we are conservative on sodium oxybate. As mentioned by Riad, it's many factors that are driving this. This is now becoming a very solid business in all aspects.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

It's got the right foundation right now. I think it's got the right foundation. It's got the right product. And the future is very, very bright. We are developing very interesting product. We're focusing on inhalation, respiratory. Interesting how to make products. So there's a lot in the pipeline as well. So beyond the medium term, also, we see a very healthy business.

Operator

Sebastian Jantet, Panmure Liberum.

Seb Jantet Liberum - Analyst

Good morning, everyone. Three questions if I may add and apologies if some of these have been answered. I've had a few problems with my line dropping on and off. So the first one is just around -- if you could just comment on the background for generic pricing and whether you've seen any signs of that improving or whether we're in the normal price cut cycle there.

Second question is just around your US capacity and obviously, Trump's pushing to onshore a lot of manufacturing. I'm wondering whether you've seen an increase in inquiries around CMO contracts and whether you're planning to lean into those.

And the third one is just around the balance sheet and obviously, shares (inaudible) today. I'm wondering whether you're considering doing a buyback to support the shares at this price.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Okay. Maybe we can start backwards. How about we start with the buyback? Khalid, you need to say something about it.

Khalid Nabils Hikma Pharmaceuticals PLC - Chief Financial Officer

Yeah. We don't do buyback because the share price is down. Of course, we, the Board would like to invest in the business. And we still see potential to invest in the business. Now, it's something that we would consider on an annual basis. But if we see that it's the right time to do a buyback, of course, the Board will consider this. Today, there's nothing on the table that we'll do a share buyback. But if the Board change the outlook and they say that it's a good investment for us and nothing available to do M&A, then they might consider this. So just to answer for you, today, we're not announcing any share buyback.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

And your second question is about US capacity and the US demand and are we getting CMO. Yes, a lot of people are knocking on our door for CMO, not only for the US, also for our European facilities. We do have a good track record for CMO. We have good quality record. Our facilities are very automated. We're investing a lot in new equipment, all state-of-the-art. So the people that we work with in CMO are very impressed and very happy with us. So we get a lot of questions if we can expand our CMO.

But today, we can't because our capacity is really at a limit where we can't take any more clients. And this is why we're looking so much forward for putting the Cleveland online because we expect that Cleveland will take a lot of our capacity to CMO.

We are expanding our manufacturing in the US. As we had announced, we will be spending a lot of money expanding our existing facilities and of course, building out the Cleveland facility. It's a big investment. It's not only in Cleveland though. In Cherry Hill, we're adding more lines. Also as well in Columbus, significant investment is going to be put there. And as we speak today, we're building new buildings, we're adding more equipment, both for our core business and for our new contract manufacturing client.

And also, with Columbus having that capacity, we also attract small CMOs. We're taking on small opportunities with small CMO whenever we can. So I think everything is getting together into the strategy of the Rx business in terms of their facility, their manufacturing, and so forth.

Generic pricing. In general, it's still as it was before. It's still not stable. It's still up and down. Really depending on -- Are you talking about -- Both, I think the generic and the Injectables, they are midpoint -- mid to high erosion that we see. Injectables, a little bit less. I would say, low to mid. But they haven't changed for a couple of years. This is where they are today, and we haven't seen a significant change.

Operator

(Operator Instructions)

Sidhartha Modi, Barclays.

Sidhartha Modi Barclays - Analyst

Hi. Can you hear me now? Hello?

Unidentified Company Representative

It's a very bad line. You try asking the question, Sid. If not, you can email it through to me.

Operator

Beatrice Fairbairn, Berenberg.

Beatrice Fairbairn Berenberg - Analyst

Hi. Thank you for taking my follow-up question. I just wanted to ask on the R&D structure change and how this is expected to more holistically impact the pipeline and product launches. And how do you expect this to evolve in terms of (inaudible) going forward? Thank you.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Thank you for the question. I think it's a great question because it's a significant change. Having all the divisions joined together with R&D, we're benefiting a lot. We're benefiting a lot in terms of redundancies. Every division had its own regulatory. Every division has its own labeling team. Every division had its own project management. We had redundancies in those. And I think putting them all

under one roof, not only we save the redundancies, but also, we reinvest that into the formulation, into the method development, into where it really counts. So that's the main structure.

We also benefit from the expertise of the team. There are some great scientists in one division that we can use it in other divisions. But what motivated us the most to do something like this are two things. One, the fact that we really need to do something about R&D. R&D hasn't been delivering what we want to deliver if we want to continue the growth. So two things we have to do. One, to spend more money on R&D; and two, structure ourselves that the money that we spend would be worthwhile, and we'll come back with a lot of benefits. So structuring was number one. And number two was spending.

So this is what we're doing, both things. And we're lucky that we have Hafrun who has experience in R&D. And structuring R&D and leading global teams and leading the global team becomes very complex. She has great experience in this. She had helped putting that structure together. And we were very happy to have her help us do all of this.

And maybe just to add, the Croatian facility that has been added to our network also played a critical role. Now, we have a lot more than we had before. We have a lot of pipeline products that were really half finished that we have to spend money to get them finished. We have to organize ourselves to make sure they're transferred into the right facility. All that motivated us to say, listen, let's just sit down and redraw it the way it's supposed to be, knowing what we have in resources and knowing how much money we would like to spend. So that's exactly what we did.

Operator

Christian Glennie, Stifel.

Christian Glennie Stifel - Analyst

Hi, guys. Thanks for the follow-up. I just wanted to follow-up on the Rx, and the margin, improvement to 20% next year, just to understand. Because on the one hand, you're saying, no real significant changes in terms of Jazz royalties, the large new CMO contract. And I think the benefit of that doesn't really follow. That's more a 2027 story in terms of that being a meaningful contribution. So I'm still a little bit struggling on the margin improvement and expansion within Rx for the next year on what the key drivers are.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Well, I think, as we said before, there are many -- although the 2027 will be very meaningful for contract manufacturing, that starts in '26 and it gets stronger in '27. So it's not only in '27. It's starting. So it does contribute to the revenues. As there's preparation, there's services that you need to do, there are some preparations of batches that you need to do, there's stability that you need to do. So there are a lot of services that needs to be done. The contract manufacturing itself, I think, we are anticipating that would be in '27. But the preparation for that, which is significant, will be in '26. So that's one benefit that we're going to get.

But I think we should underline that the base business is doing well, and this is important. We've seen good demand on our existing product. We're expanding some of the lines that we have where we added new lines, liquid lines. We will be adding another Advair line. So I think expanding in our capacity also is helping in this business. And of course, we do have products that we are going to be launching. They may be small, but collectively, they will be also contributing significantly to that. So as I said, there's not one that is working well, it's all of them are working together, and that collectively, they're contributing well to the business.

Christian Glennie Stifel - Analyst

Thanks. Clearly, on the second half. On the Injectables as well on the margin, just to clarify that there isn't some OpEx restructuring saving here to help you deliver that 34% or so in the second half as implied by retaining your full-year guidance.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

No. I think the main important part is that we've always said that contract manufacturing, which is really the biggest margins that we have of, was coming in fourth quarter. And that didn't change and that didn't deliver. Usually, contract manufacturing is the most predictable part of your business. You know ahead of time when you're going to make it because you promised your customer gives you ahead of time the forecast. And you manufacture accordingly. So it was very predictable that we will be doing contract manufacturing later on.

And as I said before, there were some products that we were out of in the market that we are relaunching in the fourth quarter and also new products like Tyzavan that we launched already. And we believe that this is going to continue picking up until the end of the year. So again, not one thing that we're contributing to, but it wasn't any restructuring or any significant thing like this. It's more had to do with the business.

Operator

Miles Dixon, Peel Hunt.

Miles Dixon Peel Hunt - Analyst

Good morning. Thank you. Forgive me if I missed it, but could I just ask on the specifics of R&D? You've talked about a 20% step-up in R&D spending FY '25. Are we thinking about a similar kind of step-up into '26? And what's the internal expectations around when that additional spend might start delivering for the business? Thank you.

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Yes, R&D, I mentioned that before, is significantly increasing year on year. We restructured for this increase. We are hiring for this increase, so that has been planned. The portfolio is being picked, and, some of the projects that we are working on today, we are in the midst of execution. So, there's not much guesses there. We have a plan. We have, the leaders identified. We have the products and the portfolio identified. When will this start paying off? Some later than others. And some earlier than others. So it really depends.

There are some projects that are towards completion. There are some projects that needs a lot more time for them to complete. But we will be seeing significant change, I think, '28. We talked about epinephrine, for example, in the Rx, and we think that's probably around the right time when it comes in. That's a big product that required a lot of spending, a lot of R&D, a lot of technical knowledge, as well as a lot of studies. And there are a few other products that are in this category.

We have also some products that we, some of the pipeline R&D products that were in Zagreb when we acquired Zagreb that needs to be completed. So there are many of these products in different phases. But I think significantly, usually R&D takes three to five years when you see the results. So this is why we're saying '28 and you should be able to see a lot of the effort that we're putting together coming to fruition.

Operator

Please note that (inaudible) has sent in their e-mail regarding their question. I would now like to hand the call back to the investor relations for final remarks.

Unidentified Company Representative

For the Barclays question from Sidharth, two very short questions. Riad, just firstly on biosimilar strategy and what the timeline is for our launches on Denosumab and Ustekinumab and any update on strategy there. And then on the Columbus CMO project, if there's any updates on the branded product there which we know is in Phase 3. Do we have any updates there?

Riad Mishlawi Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director

Well for the biosimilars, we have talked about the biosimilars, We are starting to launch the biosimilars. We launched one, And I believe that the second one will be launched in January.

There is not very high expectations that those will be a big product. They will be meaningful. They will contribute to the growth of the business. But again, we are (inaudible), so it's not that we are going to grab and take a big market share. But the market is big. We're coming in and competing on price. We have a good base for the price. We have good transfer costs from our partner. And we already have orders, and we already are launching and selling products. In fact, we had asked our partners to increase what we had anticipated will be before. So we think it's going to be better than we expected. But again, it's not those big, blockbuster products. It's just good decent products, that's what they are.

What's the other? On the CMO --

Unidentified Company Representative

Yeah. It's just that if there's any comment at all around the CMO projects and on the product itself, if there's any.

Riad Mishlawi *Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director*

Yeah. We're sorry, we can't talk much about. We are limited. But what we can say about the CMO, we just say that it's meaningful. We say that it's going well. A lot of work has been really put into it. And we hope that this is going to be as we expected, a very good contributor to this business.

Operator

There are no further questions on the conference line. I will now hand over to Riad for final remarks.

Riad Mishlawi *Hikma Pharmaceuticals PLC - Chief Executive Officer, Executive Director*

Well, thank you very much for joining us for this call. We want to reiterate two things. I think the first thing is we want to reiterate that this business is a good business. We have done a lot to continue the growth of this business. In fact, a couple of years ago, we looked at the business and we looked at all the parts of that business and we put a strategy for each of those parts.

We looked at Rx and as you remember, a lot of you had followed us before, Rx was extremely weak. We didn't know what the strategy would be with it. But since then, things have changed dramatically. This is a strong business. The growth is very bright. The future is very bright. The growth is very apparent. So we put a strategy together and we executed.

The same thing happened with the branded. We put a strategy together. We reshuffled the leadership. We put a lot of emphasis on branded and you see the results they're delivering. The growth is very healthy.

Injectables is the same. We did put a strategy together and that strategy was based on expanding our very much needed capacity, getting into interesting product, put more money in R&D, try to get some pipelines through both our organic R&D and through (inaudible). And that's also is in the works.

So there's a lot that's been happening exactly with that. New facilities have been built in Algeria, in Morocco. Italy has expanded. Portugal has expanded. Cherry Hill, new lines are coming in. And of course, the Cleveland facility with the new technology will be online very soon.

So we are in the midst of executing the injectable strategy. We will see the benefit of that very apparent in '28. During that time, we will be running a very healthy business at around 30% of margins. And I think we are going to be preparing for steep growth after that. So good business. And we just want to make everybody trust the numbers that we give out and make sure that we have looked at those numbers. And we are very confident that those numbers are achievable.

And with that, I thank you very much and hope to see you soon.

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