2024 Q3 results presentation and transcript

Webcast and presentation

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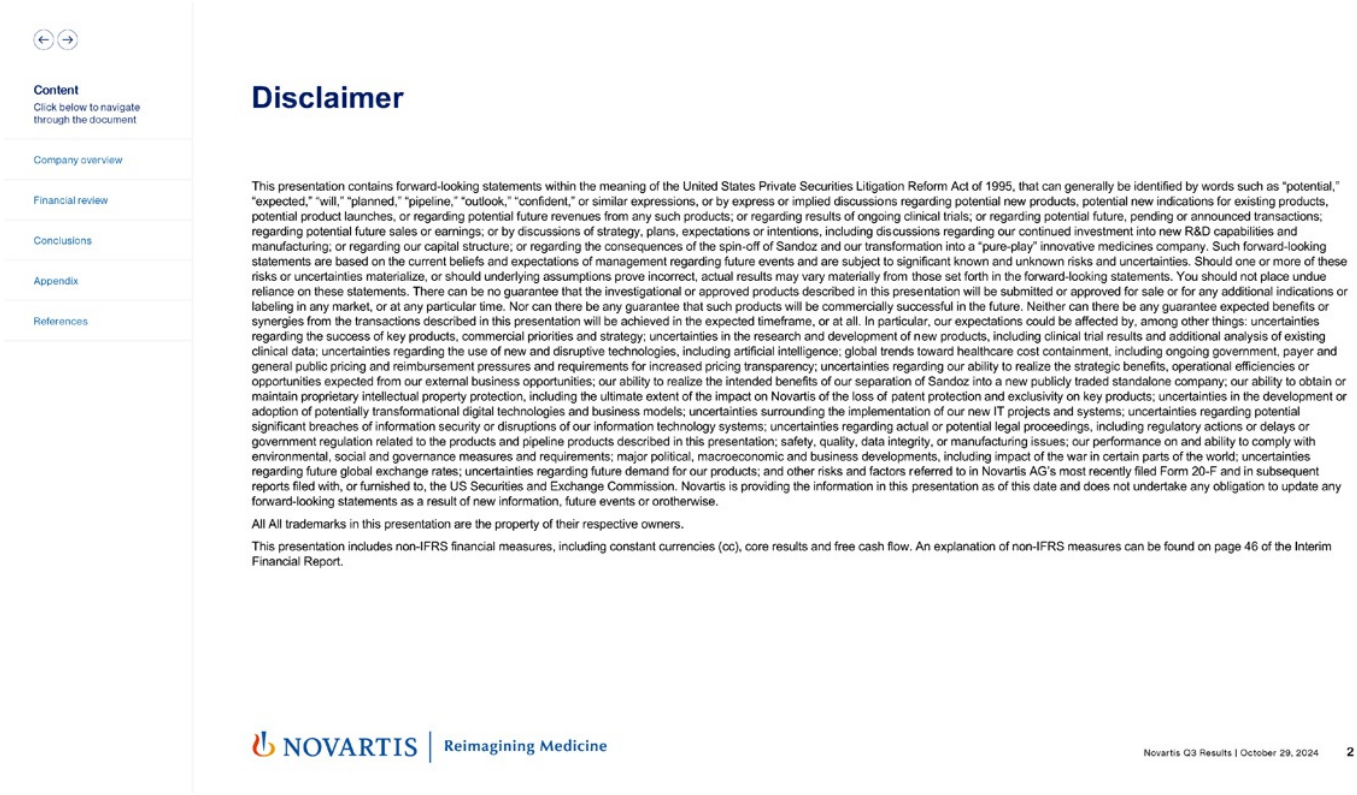
Transcript

View the 2024 Q3 results presentation and read the transcript slide by slide.

Slide 1 - Sloan Simpson, Global Head Investor Relations

Good morning and good afternoon, everyone. Thank you for joining our Q3 2024 earnings call.

Slide 2

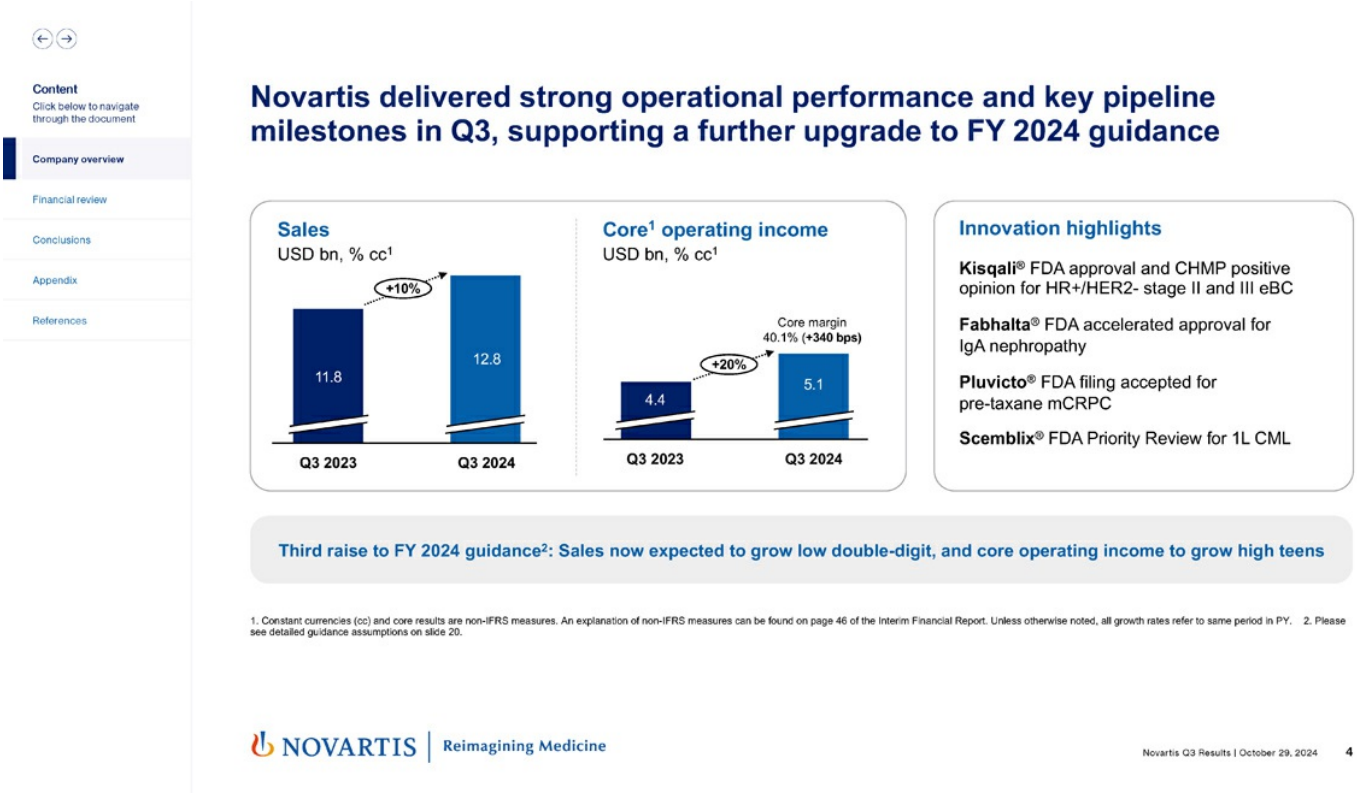


The information presented today contains forward-looking statements that involve known and unknown risks, uncertainties and other factors. These may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. For a description of some of these factors, please refer to the company's Form 20-F and its most recent quarterly results on Form 6-K that respectively were filed with and furnished to the US Securities and Exchange Commission. And with that, I will hand across to Vas.

Slide 3 - Vasant Narasimhan – CEO of Novartis

Thank you, Sloan, and thanks, everyone, for joining today's webcast. So we'll dive right in. I have Harry Kirsch on the line with me as well as always.

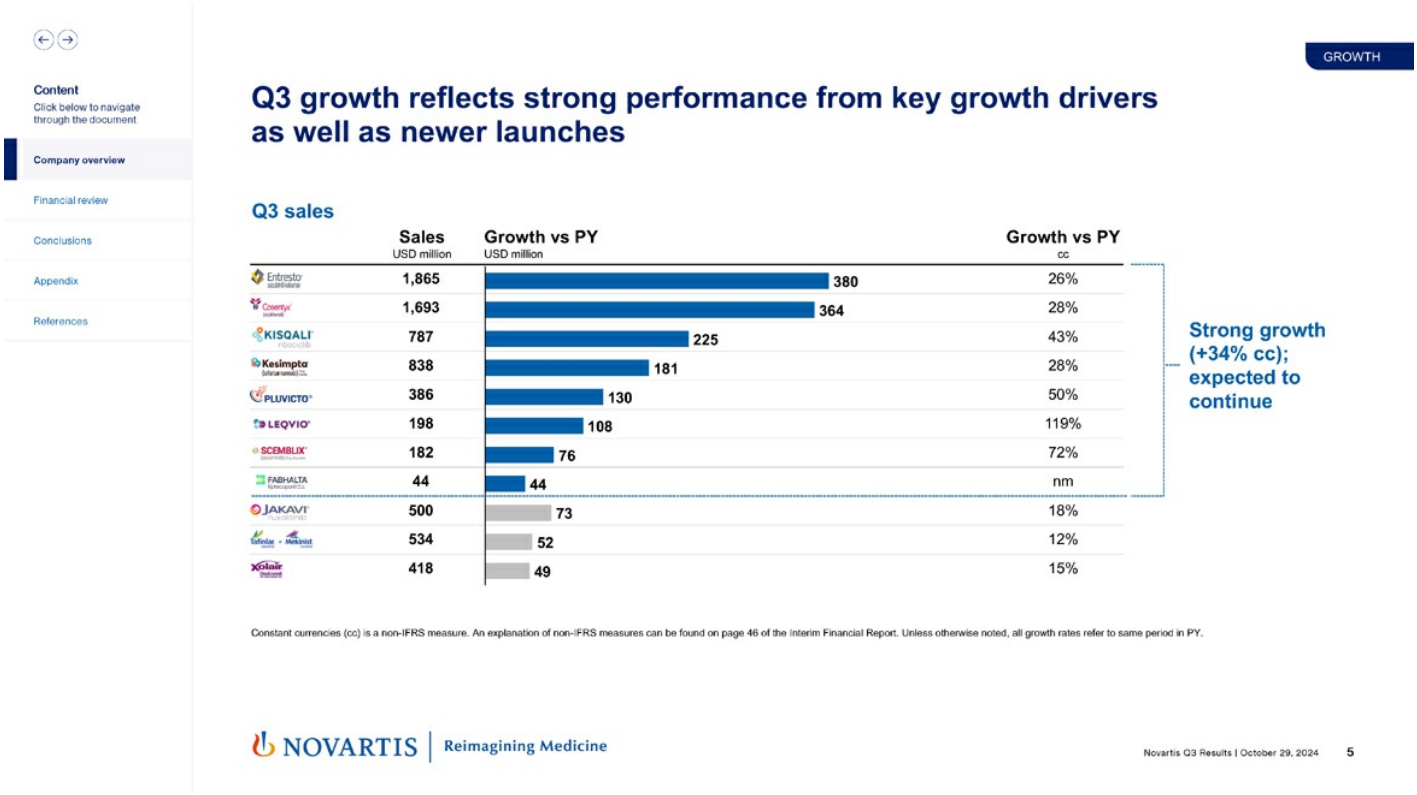
Slide 4



So moving to slide 4. You saw this morning that Novartis delivered strong operational performance in Q3, really continuing now what's been two years of very strong operating performance for the company. Sales grew 10%. Core operating income was up 20% in constant currencies. In the quarter, our core margin went all the way up now to 40.1%. And we also had important innovation highlights, which we'll talk about a bit more over the course of the call. Kisqali® FDA approval and CHMP positive opinion in hormone receptor positive HER2-negative stage II and III early breast cancer, our Fabhalta® accelerated approval in IgA nephropathy.

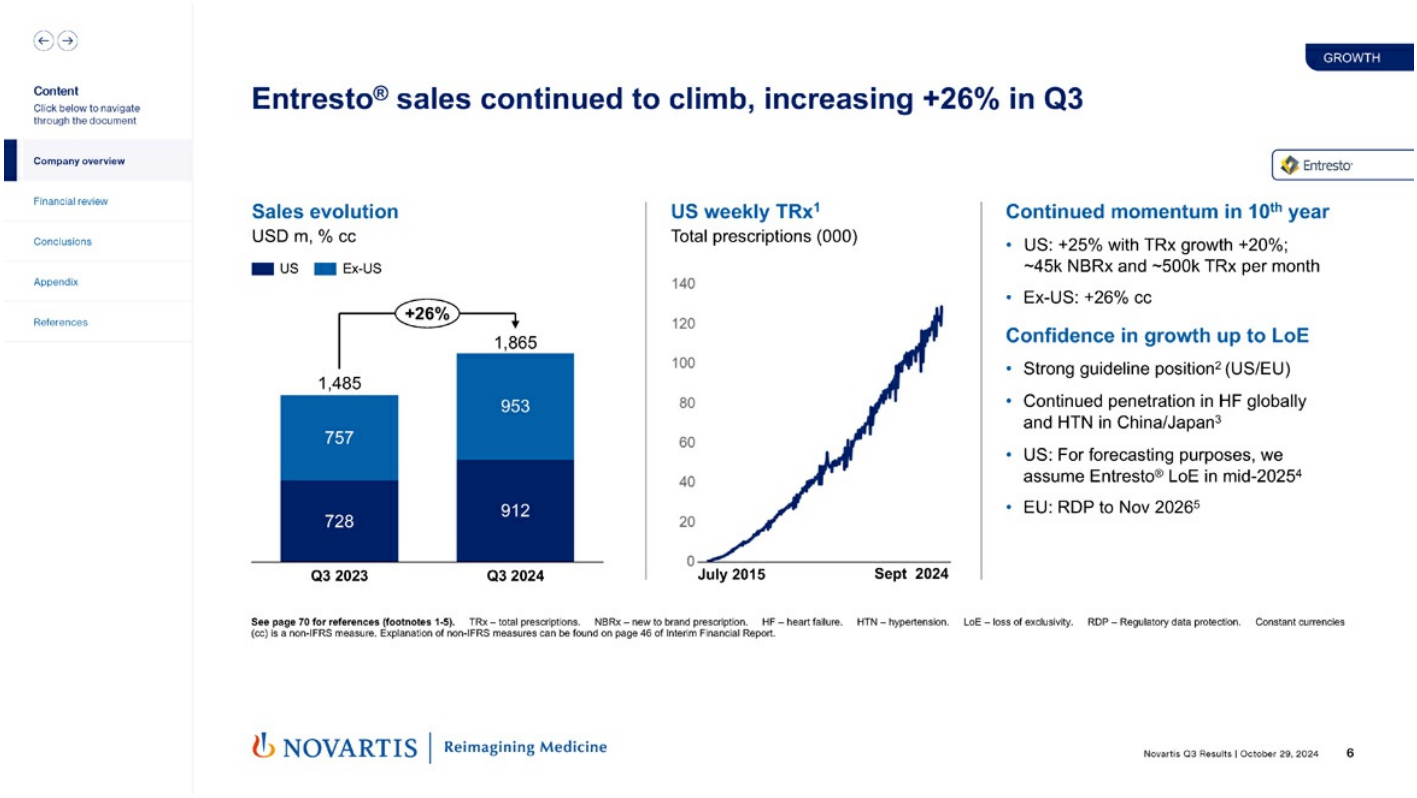
Pluvicto® had its filing accepted for the PSMAfore population in metastatic castrate-resistant prostate cancer. And then we expect the Scemblix® approval in the coming weeks. We received FDA priority review for first-line CML. And lastly and importantly, we had our third guidance raise for the year, raising both our top and bottom line guidance, and Harry will go through that in more detail.

Slide 5



So moving to slide 5. Q3 growth again reflected strong performance across our key growth drivers. You see 34% constant currency growth, which we expect to continue and help drive our 5% guide out to 2028. And also enable us to continue that strong margin expansion that you've seen. And let's go through each one of these brands in more detail.

Slide 6

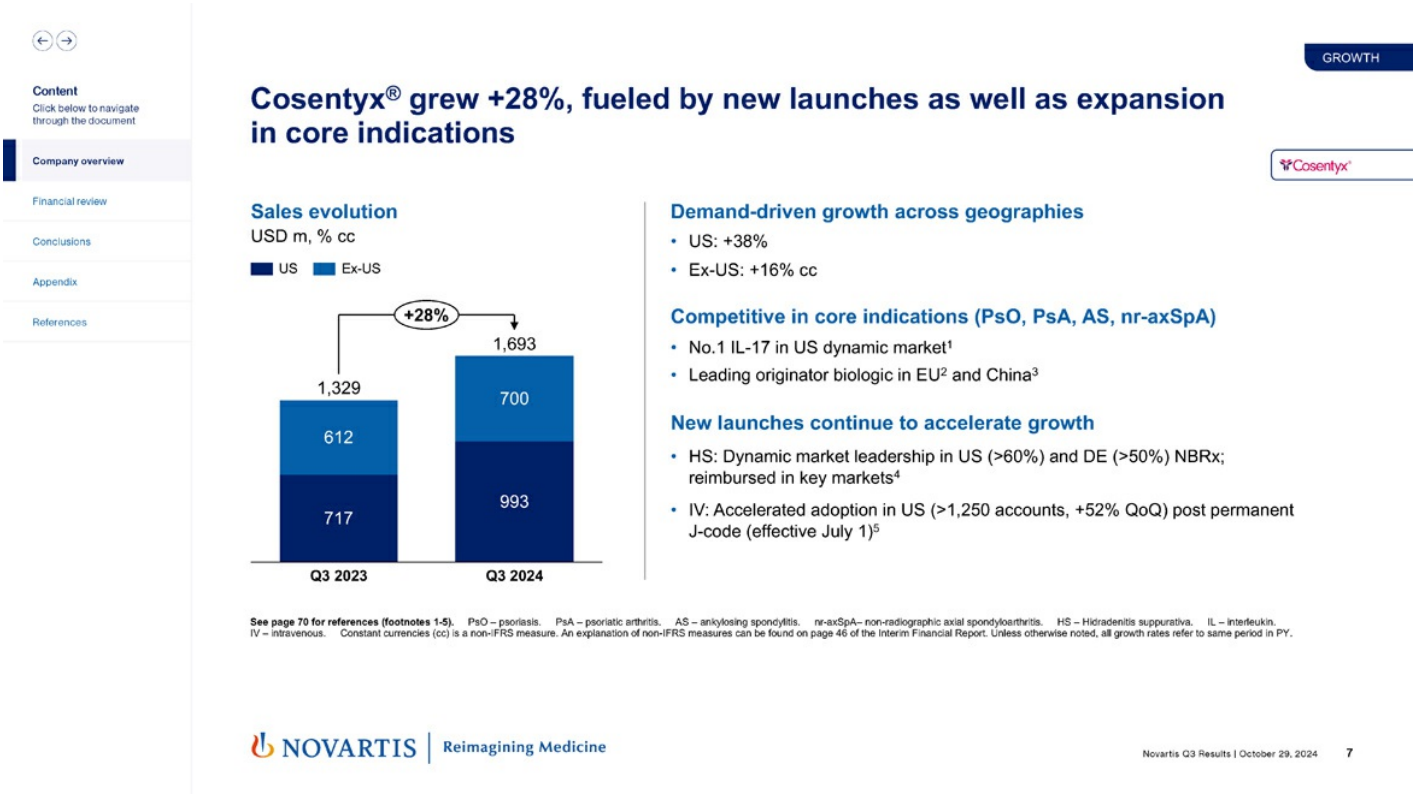


So moving to slide 6. Entresto® sales continue to climb as they have now for multiple years, increasing 26% in Q3. It's the tenth year now of continued momentum on this brand, which I think really shows our ability to create large and lasting cardiovascular medicines. 25% TRx growth, 20% NBRx growth, 500,000 TRxs per month, ex-US, we're growing 26%. So we're confident in the growth up to the LOE. We have strong guideline

positions in the US and EU.

We continue to see very strong performance in hypertension in China, in Japan. We don't expect an LOE in Japan until 2031 at the earliest, and we continue to see protection for our business in China. For forecasting purposes, we maintain our guidance of the LOE for Entresto® in the United States for mid-2025. And in the EU, regulatory data protection would expire in November of 2026.

Slide 7



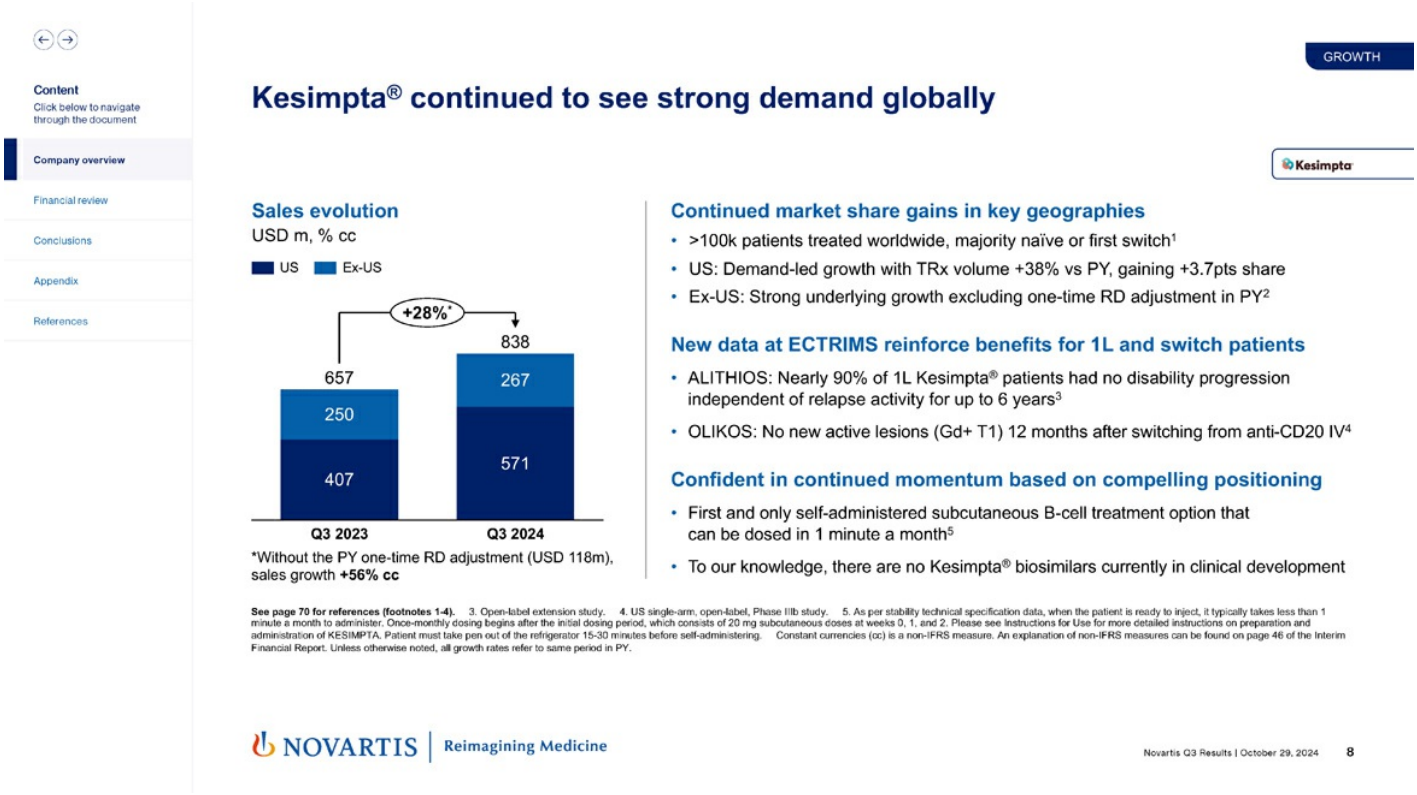
So moving to slide 7. Cosentyx® grew 28%, and this was primarily driven by the strong performance we've had in our new launches in HS and in the IV formulation. You can see 28% growth overall, but driven by very strong performance in the United States of 38% outside the US, 16% in constant currencies. We remain the number one IL-17 in the US dynamic market, and we're the leading originator biologic now in the EU and in China.

In HS, we've achieved dynamic market leadership with over 60% NBRx share. In Germany, we're 50%, and we increasingly secured reimbursement in our key markets. So we see the opportunity to continue to grow dynamically in HS. We think we have an outstanding data profile even versus the incoming competitors. And we also see an opportunity for a market that's going to continue to expand, a market that's probably USD 3 billion plus today but has the potential to be a USD 5 billion-plus market over time or even larger depending on how patients continue to see their physicians.

In the IV, we have accelerated adoption in the US with over 1,250 accounts now ordering. That's a 52% growth. I think we'll continue to see more sales delivery in IV now that we have the permanent J-code. But that, of course, will take time and we look forward to delivering that.

We have two important LCM opportunities that will read out in 2025 in polymyalgia rheumatica as well as in giant cell arteritis, both sizable indications that could give us even further opportunity to well exceed Cosentyx® USD 7 billion peak sales forecast.

Slide 8

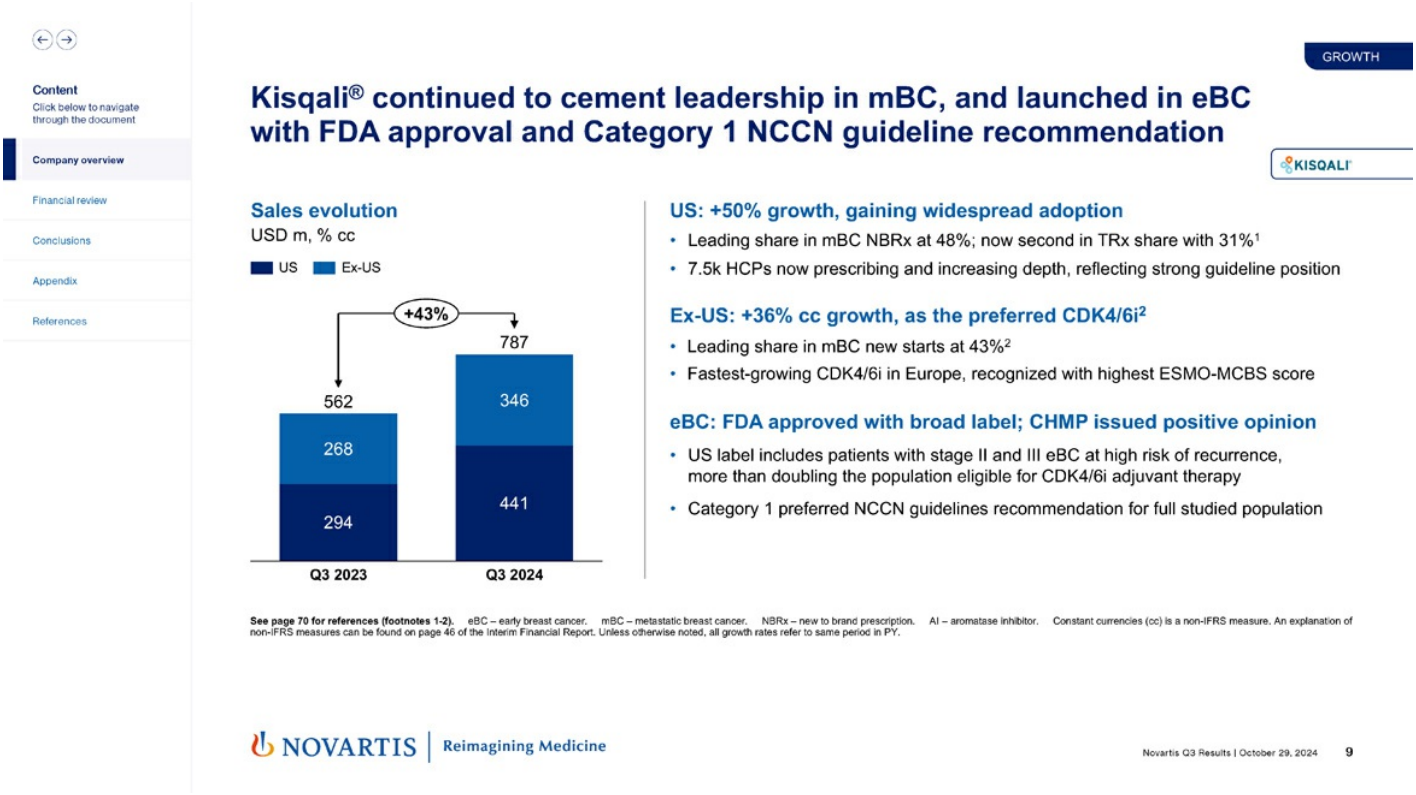


Now moving to slide 8. Kesimpta® continued to see strong demand globally, and it's a unique profile that this medicine provides for patients and physicians. So 28% growth. But when you strip out the onetime RD adjustment that we had from a European market last year, our sales growth was 56% in constant currencies. We now have over 100,000 patients treated worldwide either naive or first switch. The US, our TRx volume growth was 38% versus prior year, gaining 3.7% share. Ex US, we had strong underlying growth, excluding the onetime RD adjustment from last year.

We also presented some important new data at ECTRIMS in the ALITHIOS trial, 90% of first-line Cosentyx® patients had no disability progression independent of relapse activity up to 6 years. And we had an additional study that demonstrated no new active lesions 12 months after switching from an anti-CD20 IV therapy. So we remain confident in the continued momentum on this brand. We're annualizing now well above USD 3 billion and have the opportunity, I think, to well exceed our USD 4 billion peak sales guidance to date.

To our knowledge, there are no Cosentyx® biosimilars currently in clinical development, which should give us a long runway looking forward for this medicine.

Slide 9



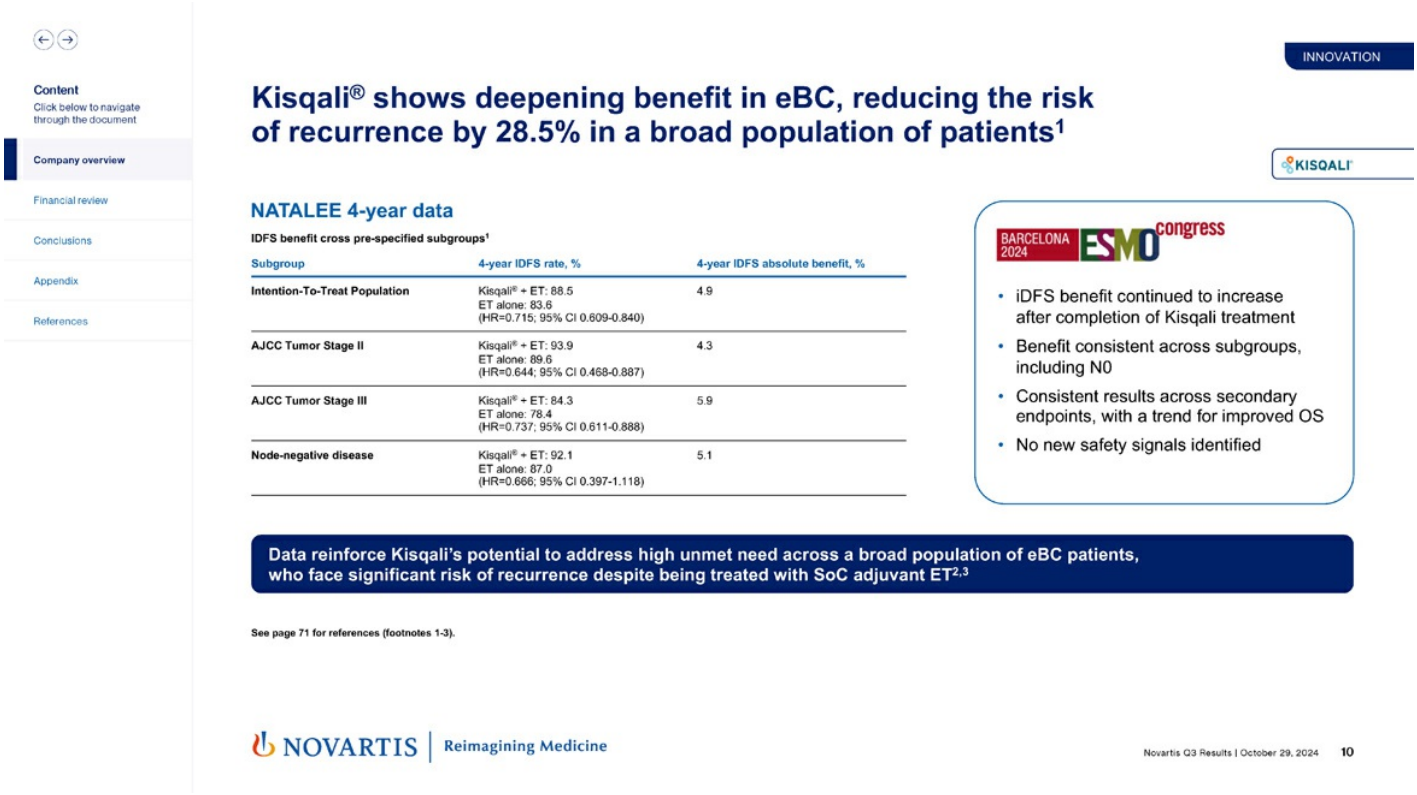
Now moving to slide 9. Kisqali® continued to cement its leadership in metastatic breast cancer and launched importantly in early breast cancer, as I mentioned. But perhaps most importantly, we achieved a category 1 NCCN guideline recommendation for the full Kisqali® population. Overall growth in the quarter was 43%. US is up 50%. It's really gaining widespread adoption, our NBRx share at 48%. We're now second in TRx share overall. We have over 7,000 physicians actively prescribing Kisqali® and I think reflecting our strong guideline position.

Outside of the US, 36% constant currency growth as the preferred CDK4/6 inhibitor in the class. We're leading – have a leading share of 43% in those international markets and we are the fastest-growing CDK4/6 in Europe.

Now as I mentioned, the FDA approved Kisqali® with a broad label fully in line with the NATALEE population. CHMP has issued a positive opinion, and we're looking forward to a European Commission approval to allow us to launch in Europe. The Kisqali®, if you go back to slide 9, the Category 1 guideline recommendation for the full study population, I believe, gives us the opportunity now to really fully realize the potential of this medicine, including in node-negative patients.

And the early feedback we're getting from the market is very strong, the early scripts we're seeing, so a very strong trend, and we look forward to now building upon that as we get broad access for this medicine. We would expect access in the early breast cancer setting in the range of 90%, which is what we have for Kisqali® in the metastatic setting.

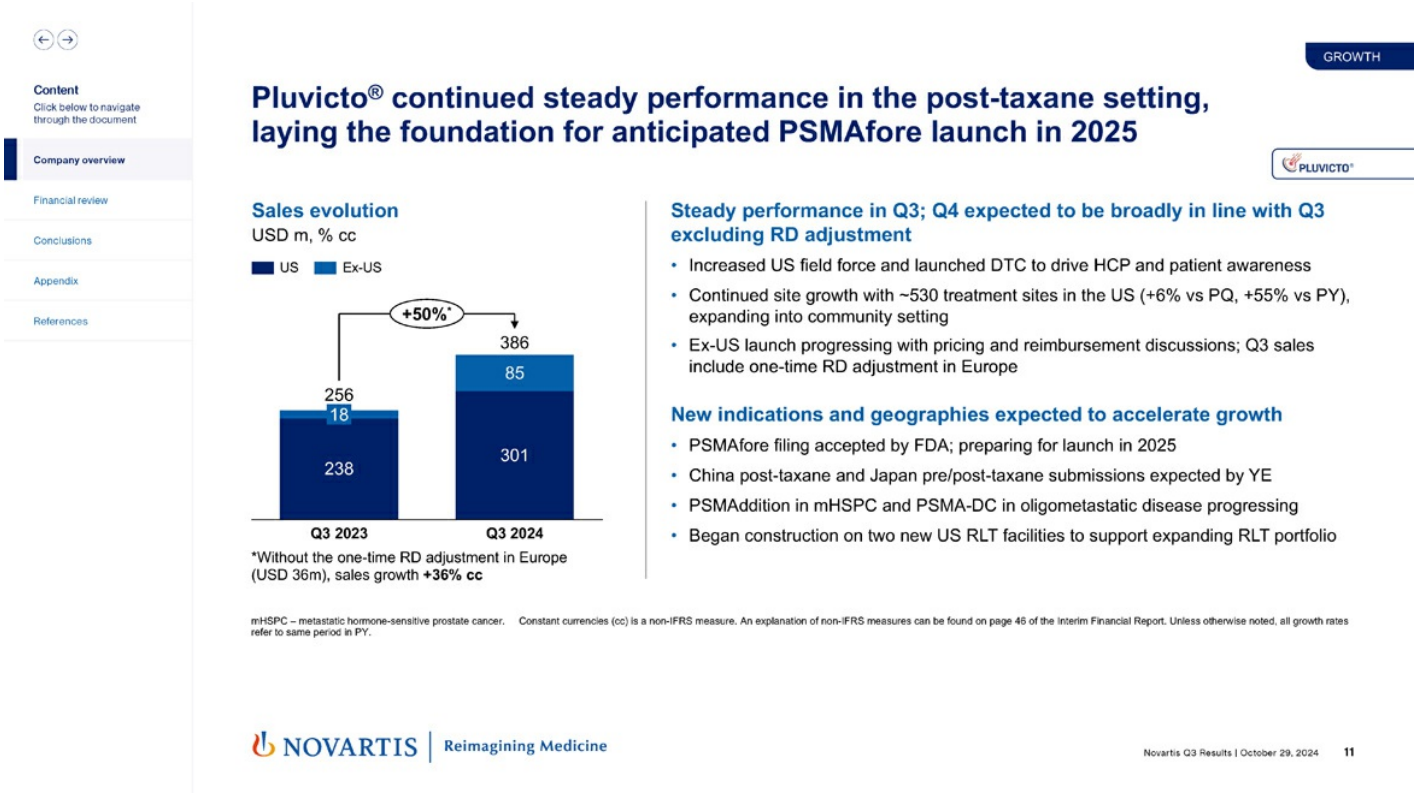
Slide 10



Now moving to slide 10. As a reminder, Kisqali® showed really strong deepening benefit at the update that we showed at ESMO. When you look at the graph on the left, across the intention-to-treat population as well as stage II and stage III patients as well as node-negative disease and a really strong 4-year IDFS absolute benefit that's consistent, consistent also across secondary endpoints. We have a trend of improved OS, which we expect to continue to deepen over time. No new safety signals were identified. So overall, we think we now have really the perfect positioning that we would want for Kisqali® to succeed in the long run.

As a reminder, the early breast cancer indication doubles the number of patients that are eligible for Kisqali® versus the metastatic indication, and we estimate it is a 3x larger population than is currently labeled for the competitor product in the class in early breast cancer.

Slide 11



Now moving to slide 11. Pluvicto® continued what we would characterize a steady performance in the post-taxane setting. Our focus at the moment is really laying the foundation for the PSMAfore launch in 2025, which would triple the number of patients eligible for Pluvicto®. We saw 50% growth in the quarter. When you adjust for the onetime price adjustment in Europe, our sales grew 36%. Just to provide more context, that was true volume growth that we had in earlier quarters. As is always the case in certain European markets, our prices get adjusted over time. So that was the reason for the uplift we saw in Europe.

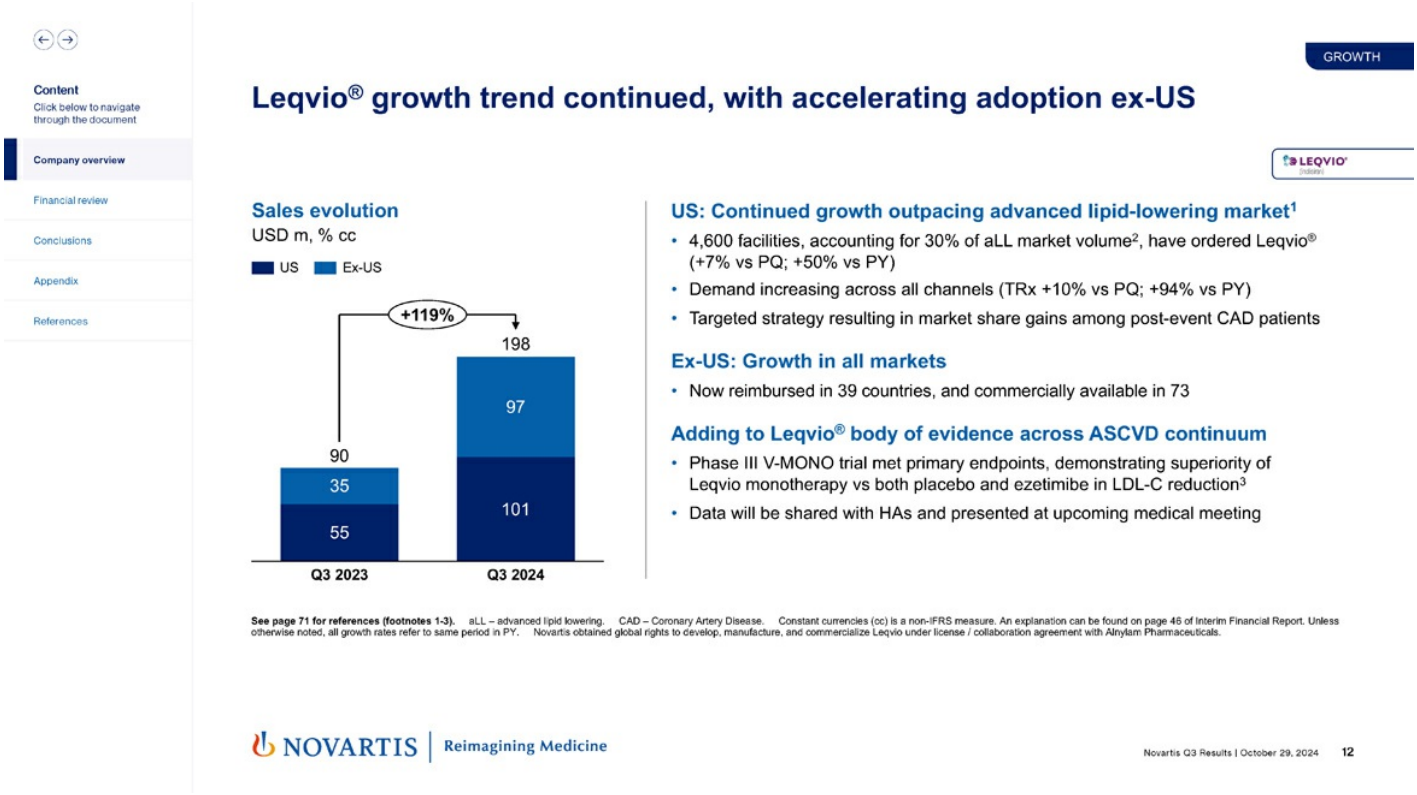
Overall, we would expect Q4 to be broadly in line with Q3, excluding the RD adjustment. And I think for us now, it's really about preparing the market for Pluvicto® PSMAfore opportunity. Our US field force has now expanded. We've launched a DTC to drive HCP and patient awareness. We now have 530 treatment sites in the US, which we feel like cover the key geographic areas. We will continue to expand that over time quite significantly. But we feel comfortable that we have capacity now to fully support the Pluvicto® PSMAfore launch, and we'll expand deeper into the community setting step by step.

Our ex-US launch is progressing well with good pricing and reimbursement discussions. And so we feel very good about where we are to prepare for that launch next year.

In terms of new indications and geographies, the PSMAfore filing was accepted by FDA. We're preparing for a launch in the first part – first half of 2025. In China, both the post-taxane and in Japan, the pre- and post-taxane submissions have happened. We're in the midst of building up manufacturing facilities in both of those markets as we expect them to be sizable opportunities. the PSMAddition and PSMA-DC studies are progressing according to plan.

And we have also begun construction of two additional facilities in the US to support our expanding RLT portfolio, which now includes multiple additional programs that have entered the clinic, including assets such as a B7-H3 actinium RLT as well as a HER2 RLT and a folate RLT, all of which now either have first patient first visit or will soon have first patient first visit, giving us a broad portfolio that we need to now prepare for.

Slide 12

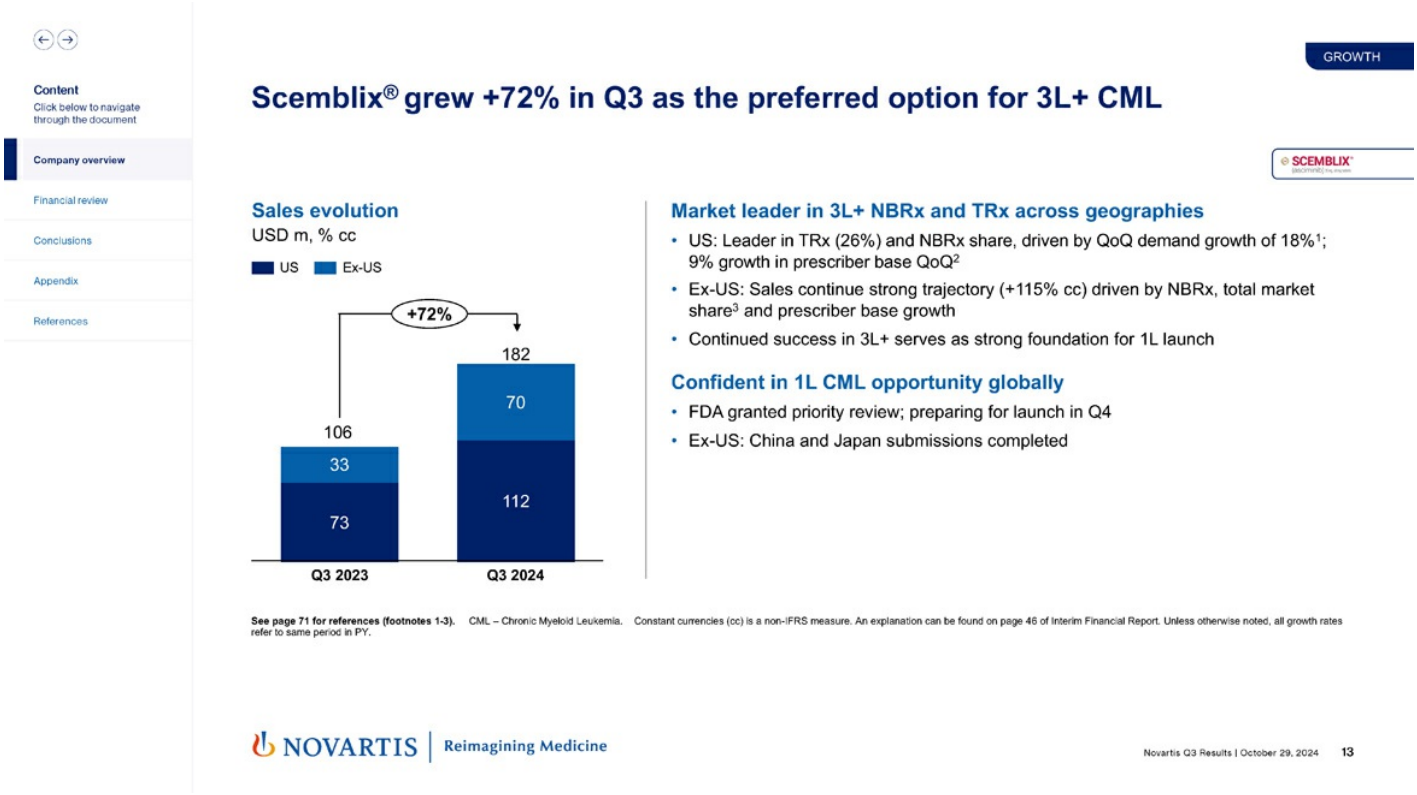


Moving to slide 12. Leqvio® continued its strong growth trend with accelerating adoption outside of the US. And we're very pleased by both the solid US performance both the acceleration that we're seeing in our international markets. We have continued growth that's outpacing the overall advanced lipid lowering market. 4,600 facilities have ordered Leqvio®, which is a substantial increase versus prior year. We see demand increasing across all channels. And I'd say our targeting strategy in the US to really focus on patients and physicians that are treated in the post-event setting where there's a high propensity to add an additional lipid-lowering therapy has worked really well.

Now outside of the US, we're reimbursed in 39 countries commercially available in 73. And as I said, we're seeing steady and strong uptake, particularly in markets such as Japan, where we recently launched, and our launch is well exceeding our expectations.

Now adding to the overall Leqvio® body of evidence, we did read out the V-MONO trial, which demonstrated superiority as Leqvio® monotherapy versus both placebo and ezetimibe in LDL-C reduction. And we are looking over time to think about how we can further expand Leqvio® into the monotherapy or frontline indication, depending on the geography.

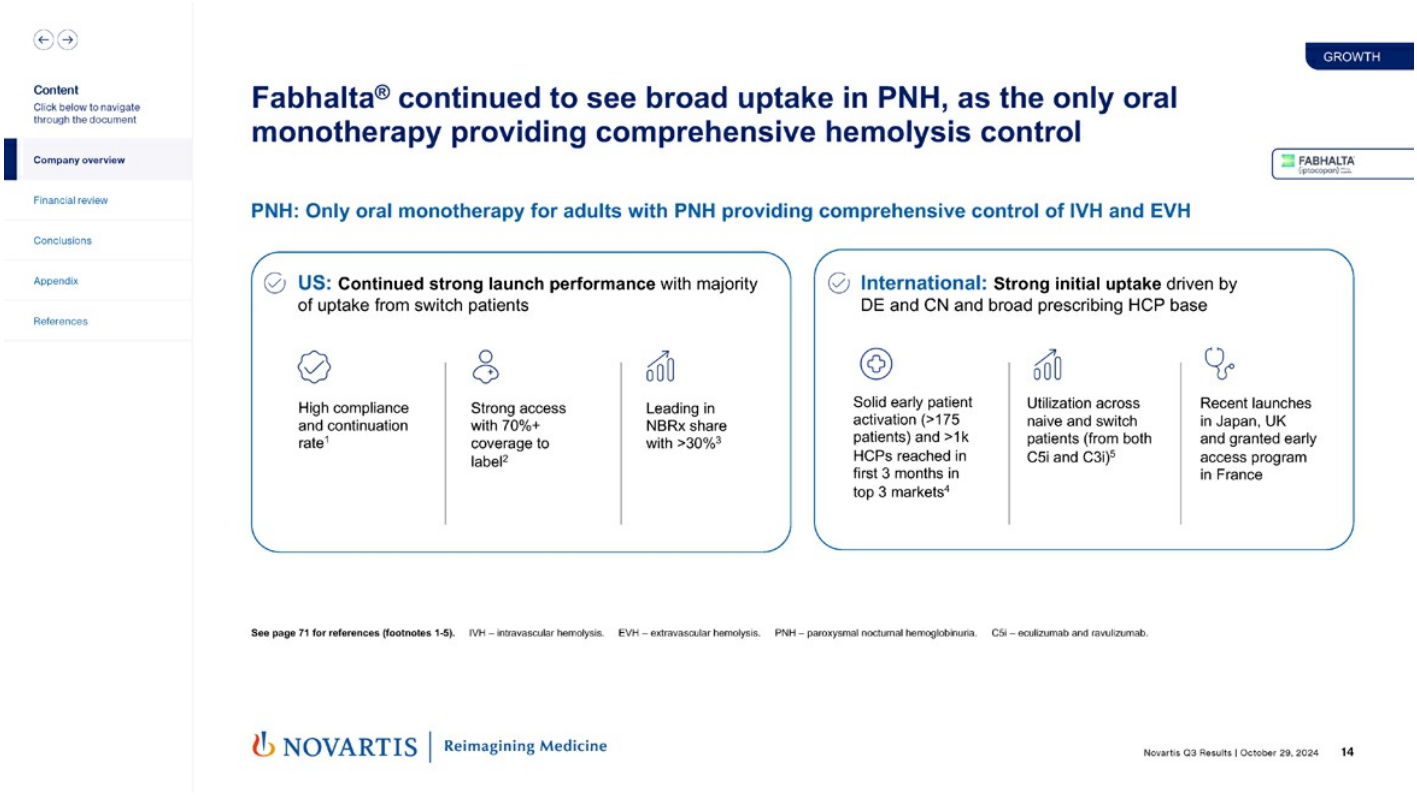
Slide 13



So moving to slide 13. Scemblix® grew 72% in quarter 3. As you know, it has really become a preferred option for third line CML. It's the market leader in NBRx and TRx across geographies with 26% TRx share growth. It's driven by 18% quarter-over-quarter demand. Outside of the US, we see a very strong sales trajectory for the product with total market – with a growing total market share and growing prescriber base. And that's critical for us to continue to build that strong base in third line because as we approach the first-line launch, those physicians get more and more comfortable with the overall profile of Scemblix®.

So as I mentioned, we have FDA priority review. We do expect the approval in the coming weeks. We're fully prepared for launch. We're also fully prepared to obtain rapid market access to really ensure a rapid launch in the US and eventually around the world. And outside of the US, China and Japan submissions have now been completed, and we're also on track for a European submission in 2025.

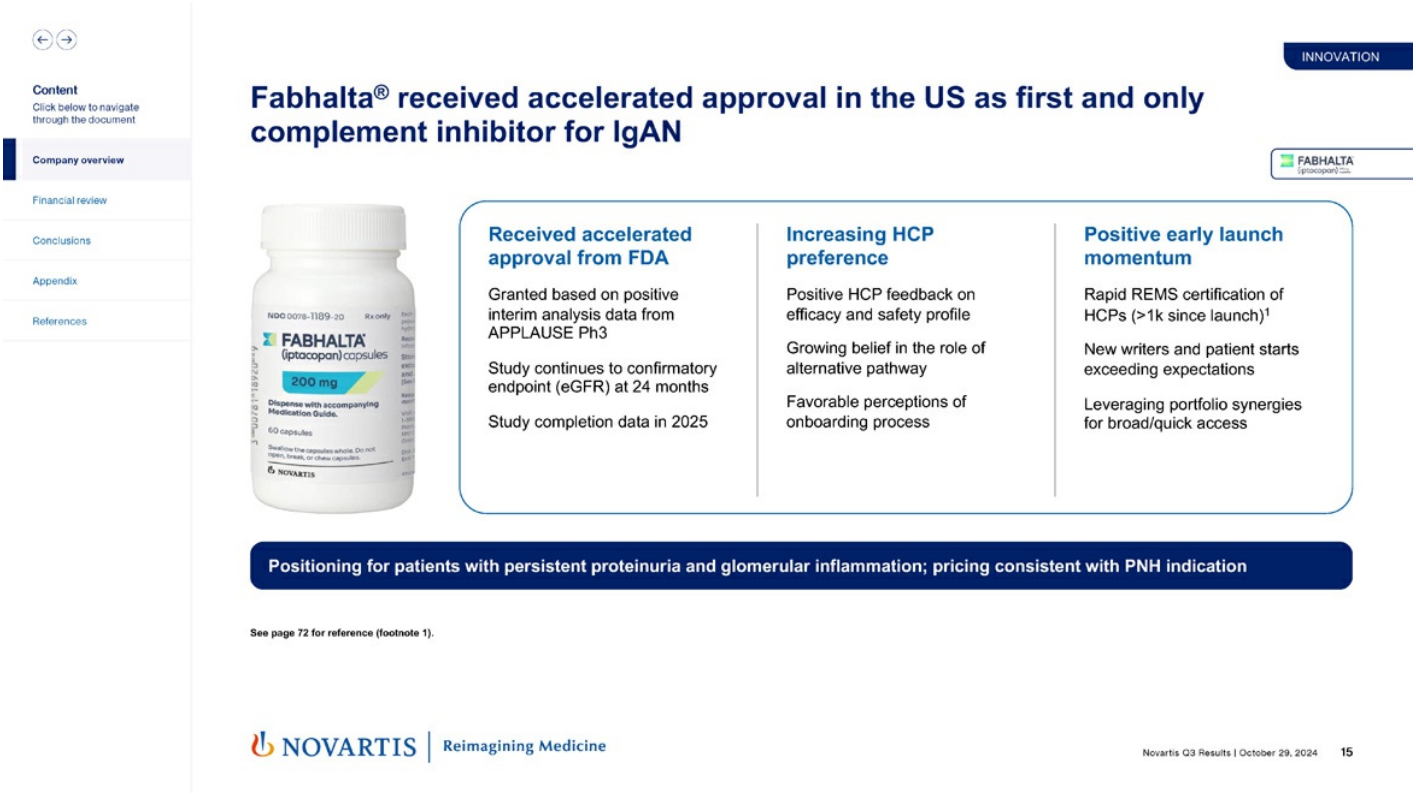
Slide 14



Now moving to slide 14. Fabhalta®, it's early days, but we are pleased by the performance in GNH ultrarare disease, not a lot of cycling of these patients. So it will take time to build this brand. But as the only monotherapy – oral monotherapy to provide extravascular and intravascular hemolysis control, we're seeing strong launch performance overall. We see a high compliance and continuation rate on the medicine. We have over 70% coverage to label. We have NBRx share now of over 30%. And outside of the US as well, we're seeing solid early signs of success with good patient activation with over 1,000 HCPs now reached in the first three months post launch.

We're seeing utilization across naive and switch patients. And we also have recent launches in Japan, UK, and we were granted early access as well in France. So taken together, early days, but step by step, this is an important building block as we build Fabhalta® across multiple indications to be over a USD 3 billion-plus medicine over time.

Slide 15

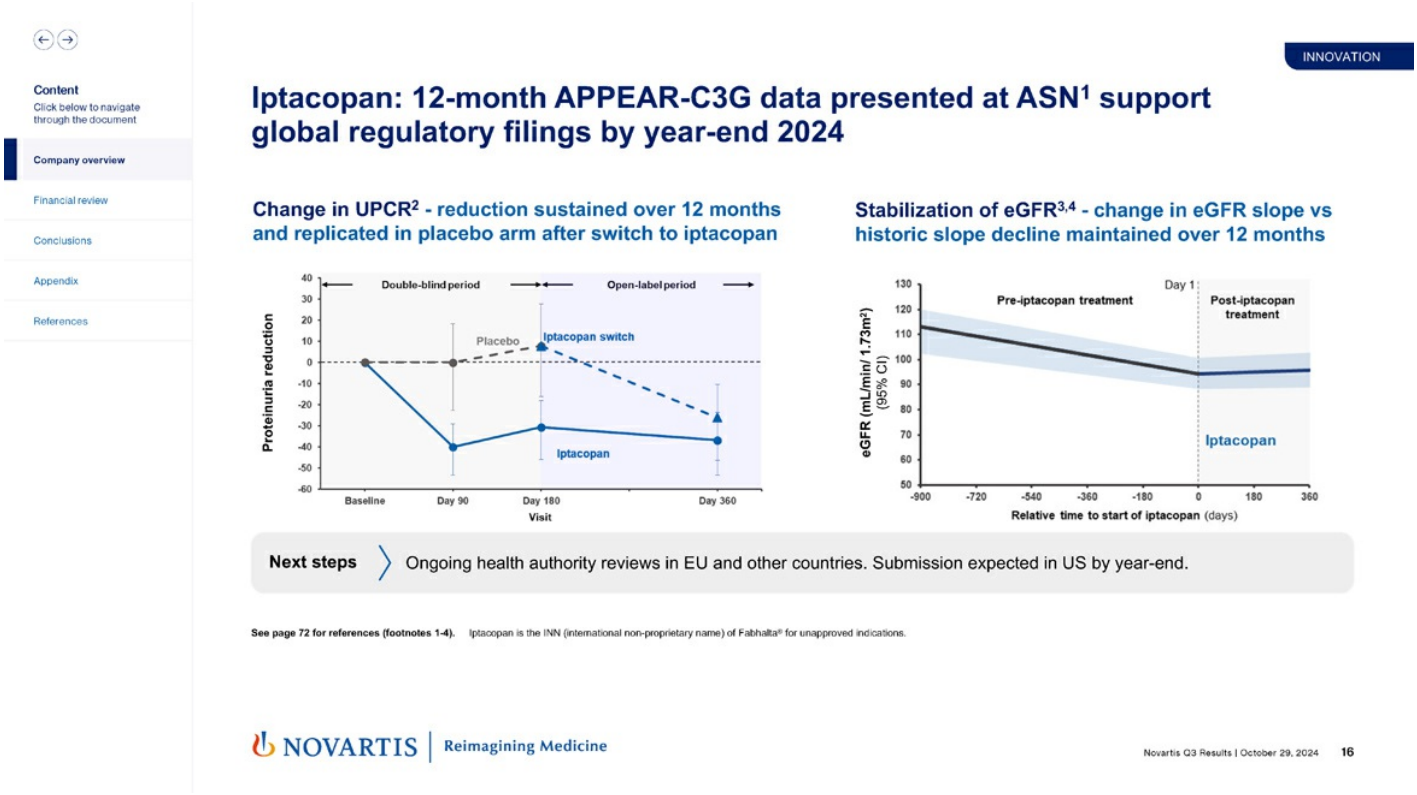


Moving to slide 15. In addition, Fabhalta® received the accelerated approval in the US as the first and only complement inhibitor in IgA nephropathy. That was based on the positive interim results of the applause Phase III study. The study is continuing to the confirmatory endpoint of eGFR at 24 months. We expect the completion date in 2025.

We see very positive HCP feedback on the efficacy and safety and understanding of the role of the complement pathway in this disease. We also see important early signs from a utilization standpoint. Over 1,000 HCPs are now REMS certified, and we're leveraging our portfolio to ensure that we have broad and quick access for this medicine.

Perhaps most importantly, we're seeing positioning of this medicine for patients with persistent proteinuria and glomerular inflammation as really getting traction in the marketplace. And that's enabling us to maintain the price of Fabhalta® consistent with the PNH indication which will also be important for the subsequent indications that we have for Fabhalta®, including C3G.

Slide 16



And if we go to the next slide, slide 16, we released results over the weekend of the 12-month APPEAR-C3G data at ASN. On the left-hand side, you see the sustained proteinuria reduction over 12 months and that that was replicated in the placebo arm after switch to iptacopan. So that was very positive and something the regulators had asked us for.

But importantly as well, we're seeing stabilization of the eGFR slope versus the historic slope decline, and that's been maintained now for 12 months. So we're seeing the important outcome measure as well, very positive data.

So we have ongoing health authority reviews in the EU and other countries. And we expect to make the submission now in the US before the end of the year.

Slide 17

Continued progress on innovation milestones in Q3

2024 selected key events (expected)

		H1 2024	H2 2024	Q3 status update
Regulatory decisions	Fabhalta® PNH		EU, JP	EU, JP and China approval in Q2
	Kisqali® HR+/HER2- adj.BC		US, EU	US approval in Q3; CHMP positive opinion in Q4
Submissions	Atrasentan IgAN	US		US submission in Q2
	Fabhalta® (iptacopan) C3G		US, EU	EU, JP and China submissions in Q3
	Fabhalta® (iptacopan) IgAN	US		US accelerated approval and China submission in Q3
	Pluvicto® mCRPC, pre-taxane		US	US submission in Q3
	Remibrutinib CSU			Ph3 REMIX-1 and -2 52-week readout in Q1; submissions expected 2025
	Scemblix® CML 1L	US	JP	FDA granted priority review; China and Japan submissions in Q3
	Lutathera® GEP-NET 1L G2/G3	EU		EU submission in Q2
Readouts	Scemblix® CML 1L	Ph3 (ASC4FIRST)		Ph3 ASC4FIRST readout in Q1
	Zolgensma® SMA IT		Ph3 (STEER)	On track
	XXB750 Hypertension		Ph2	NVS will not advance further development following current scientific assessment and review of available data
Ph3 starts	Pluvicto® oligometastatic PC	Ph3		Ph3 PSMA-DC started in Q1
	Opnurasib 1L NSCLC (combo)[1]	Ph2/3		Program discontinued to prioritize other key programs in portfolio

Adj.BC – Adjuvant breast cancer. C3G – complement 3 glomerulopathy. CML – chronic myeloid leukemia. CSU – chronic spontaneous urticaria. GEP-NET – gastroenteropancreatic neuroendocrine tumors. IgAN – immunoglobulin A nephropathy. mCRPC – metastatic castration-resistant prostate cancer. NSCLC – non-small cell lung cancer. PNH – paroxysmal nocturnal hemoglobinuria. SMA – spinal muscular atrophy. 1. This is a seamless Ph2/3 trial.

So moving to slide 17. Overall, we had good progress on our innovation milestones. We did suffer a few setbacks. With XXB, we will terminate this program. We saw a safety signal in heart failure. And overall, the hypertension, blood pressure reduction we saw on top of standard of care was not sufficient to meet the TPP we think we need to achieve for this medicine. So we'll be stepping back and focusing on our siRNAs for hypertension as well as other assets we have in our cardiovascular portfolio. So with that, let me hand it over to Harry.

Slide 18 – Harry Kirsch – CFO of Novartis

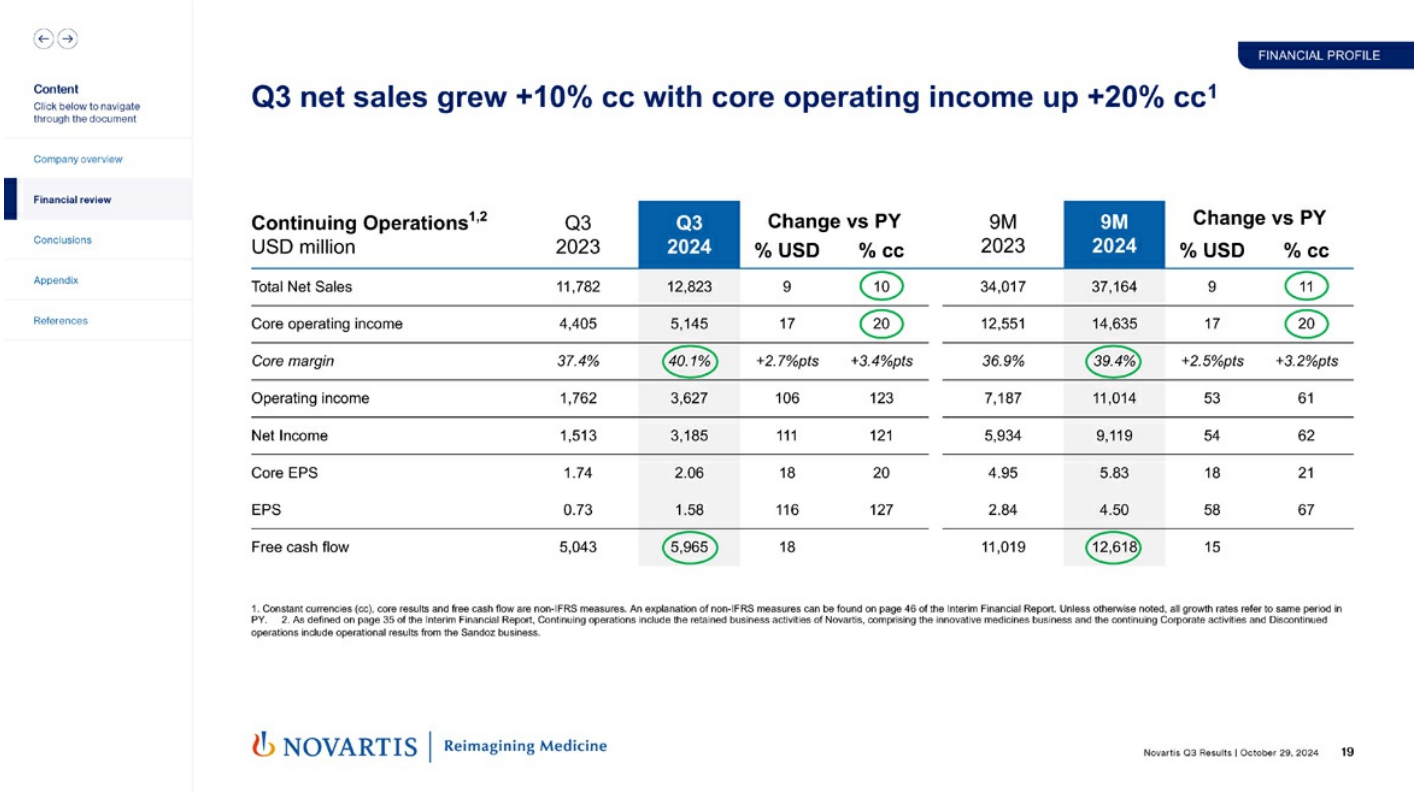
Financial review and 2024 guidance

Harry Kirsch
Chief Financial Officer

Yes. Thank you, Vas. Good morning, and good afternoon, everyone. I will now talk you through our financials for the third quarter and the first nine months, which were very strong. As always, my comments refer to

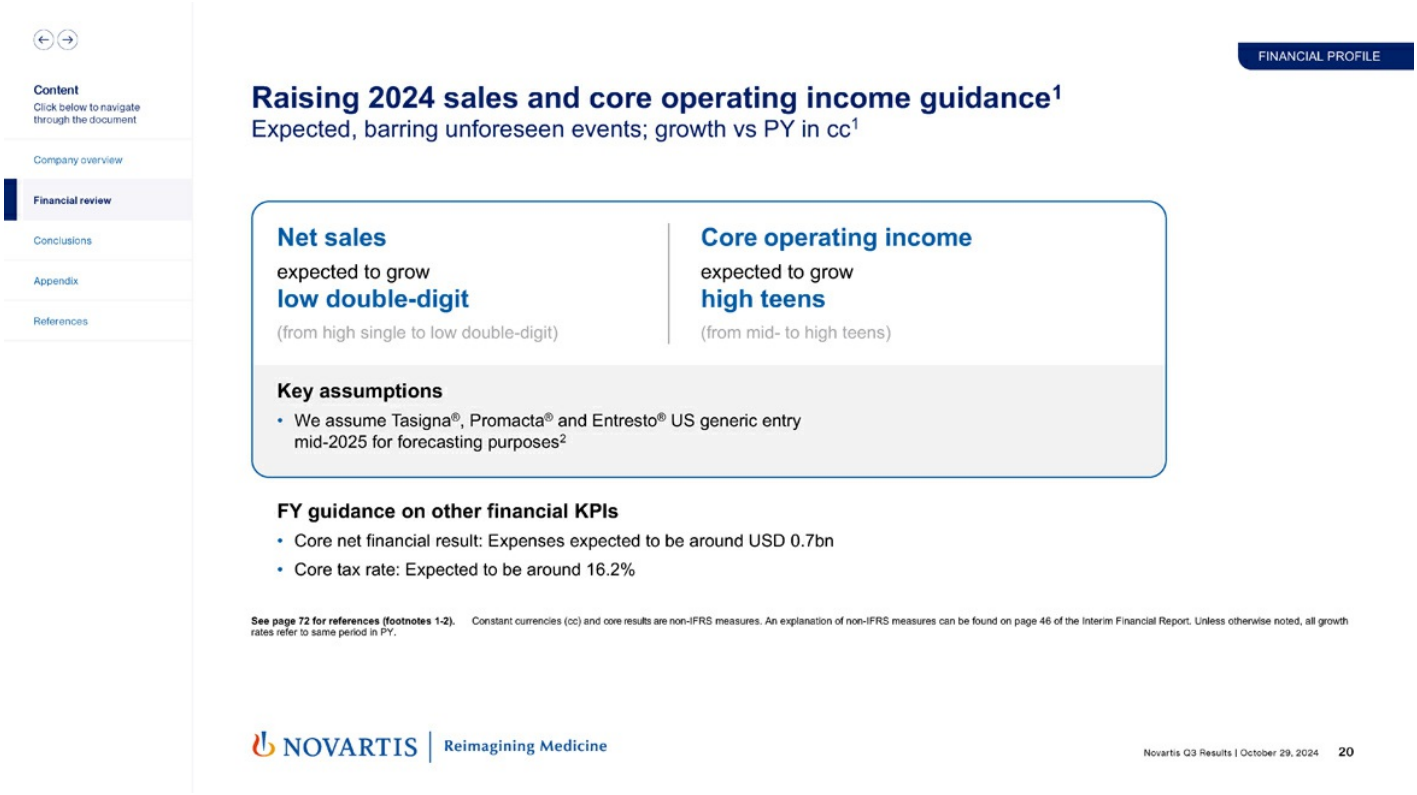
continuing operations and growth rates in constant currencies, unless otherwise noted.

Slide 19



On slide 19, it's a pleasure to present results like those that we have on slide 19. I think you hopefully agree with that. Quarter 3, net sales grew 10%. Core operating income was up 20%. Our core margin, as Vas already mentioned, 40.1%, which reflects a 340 basis point improvement versus prior year. Core EPS was USD 2.06, also up 20%, and free cash flow was basically USD 6 billion, the highest we have ever achieved in any one quarter. For nine months, net sales grew 11% and core operating income was also up 20%, when the core margin increased to 39.4% in the first nine months, demonstrating continued good or very good progress towards achieving our midterm margin guidance of 40% plus by 2027. Core EPS was USD 5.83, up 21%. And the free cash flow in the first nine months grew 15% to USD 12.6 billion.

Slide 20



Now on to the next slide, please. Our continued strong business momentum, together with operating efficiencies despite the many launches we are fully funding and of course, the R&D pipeline, allowed us to once again raise our full year guidance on both top and bottom line, which you will see on slide 20. We now expect sales to grow low double digits from high single to low double digits previously, and we expect core operating income to grow in the high teens from mid- to high teens previously.

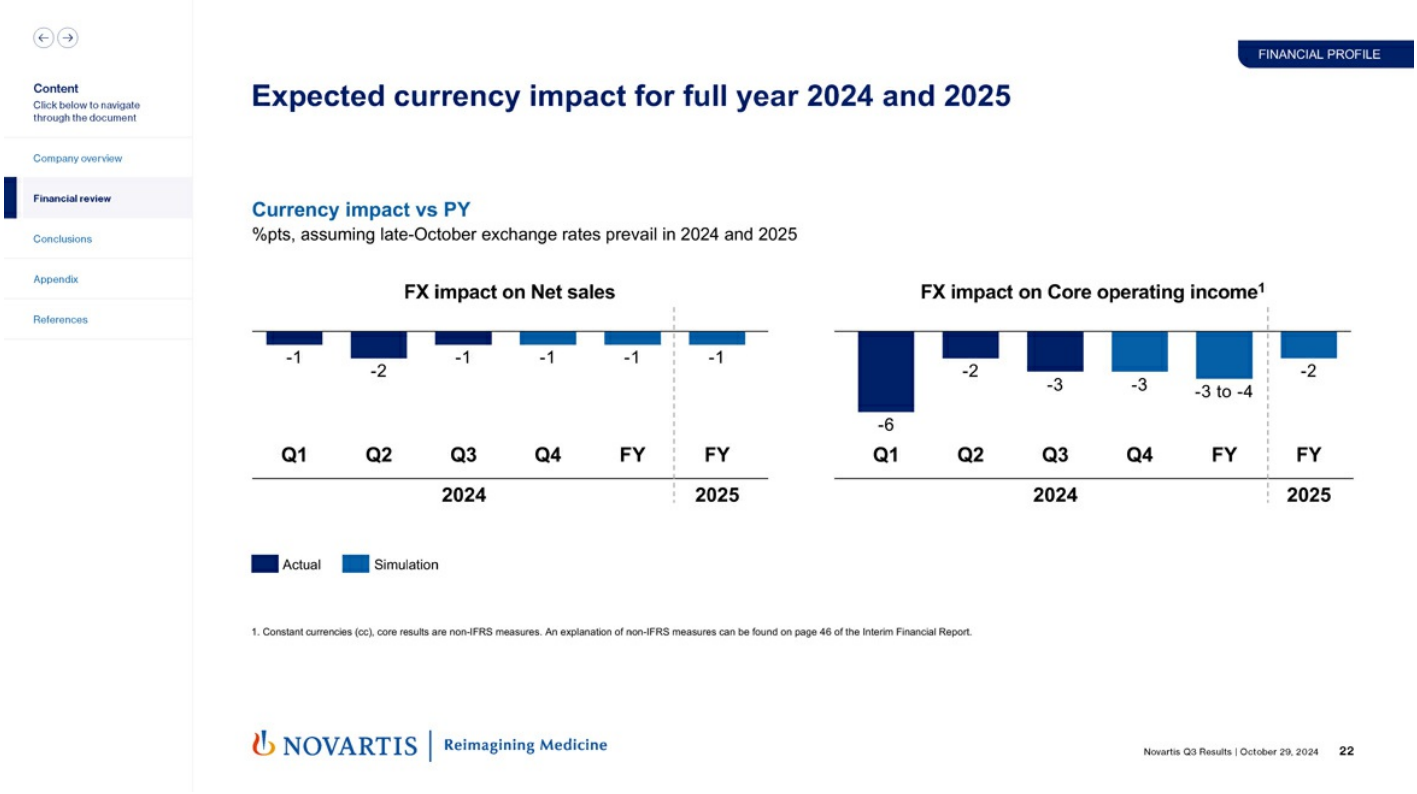
Embedded in our guidance is the key assumption that there will be no Tasigna®, Promacta® or Entresto® US generic entries in 2024. And we also expanded a bit so that you can start with the modeling for next year, and we make an assumption that these generic entries in US will happen in the middle of 2025 for forecasting purposes. And to complete our full year guidance is always the other two components from core operating income down to basic core EPS. Please note that we expect core net financial expenses to be around USD 0.7 billion for the full year. And our core tax rate continues to be around 16.2%.

Slide 21

Moving to slide 21. We remain committed to our shareholder-friendly capital allocation strategy to invest in the business whilst also returning attractive shareholder returns. In the first nine months, we executed multiple bolt-on M&A and BD&L deals, particularly to strengthen our RLT platform, our renal pipeline and AI capabilities. In addition to having invested, of course, in our internal R&D engine.

In terms of returning capital to shareholders, we paid our growing annual dividend per share in Swiss franc this time, USD 7.6 billion in March of this year. And we also continued our USD 15 billion share buyback which has approximately USD 8 billion left to be executed by the end of 2025.

Slide 22



Now on to my final slide already, where we have outlined details regarding the expected currency impacts. In quarter 3, FX had a mild negative 1 percentage point impact on net sales, a negative 3% points on core operating income, of course, driven by (inaudible) dollar strengthening, but also, of course, on the bottom line due to our Swiss franc cost base.

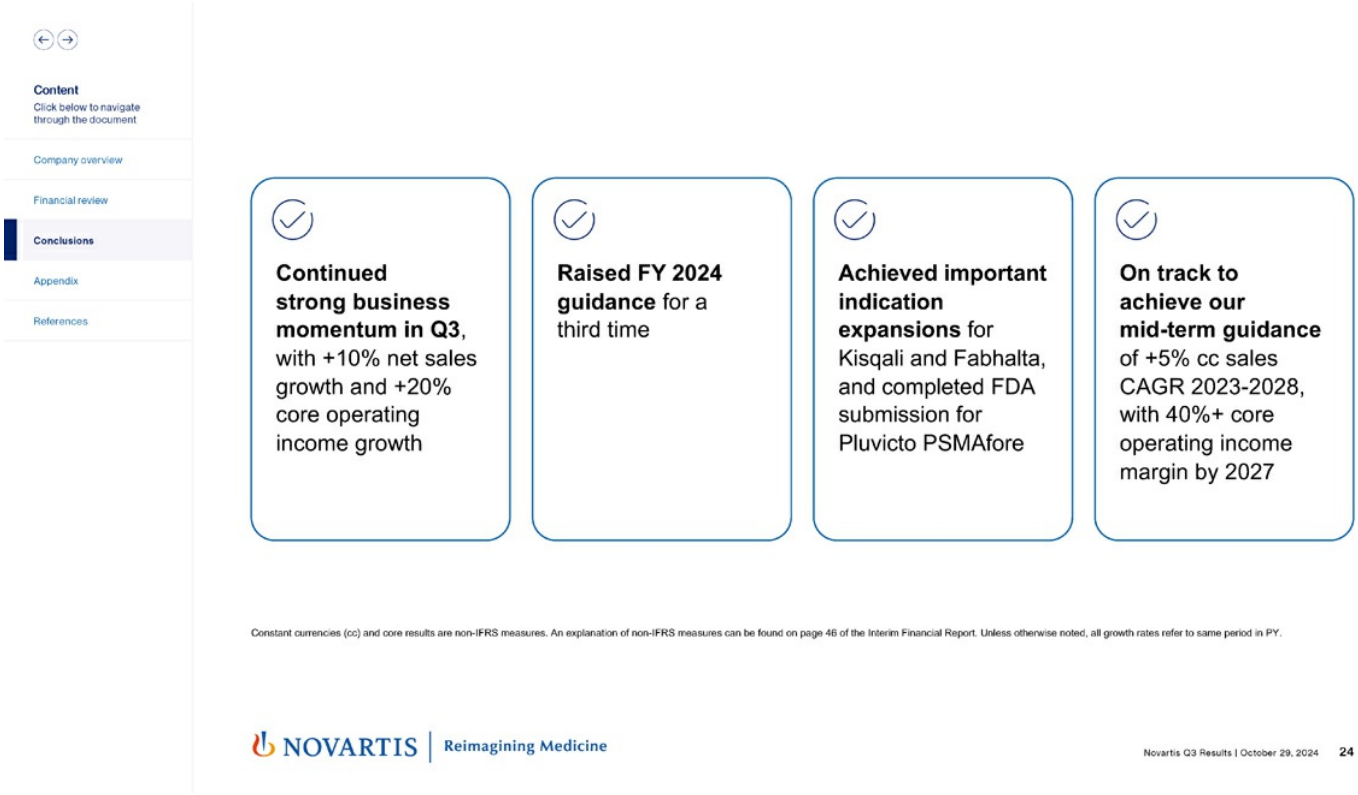
If late October rates were to prevail for the remainder of 2024, we would expect full year currency impact to be again around 1% negative on net sales and negative 3 to 4 percentage points on core operating income. As we already start to look forward into 2025 again to inform your modeling assumptions, we expect a negative 1% point impact on net sales and negative 2 percentage points on core operating income. Again, if currencies stay for next year where they are right now.

Of course, as we all know, currencies move every minute. And so we will – given it's hard to predict this from outside of the company each month, in the middle of the month, we will give you an update, which is posted on the website. So you always have that element of the forecast as well. And so thank you for your interest, of course, and back to you, Vas.

Slide 23 – Vasant Narasimhan – CEO of Novartis

Great. Thank you, Harry.

Slide 24



So moving to slide 24. In summary, we see continued strong business momentum in the quarter and I think the numbers speak for themselves, the 10% and the 20% growth. We raised our full year 2024 guidance for the third time just showing the underlying momentum we're seeing across our growth drivers and new launches. We continue to deliver on our pipeline building off of 10 Phase III readouts – positive Phase III readouts with indication expansions of Kisqali®, Fabhalta® and the submission of Pluvicto® PSMAfore. And we're well on track to achieve our midterm guidance of 5% sales growth '23 to '28 and 40% plus operating income margin by 2027.

Slide 25

So moving to my last slide, we also wanted to just (inaudible) for all of you. We will have Meet Novartis

Management on November 20 and 21 in London. It will be a great opportunity for our investors to meet our leadership teams across the company with a focus on our TA leaders in R&D. We'll also be able to provide an update on our '23 to '28 midterm guidance as well as a '24 to '29 sales guidance as well. And then lastly, we'll also provide an update on the peak sales outlook for many of our brands, which continue to have really strong momentum. So with that, operator, we can open the line for questions.

Q&A

- Operator

(Operator Instructions) And your first question comes from the line of Richard Vosser from JPMorgan.

- Richard Vosser - JPMorgan Chase & Co

Q. It's a question on the impact of coverage gap reform on the business in '25. I'm particularly thinking about the impact on Cosentyx® and Entresto®. If you could give us any color on how that's panning out, that would be great.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Richard. And I also want to add, we should have one question. I thank you for adhering to that already, Richard, but one question per person, and then we'll cycle through the list as many times as we can.

So in terms of the coverage gap reform, there's going to be pushes and pulls, which we'll have to understand better over the course of 2025. On the positive side, we'll see how demand generation increased with the 20% out-of-pocket cap, especially depending on how many patients sign up for the smoothing, you could see that those impacts happening relatively early in the year, but that's something we'll have to see how it ultimately plays out on the positive side.

In terms of headwinds, certainly, our cost sharing within the system will go up, and that's something we'll have to manage. But on the flip side, our patient support programs also should be adjusted down given the number of patients who would qualify. I would not no longer qualify given adjustments given the IRA being in place. So

net-net, we see this as neutral to slightly negative, but that's already factored into the guidance that we've given for the long run. So that's already in the 5% up to '28. So a material impact on how we look at the business. And I think we're going to learn more over the course of the year.

- Operator

Your next question comes from the line of Emily Field from Barclays.

- Emily Field - Barclays Bank

Q. Just one on Pluvicto®. I was just wondering when you'd expect some of these new promotional efforts to have an impact on Pluvicto® patient growth in the US in the VISION population? Or should we more expect sales to really start to grow again once PSMAfore has launched? I believe, early in the year, you said that, that launch would be an inflection in sales. So any color you can provide would be helpful.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Emily. So we know in terms of the time lines for those investments, we started the DTC in September. We got the full field force out really in the August, September time frame. So it usually takes six months before you see any impact for those expansions and investments. So I think for us right now, we want to maintain the VISION population. We always guided to VISION to be about a USD 2 billion peak sales globally. So in the US, we're already annualizing in that kind of 1.2 to 1.4 range. We expect as we bring China, Japan and other markets on board, we can reach that USD 2 billion over time.

But the real inflection for this medicine is the tripling of the patient population with PSMAfore and then a further large addition of additional patients with the HSPC PSMAddition studies. So we've got to make sure that we have adequate capacity, which we feel pretty good about in terms of bed capacity. A lot of our work now is getting the referral systems in place to ensure that community oncology understands how they can refer, when to refer to be able to get Pluvicto® and get those patients also then back to community oncology. Also making sure that large academic centers are prepared for what we expect will be a surge of patients on the approval of PSMAfore. So all of that work is very much in focus, but I wouldn't expect a significant inflection point before we get PSMAfore fully launched.

- Operator

Your next question comes from the line of Florent Cespedes from Bernstein.

- Florent Cespedes - Societe Generale Cross Asset Research

Q. A quick one on 2025, I know it's early days and you won't provide any guidance. But could you remind us which are the main tailwinds and headwinds for next year? And how you see this challenging year given the generics expected to be launched mid-2025?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Florent. Obviously, we don't provide guidance until January. But I can say we're confident we'll grow top and bottom line, and we'll provide more color on that, obviously, in January.

When you think about the tailwinds that we have, it's clearly the new indications and launches. I mean you've already seen Cosentyx® is continuing to have strong performance in HS and IV. We, of course, have now the Kisqali® early breast cancer with a broad label and a broad NCCN Guideline, we're in the early days of the iptacopan launch, both in PNH and IgAN, we expect to accelerate over the course of next year. Importantly, the Scemblix® first-line launch in CML will continue to allow us to expand that drug hopefully substantially. And

then, of course, Kesimpta®, you've seen is already on just a steady, strong pace and Kisqali® in metastatic breast cancer also in a really strong pace. And then Entresto®, outside of the US, also with continued strong performance.

I think the biggest headwinds we're going to have, as we noted, is the LOEs that we currently forecast for forecasting purposes for mid of next year on Tasigna®, Promacta® and Entresto®. Of course, it depends on how those ultimately all the various litigations go and whether our products are appropriately – are approved, et cetera, but that's our current forecasting guidance on those medicines.

But beyond that, we see continued opportunities for strong margin performance, strong free cash flow performance. We feel very good with where the business is. So I think we can navigate that. And as we said all along, we factor those patents in – those LOEs into that 5% plus guidance up to '28. So it's well captured in our long-term guidance, and we'll navigate it and continue to grow the company strongly.

- Operator

Your next question comes from the line of Simon Baker from Redburn Atlantic.

- Simon Baker - Redburn (Europe) Limited

Q. One on Cosentyx® in HS, if I may. You've seen a very, very fast adoption in HS, which is testament to the superiority of Cosentyx® over previous treatment options. But there were quite a few behind Cosentyx® coming into HS. So I just wondered if you could update us on your thoughts on the competitive dynamics there? How long do you expect that preeminence of Cosentyx® to persist, bearing in mind what is coming behind over the next 12 to 18 months?

- Vasant Narasimhan – CEO of Novartis

A. Yes. I mean, look, we – Simon, thanks for the question. We continue to expect Cosentyx® to be over USD 1 billion plus in HS. And the reasons we have that conviction, as you noted as well, there's a tremendous support for Cosentyx® amongst dermatologists. We're very comfortable using this medicine given the long period of time that it's been on the market and successfully used.

But the other thing is I think there's confusion in the market in terms of the comparison of Cosentyx® to the IL-17 AF in psoriasis versus what at least we see in HS. Importantly, in HS, when you look at the HIS CR 50, you have pretty comparable results – cross-trial comparisons are always, of course, challenging different patient population, so have to be taken with appropriate caution. But very similar.

And then when you look at flares in our study, we had 60% of patients free of flares. And in pain, we showed a meaningful reduction of 50% for these patients in pain. I would encourage the investor base to look at that data versus the competitor entry. And I think that would enable us to have really a strong clinical positioning on top of the strong account positioning and long history that we have.

So then really, the focus is in a growing market with additional patients who hopefully will come in. Can we continue to maintain a strong share position, given that data, given our access position which is why we think HS will be a very substantial opportunity for the medicine. But I think that distinction between psoriasis and HS data is absolutely crucial for everyone to understand.

- Operator

Your next question comes from the line of Graham Parry, Bank of America.

- Graham Parry - BofA Securities

Q. Question on Pluvicto®. So the flat fourth quarter guide implies no growth ex US as well as in the US. So I understand US centers are pretty fully penetrated in the VISION population, but why no growth ex US? And on PSMAfore I just wondered why you didn't use a priority voucher or attempt to accelerate the review there in any way?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Graham. So on Pluvicto®, so I think ex US right now, we do continue to see growth generation, but of course, with the pricing dynamics as we continue to work to secure the final pricing, we don't expect that to translate yet into revenues. And then I think China and Japan will be absolutely critical to really get the ex US going.

In Europe, we're primarily focused in Germany and France, and we have ongoing negotiations in those markets regarding the pricing situation. So I think that's why we want to be realistic and say, in addition to that dynamic, we also have the holiday period in the US. We know from prior years that for Pluvicto®, Thanksgiving and the Christmas holidays, is not a time that patients want to initiate therapy because post dose, they can't be around family or be around children. At least that's the current guideline. Whether biologically sensible or not is irrelevant. That's the current guidance. So that leads to a few weeks that we lose in quarter 4 always.

So taking all of that together, we think it's reasonable and prudent to provide guidance that will be in line net of the adjustment.

Now in terms of Pluvicto® PSMAfore, we chose not to use a priority review voucher purely because we had discussions with the FDA. The FDA view was, given that we'll provide the 100% OS during the review period, they wanted flexibility for the timing to review that data. Now hopefully, given that data continues to trend positive, assuming that hold and that we have a very compelling package, we hope that we can get an approval on a faster time line than the typical PDUFA time line. But in consultation with the FDA, that was their request, hence, we didn't use the voucher.

- Operator

Your next question comes from the line of Matthew Weston, UBS.

- Matthew Weston - UBS.

Q. My question is about payer dynamics in 2025 as well. Vas, I'm just aware that you have a very strong position in immunology and commercial PBMs have lost a significant amount of rebates from Humira® over the course of this year. I wonder whether we should expect a particularly strong and dynamic rebate environment at the beginning of 2025, and we should be prepared for that as we look at the forecast into next year. If I can cheekily sneak a second. It's just can you remind us factually when do you anticipate Kisqali® ex US patent expiry?

- Vasant Narasimhan – CEO of Novartis

A. Thank you, Matthew. So first, on Cosentyx® and the overall immunology dynamic. We've completed largely our payer negotiations, and we're really pleased with the broad access we've been able to maintain for Cosentyx®. And I would say, while we do see increased rebates, it's modest and not substantial. So we've been able to keep that as a single-digit increase overall across the portfolio. So we shouldn't expect – well, of course, that is a headwind. We do expect overall the opportunities in HS and IV alongside the opportunities that we have with additional launches as well as the overall momentum we have globally, that globally, Cosentyx® should continue to grow in the double-digit range. And so that's our current expectations for

Cosentyx®.

Now in terms of Kisqali® LOE, it is August 2032 is our current estimate in Europe.

- Operator

Your next question comes from the line of James Quigley from Goldman Sachs.

- James Quigley - Goldman Sachs Group, Inc.

Q. Got a quick one on Xolair®. So Vas, you've seen some strong uptake in the US for the food allergy indication, does Novartis plan to use the data from the OUtMATCH trial to potentially (inaudible) the indication in the Novartis territories? And what would you think about the potential opportunity here? Obviously, there's a (inaudible) in ligelizumab in this indication as well. So does that be a potential clear one for you and Xolair® in ex US markets.

- Vasant Narasimhan – CEO of Novartis

A. Yes. So James, I have to come back to you. I don't actually know off the top of my head on what our plans are on Xolair® for ex US food allergy. Obviously, in the US, we have our existing contractual obligations with Roche Genentech.

In general, my first instinct to say is if food allergy ex US is challenging given the overall payer dynamics, particularly in Europe. But let us come back to you because I don't want to make that a definitive statement without knowing for sure. We do continue to develop remibrutinib as an oral option in food allergy, and we're going to see how that data pans out because we think the option of giving patients the twice-a-day oral therapy for food allergy could be quite attractive. So that development program is continuing on track.

- Operator

Your next question comes from the line of Peter Welford from Jefferies.

- Peter Welford - Jefferies

Q. My question is on the broader cardiovascular portfolio now at Novartis, particularly focusing on the pipeline. I mean, obviously, we're aware of pelacarsen which I wonder if you can confirm we're still expecting the Phase III readout there next year. But obviously, following the news on XXB, when you now look at the late-stage cardiovascular portfolio outside of nephrology, I guess how do you now think about the need perhaps in Novartis to bolster that, or are you comfortable given the long life that we see still with Leqvio® ahead despite the loss of Entresto® in the US, so you will basically just build the cardiovascular pipeline largely internally through the early stage Phase I preclinical programs that you have?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Peter. So obviously disappointing with XXB. But overall, we feel confident given where we see Leqvio®'s continued expansion and the adjustments we've anyway made to the field force, we think we're rightsized for Leqvio®. Pelacarsen on track, it's event driven. So we'll have to continue to track the events, but we currently guide to a 2025 readout. And then behind that, right now, we're really focused on accelerating our siRNA portfolio.

Those siRNAs could either be as mono indications or in combination with Leqvio®, so we're exploring a range. And we have, now a couple in Phase II, or one, it's even a bit later than that. So we'll be providing updates on those over time. But certainly, siRNAs in hypertension, siRNAs against HMG-CoA, which could be then used

in combination or independent of Leqvio® as well as other earlier Phase I siRNAs are all advancing. So we continue to want to build out a broad siRNA portfolio and then also look as appropriate for combinations with Leqvio®.

The other element – two elements of our story, I think, on cardiovascular. One is a portfolio of agents in arrhythmia, high risk, very high risk, but we're relatively on our own in arrhythmia. And so we have a few agents now in Phase I or proof-of-concept studies. So we'll certainly see how those ultimately play out. And then we have, obviously, as all companies do a broad preclinical portfolio, but including preclinical efforts on novel targets in obesity as well as in other areas of cardiovascular risk reduction, particularly around nephrology. So we'll see how those advance as well. So obviously, we'll always look externally, but there's no urgency to plug any gaps at this point.

- Operator

Your next question comes from the line of Etzer Darout from BMO Capital Markets.

- Etzer Darout - BMO Capital Markets Equity Research

Q. I had a question on pelacarsen readout next year for Lp(a). And apologies if you've commented on this in the past. Just curious, there's literature on the impact of Lp(a) on GLP-1 levels, but curious as to the reverse. And I guess, given the increasing use of GLP-1s broadly, just curious if GLP-1 use matters in the study? And if so, how you're accounting for its use in the trial?

- Vasant Narasimhan – CEO of Novartis

A. Yes, absolutely. So I think GLP-1s are noted to have, I think, modest reductions of Lp(a). I mean the focus of this study is on patients that are much higher on the range of Lp(a). So the top quartile and the top decile, which we believe you need to have pretty substantial knockdown 70% to 90% of the Lp(a) levels. 90% plus ideally that would then enable you to have the hopeful – hope for at least the genetically validated efficacy benefit.

So we don't believe GLP-1s alone or PCSK9s alone, PCSK9s also knocked on Lp(a), are going to be sufficient for this patient population that is at a very high risk of cardiovascular events due to their Lp(a) levels.

In terms of (inaudible), I don't know offhand how many patients were on a GLP-1 at baseline. But with all of these trials, we always have, of course, patients who are on standard of care for their various comorbidities. And then, of course, we would do subgroup analyses based on the various patient populations. Those would not be powered, of course, and would be post hoc, as always, we generate those 4 slots to demonstrate how different patient groups responded to the medicine. So that's what I would expect would happen in this case.

- Operator

Your next question comes from the line of Kerry Holford from Berenberg.

- Kerry Holford - Joh. Berenberg, Gossler & Co. KG

Q. Just going back to the theme of M&A. Given your strong balance sheet and a growing patent expiry burden, just interested to hear you talk about your appetite for more M&A in the future here. I wonder if you can comment specifically on your degree of interest in obesity? Just any bad with regard to your early-stage internal pipeline. But interest in potentially bolstering that externally?

And tied to this, I think somewhat disappointing that we should see an impairment so soon onto the MorphoSys deal closure. So my question then is, how can investors gain confidence in your future M&A

choices? Any commentary you would have there.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Kerry. So on overall, we have, of course, adequate firepower. And as Harry mentioned, we have a balanced approach to capital allocation, invest in the business, growing dividend in Swiss Francs, ongoing share buyback with adequate capacity to continue share buybacks as deemed appropriate. And then we've been very active in the deal front, really in the sub-USD 1 billion asset space.

I mean most of these don't hit the radar, but we've built out, I think, a pretty – and I'll line this in a bit more detail at Meet the Management. But a really broad range of assets across our key therapeutic areas as well as key technology areas to fill either mechanism of action gaps or technology gaps which we think are critical for us to succeed in those four core TAs or in our three key technology platforms.

A great example being the various deals we've done in RLT, including Mariana oncology to build out a strong actinium profile or even the deal we announced, I think, yesterday with Monte Rosa Therapeutics, which gives us a strong opportunity within the world of molecular glues for immunology.

I think regarding your specific combination – question on obesity, no change. We think GLP-1, GIP, et cetera, are well served by the current incumbents, and we expect a flood of companies from China and elsewhere to attempt to enter these spaces. And so we don't see an opportunity to really build a differentiated profile, especially given what will likely be a very intense payer rebate environment in the US as well as genericization of first-line GLP, or older GLP-1 agents over the coming years. So we don't think that's a game to play in as a fast follower – late follower, rather focus on novel assets.

And I think overall, when we look at our – I mean, our M&A track record, we've done it very carefully, and we systematically look at it. We see our overall success rate in line with the overall sector. There are companies that are worse than us. There are a few that are a little bit better than us. But of course, if you look at the GSK oncology acquisitions, if you look at Kesimpta®, if you look at building out a strong RLT portfolio, I expect that with AveXis ultimately showing the positive impact of our intrathecal readout later this year or early next year in the 2- to 18-year-old patients. Well, that will also be a strong payback.

So obviously, whenever you do clinical stage deals like we did with pelabresib, you will have updated clinical data. I think that's normal in this business. I would expect sophisticated investors not to read too much into one-offs, but rather look at the overall portfolio of how a company does, it executes M&A.

- Operator

Your next question comes from the line of Seamus Fernandez from Guggenheim Securities.

- Seamus Fernandez - Guggenheim Securities

Q. So really just one question to follow up on business development in areas of interest. The dynamics in immunology are obviously keying up accelerating across bispecifics, long-acting assets and overall asset development. I wanted to just ask, I guess, a bit of a blended question, not two, but what the effort with Generate is really seeking to execute? And if there is an awareness or when we might have the targets potentially disclosed in that collaboration? And how you're thinking about immunology writ large from a BD perspective simply because we know that Generate is also doing quite a bit there along those lines?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Seamus. So I'll divide my commentary into first AI and then separately into specific

immunology.
So with Novartis, our primary collaboration is with Isomorphic Labs, where we partner with the noble Prize winning team there to really work on novel targets to generate hits and leads that we can take them further into development. So that's a collaboration that's ongoing for small molecules and potentially could expand over time into other areas of drug development.

And then with Generate, we focus on biologics. We have not disclosed the targets that we're working on, but generally speaking, it would be difficult to drug targets or we want novel biologics with novel formats, as you mentioned, bispecifics, trispecifics, et cetera. So that's the focus of the Generate Bio collaboration.

And then we're going to learn and see how it goes as we continue to use AI to hopefully speed up our research and early development process. We could expand into additional targets with both of those collaborations over time. But I think it's early days, and I think we need to see the results of those efforts – the first efforts and then, of course, progress step by step.

I think more broadly, in immunology, in-house on top of remibrutinib and VAY, both of which will have readouts over the course of 2025, 2026, which will allow us to, I think, build two more very substantial medicines to continue to build off of the success of Cosentyx®. We have a number of bispecifics and trispecifics programs that are in Phase I, Phase II. And then, of course, we have YTB now in either (inaudible) Phase I or Phase II development for immune reset. That's our rapid CAR T therapy I think now enrolling in six or seven indications, continuing to look to expand across immunology as well as in neuroscience indications.

And so I think our BD and M&A efforts are either to bolster the areas I just mentioned, bispecifics or cell therapies, or to look at novel targets like Monte Rosa that we recently have done. Those are the things I think we're broadly looking at. But I would say we do believe you need to move now into more specialty immunology, more targeted immunology going into the mass market with a number of biosimilars coming out at the end of the decade. And high rebate pressure, you need to really find places where you can have a differentiated offering in the United States, particularly given that payer dynamic.

- Operator

The next question comes from the line of Rajesh Kumar from HSBC.

- Rajesh Kumar - HSBC

Q. On capital allocation, can you help us understand how you think between your choice of doing deals versus buying back shares? And then at what share price of multiples would doing a deal would become the only good use of capital? Then – your share price has been quite strong if we leave today aside, but if we look at the earnings momentum, et cetera, at what point would you stop share buybacks and deploy more capital towards steelmaking?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Rajesh. I'll give that to Harry. Harry?

- Harry Kirsch – CFO of Novartis

A. Yes. Thank you, Vas. Thank you, Rajesh. I think it's, of course, a question that has just never had an absolute answer, right? Obviously, we believe that our share price has much more potential. If I just look at our 5-year growth rate outlook or even consensus is not there yet at the 5%, slowly creeping up every few months. No, I think consensus just makes it to 4%. Of course, we keep that dynamically.

In terms of balance sheet and cash flow, if you – we call it firepower, so nicely, right? But anyway, we have such a nice capacity that we have the situation we can do all M&A bolt-on deals that we come up with. And by the way, it's not so easy to cut up with good ones, right, given the premiums one has to pay and the high conviction we have to have to have a great deal for our shareholders, also in terms of returns.

And – but we can do both. We can do bolt-on M&A, right? Our net debt is even below one time EBITDA at the moment with USD 16 billion, right, EBITDA is higher, USD 18 million, USD 19 billion, and growing. And so we have that luxury situation. On the one hand, we keep doing, I would say, continuous good share buyback at an attractive level. As you may know, Switzerland has an interesting situation. I think it's unique in the world that we can only do over time, right, roughly USD 10 billion a year max. And on the other hand, do all the bolt-on M&A to continue to further strengthen our four TA pipelines. And again, obviously, we believe that our share price has significant upside potential. And that's why we continue to do both for the foreseeable future. Thank you.

- Operator

The next question comes from the line of Steve Scala from Cowen.

- Steve Scala - TD Cowen

Q. No generics of Entresto® and Promacta® were already assumed in the 2024 guidance. So Tasigna® is the only update. What amount of the guidance raise is attributable to no generics of Tasigna®. And it sounds like the extension to 2025 for all three is due to litigation for Tasigna® and Promacta® in addition to Entresto® and not slower generic progress and/or settlement, is that correct?

- Vasant Narasimhan – CEO of Novartis

A. Yes, Steve, I can take the second part, and I'll give it to Harry on the contribution of Tasigna® to the overperformance on – overall, I mean, we're not going to comment on specific legal cases. But I think it's a combination of our litigation, our settlements and our kind of competitive intelligence as to where various players are in their approvals that gives us our current forecasting estimate of middle of next year, but that's not a definitive date. It's really going to depend on a number of factors.

As you know, we have three litigations ongoing with respect to Entresto®, with respect to the approval with FDA, the combination patent, where we're appealing the decision in the first instance hearings on the cocrystal patents. So that's all unfolding. And then Promacta® and Tasigna® is not something we've disclosed, but we continue to estimate a mid-2025, and we'll see how the actual market develops.
Harry, in terms of the Tasigna® contribution?

- Harry Kirsch – CFO of Novartis

A. Yes. Thank you. Yes, Steve, still have some contribution. I mean also on the Q2 call, I mentioned that if there is no generic entry, likely we will be at the higher end of our guidance. And that's what has happened now, right? So we don't expect any generic entry still. We have a bit of SAS LAR. There is a small entry in the US, but it's only in one account, 10% of business. So has very little in terms of impact model this year for Sandostatin® LAR.

But – so there is a contribution of Tasigna® to it. We also have some gross to net favorability in quarter 3, prior I guided to high single digits. Now we came in at 10%. So there was a contribution that was basically offsetting prior year favorability at one timers.

But overall, if you look at our business, our model at the moment is like we have a 14%, 14% volume growth.

Then we have 2 points of generic impact and 1 point of negative pricing, adding up to the 11% year-to-date net sales growth, right? And that's the model we go into operationally into Q4 as well into next year. And then what is expected to happen with the generic component goes a bit up and then a bit of pricing, not too much, but also partly or fully offset by some volume impact the US.

So overall, some slight contribution to getting to the high end, but overall, what we just see at the moment is a fantastic continued very good business momentum. And the only dynamic next year is really when are these generic impacts happening. But the underlying growth of the portfolio is really excellent. And that's why we are also very confident in our 5% plus CAGR for '23 to '28.

- Vasant Narasimhan – CEO of Novartis

A. Great. Thank you, Harry. I think we have a few more questions. So operator will continue down the line.

- Operator

Your next question comes from the line of Emmanuel Papadakis from Deutsche Bank.

- Emmanuel Papadakis - Deutsche Bank AG

Q. I'm trying my luck and squeezing 1.5. The half is a follow-up on pelabresib, just to understand what has changed versus – Harry, I noted your high conviction at the time of completing that transaction.

And the one is on Kisqali®, if I may, next year. It looks like it's going to be a particularly important offset to some of the potential headwinds you may face. Could you just talk about the realism of consensus or conservatism of consensus expectations of USD 4 billion – is it realistic to expect you to add another USD 1 billion of sales? And are you expecting a gradual increase in pace of prescription adoption or some inflection both NCCN, et cetera?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Emmanuel. On pelabresib, it's nothing new. I think the data was presented in ESMO in other settings. This is a medicine that had a safety imbalance that (inaudible) has to get fully resolved prior to being able to use the data for any kind of filing.

We need to follow these patients longer to see how the two arms perform. There is an indication that OS is going in a positive direction. However, early, we need to think see this unfold, I think, for a longer period of time. And also determine what additional trials will be required given that safety signal to have a positive benefit risk. So that's what we're monitoring and we'll continue to monitor these things, I think, happened in clinical development that safety signals emerge and then you have to deal with them. So that's, I think, normal course of business in our industry.

With respect to Kisqali®, I don't think we're prepared here to give additional peak sales guidance, but we will update our peak sales guidance for Kisqali® given at Meet the Management. I think it's pretty clear you can all annualize right now the metastatic indication and where that's heading. So that already, I think, is really strong momentum in that area. And then now that we have the broad label, including node negative patients as well as the NCCN guidelines and node negative patients as well as a positive overall label at CHMP. I think we clearly are very optimistic for the overall size of this medicine, and we'll provide that update at Meet the Management.

I think one more – three more. Next question, operator.

- Operator

Your next question comes from Richard Vosser from JPMorgan.

- Richard Vosser - JPMorgan Chase & Co

Q. Just one on Kesimpta®. Just a competitor is rolling out their subcutaneous formulation. Just thoughts on how that's impacting, you see any impact at the moment?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Richard. So we haven't seen, in our experience, impacts today. We see a steady overall share, slightly increased NBRx share. Our focus right now is to capture more of the growth of the B-cell class as it's been our real focus, as the B-cell class continues to grow 60% plus to hopefully, a greater and greater proportion of first line for switch for MS patients.

Most of the impact that we hear about is primarily to the competitor product within the IV class of these medicines. I think given the fact that there is required for a health care professional that you need the various pretreatments and post-dose monitoring and then you have a pump involved with the subcu administration. It's not viewed as comparable to the experience of having Kesimpta®, which takes seconds or minutes to inject and is relatively straight forward at-home administration for patients. So we haven't seen that impact to date.

That said, we have to be really diligent and our teams are fully prepared to continue to argue for the value proposition.

I think outside of the US, we really don't see the impact. I think there, we feel really confident that given the structure of those ex US markets, there is a preference for when you can get patients out of the medical home using Kesimpta®. So I think that's a continued – allowed us to continue to have strong momentum outside the United States as well.

- Operator

Your next question comes from Graham Parry, Bank of America.

- Graham Parry - BofA Securities

Q. A follow-up is just on the Kisqali® (inaudible) challenge from MSN just on time lines of ruling from the Delaware Court on that. And if MSN was actually successful in invalidating the patents, just your expected time lines for resolution of an appeal. And just correct me if I'm wrong, but are you sort of past the stage of settlement here? Or that would still be – could that still be an option?

- Vasant Narasimhan – CEO of Novartis

A. Yes. So no updates. Ruling could come at any point. So we'll continue to monitor that. We are prepared to immediately follow the necessary injunctions and appeals and that process can take, as you know, some period of time. In addition, the – I think the – of course, the approval has to also happen. So there's a number of things here as well. And we think we have some important elements as well to highlight with respect to that. And so I think there's – I think we're in a good place, but we'll have to see how that really happens.

Difficult to say, I mean, I think without knowing exactly how the courts would time the various appeal hearings, we would say '26 and beyond. But I think we'd have to see the timing of the ruling and the appeals and the hearings to provide more granularity on that.

- Operator

We will now take our final question for today. And the final question comes from the line of Matthew Weston from UBS.

- Matthew Weston - UBS

Q. It's a question about politics and siRNA. So clearly, siRNA as a mode of action is very important to Novartis. I believe you're very active in the legislation to try and get an amendment to IRA to extend the life from 9 years to 13 years in terms of government pricing action. Can you give us any update as to where that legislation is, please?

- Vasant Narasimhan – CEO of Novartis

A. Yes, absolutely, Matthew. So I'll take the opportunity given that nice broad question, and thank you, Matthew, for your third question today to provide, I think, a broader perspective as well.

So first, on the IRA, which, of course, is a top priority for the industry. The broader desire to, and I think important for public health and of course, pipelines in oncology, neuroscience, cardiovascular disease indication expansion to get the 9 to 13 small molecule versus large molecule aberration corrected. And there is legislation table that currently in Congress to try to get that broad correction to happen. I believe now there's bipartisan support in the house for that broad correction.

Alongside that, there's a number of limited fixes that are being proposed by various actors. One of those is the MINI Act, which targets correcting for genetically targeted therapies such as siRNAs, ASOs, et cetera, and trying to get their definition more in line with what was done in 21st Century Cures. That also has bipartisan support in the Senate and the House and a relatively low pay for. So that's also out there as well. Actually have minimal pay for, I should say.

So I think now it's much more of moving through the election period, moving through, obviously, the establishment of a new session and then trying to get those bills, whichever combination of the various bills that are out there, there's also efforts to correct the rare disease, multiple indication for single indication situation, biosimilar definition, et cetera. And finding the right context to get those bills put in place as well as trying to get the broad fix overall for IRA. So I think all of those efforts are ongoing.

And a completely separate track are the various litigations that are ongoing to repeal the IRA. We have one, other companies have them. The industry overall has one. So we'll see how that also plays out. I think it will be in the two- to three-year period, we get more understanding of all of those various pieces.

We continue to, of course, push for PBM reform in as broad way as we can and then also to get hopefully, a more sensible 340B environment, which is, I think, a significant issue for the overall industry, starting with transparency of who are the patients and what are the centers getting this money and how is it used for.

Those are, I think, the three big priorities for us as a company and overall for the industry from a legislative standpoint as we move to a new Congress and a new President.

So thank you all very, very much. I really appreciate all the great questions and interest. I hope we'll see all of you at Meet the Management in London. And in the meantime, wishing you all a very nice autumn. Take care.

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