2024 Q4 and full year results presentation and transcript

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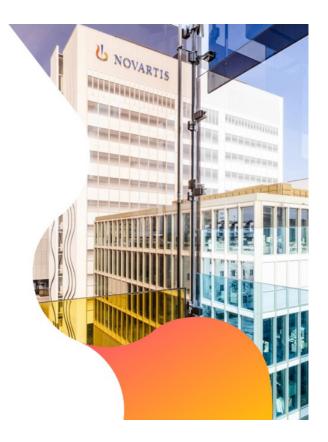
Slide 1 - Sloan Simpson, Global Head Investor Relations



Q4 2024 Results

Investor presentation January 31, 2025





Good morning and good afternoon, everyone, and welcome to our Q4 and full year 2024 earnings call.



Disclaimer

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This presentation includes non-IFRS financial measures, including Constant currencies (cc), core results and free cash flow. An explanation of non-IFRS measures can be found on page 47 of the Fourth Quarter and Full Year 2024 Condensed Financial Report.



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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.

Before we get started, I just want to echo Sharon's comment for all of our analysts, please limit yourselves to one question at a time, and we'll cycle through the queue as many times as we can. And with that, I will hand across to Vas.

Slide 3 - Vasant Narasimhan - CEO of Novartis



Company overview

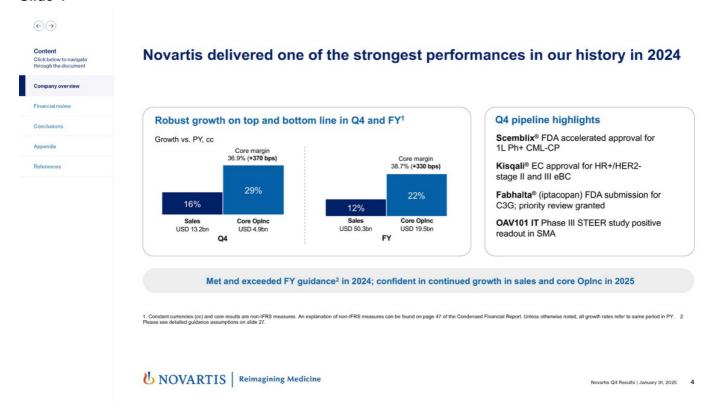
Vas Narasimhan, M.D. Chief Executive Officer





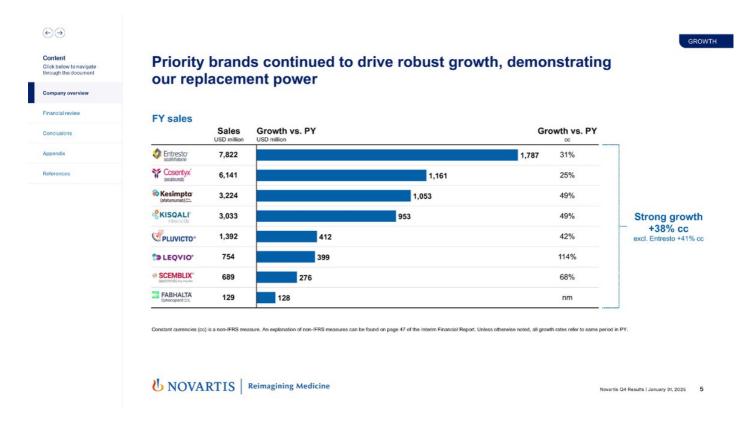
Terrific. Thanks, Sloan, and thanks, everybody, for joining today's call to review our quarter four 2024 and full year results.

Slide 4



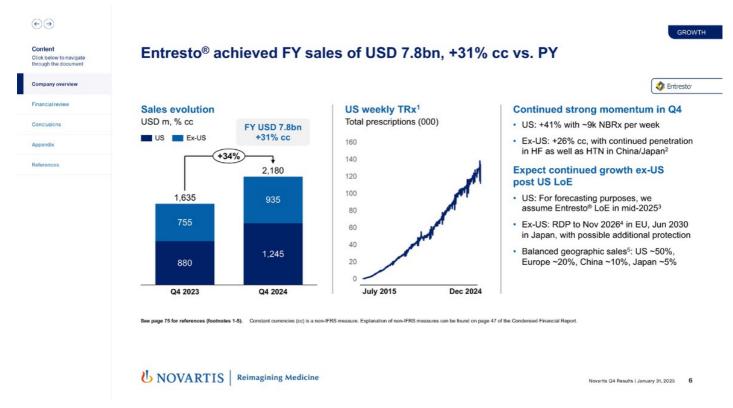
So moving to slide 4. As you saw this morning, Novartis delivered one of the strongest performances that we've had in our history in 2024. When you look at quarter four, our sales grew 16% and core operating income grew 29% in constant currency. And on the full year, we had 12% sales growth and 22% core operating income growth with our margin reaching 38.7%, well on our way to our goal of 40% plus margin.

We also had important pipeline highlights in the quarter, including Scemblix® and Kisqali®, which we'll go through in more detail later on in the call. Overall, we met and exceeded our full year guidance in 2024, and we're confident in continued growth in sales in core op inc in 2025, as Harry will outline later in the call.



So moving to slide 5. Our priority brands continued to drive robust growth in the quarter. And I think importantly, that demonstrates we have the replacement power to consistently grow through the end of the decade. Overall, this portfolio of brands grew 38% in constant currencies and excluding Entresto®, grew 41%. So we feel very good about the momentum we have. And this is what gives us confidence in the 5% plus sales guidance out to 2029 and the mid-single-digit growth we believe we can deliver in the long term.

Slide 6



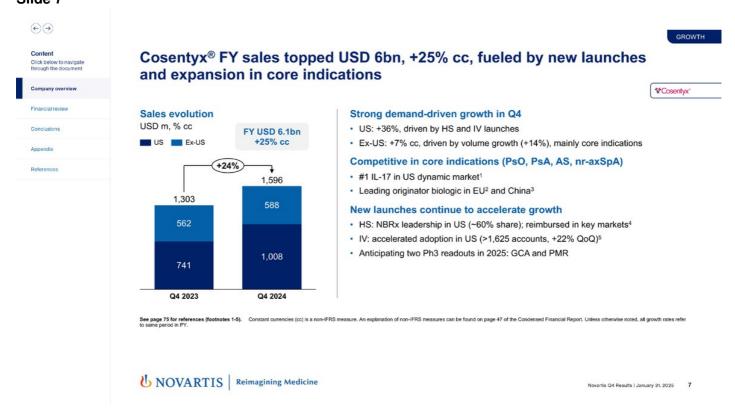
Now, moving to slide 6. Entresto® achieved sales of USD 7.8 billion on the full year. That's up 31%. And when you look at the left side, you can see we had very good growth, both in the United States and in our international markets. The total prescriptions for Entresto® in the weekly TRx in the US continued to climb. We

had plus 41% growth in the United States with 9,000 NBRxs per week. Ex-US continued to perform well. And I think importantly, we see very good performance in heart failure as well as hypertension in China and Japan.

Now, when we look at the outlook for Entresto®, we've updated the market that for forecasting purposes, we assume Entresto® LOE in mid-2025. As you likely have seen, our combination pattern is upheld and we currently believe we will be able to secure pediatric exclusivity, though we'll continue to monitor the situation closely, and that enables us to guide to a mid-2025 LOE.

Outside of the US, our RDP protection lasts until November 2026 with a protection in Japan until 2030, and we continue to pursue additional options for further protection in these markets. I think when you think about forecasting Entresto® for the rest of the decade, it's important to note that the US sales are about 50% of the global sales. But importantly, Europe contributes 20% and China and Japan in total of 15% of this brand.

Slide 7

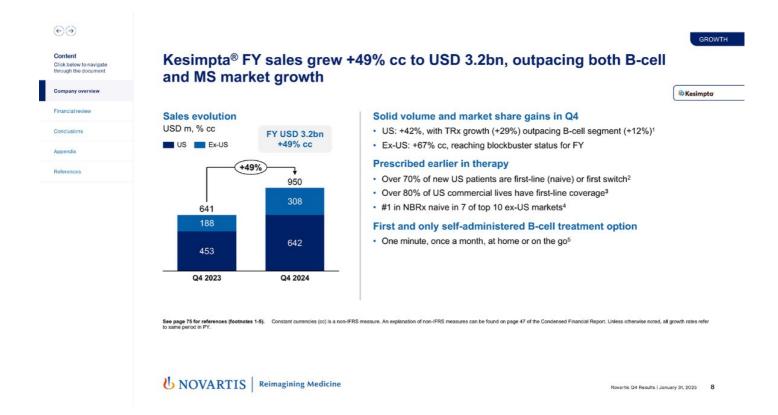


So moving to slide 7. Cosentyx® topped USD 6 billion of sales in the full year, growing 25%. This was fueled by our new launches in HS as well as the IV launch. When you look at the fourth quarter, we had US sales up 36%, as mentioned by the key launches. Outside of the United States, we had 7% constant currency growth driven mainly by volume in our core indications.

Now, when you look at how things are unfolding for the brand, we remain number one – the number one IL-17 in the US dynamic market, and we remain the leading originator biologic in both the EU and China. Now, looking ahead, we plan to accelerate growth through the HS launch with the NBRx leadership we've already established with 60% NBRx share and continuing to secure reimbursement in our key markets.

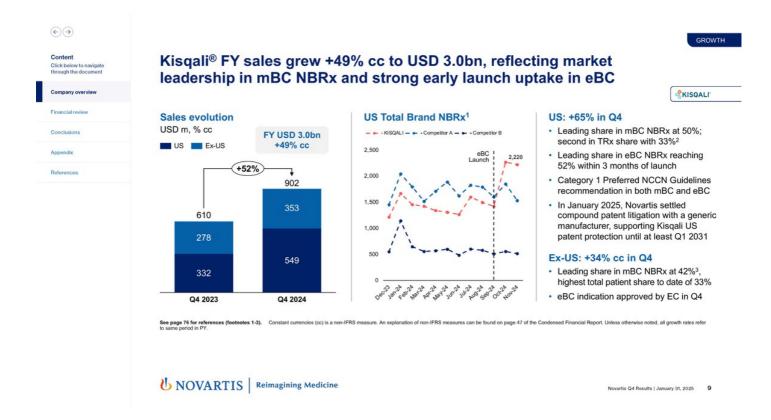
Now, IV has started to see accelerated adoption in the US. We have about 1,625 accounts ordering. We saw 22% quarter-on-quarter growth, but it's still early days, and we're working through now really accelerating the IV adoption. And over the course of the year, we expect two Phase III readouts in giant cell arteritis and polymyalgia rheumatica which, if positive, would provide further engines for growth for Cosentyx® through the remainder of the decade.

Slide 8 5/33



Now, moving to slide 8. Kesimpta® grew 49%, reaching USD 3.2 billion on the full year. It was outpacing both the B cell and the MS market. We're really pleased by the performance in the US and also very solid performance outside of the United States, growing 42% in the US with TRx growth at 29%. We're outpacing the B-cell segment. We see our NBRx share in the high 20s in the B-cell segment. Outside of the United States, we had 67% constant currency growth, which we're really pleased with.

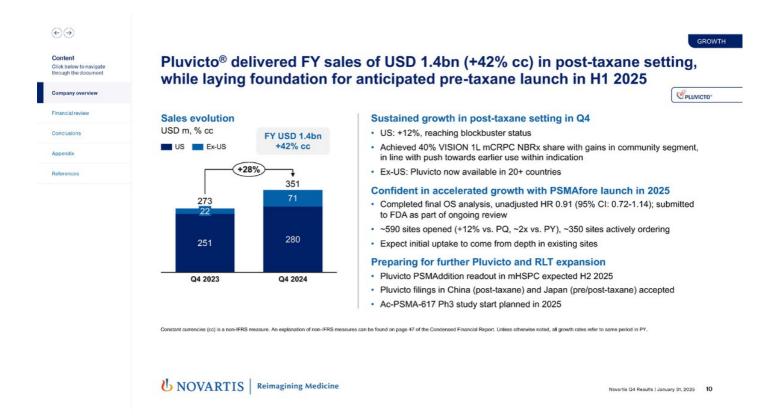
Overall, 70% of the new patients in the United States are first line or first switch. 80% of the US commercial lives have been – have now first-line coverage. So we're in a very good position from that standpoint. And we are right now the number one NBRx naive medicine and seven out of the 10 ex-US markets. So I think the setup overall for Kesimpta® looks really good, very strong performance. US and ex-US, and that gives us confidence in reaching the peak sales guidance that we've set out for this brand.



Now, moving to slide 9. Kisqali® grew 49% in the full year, reaching USD 3 billion in sales, and this is a reflection of both of the strong performance we're seeing in the metastatic setting and in the early breast cancer setting. So as you can see in the middle panel here, we've outlined the total brand NBRx across the market, and you can see the significant increase we've seen in total brand NBRx post the approval in early breast cancer and the positive NCCN guidelines. The brand grew 65% in the US in quarter four. We have metastatic share at 50% now and TRx share at 33% and climbing.

In the eBC setting, the early breast cancer setting, we've already reached 52% in NBRx share within three months of launch. And so, we're getting very positive feedback from physicians and seeing solid uptake both in node-negative and node 1 patients without risk factors as well as the overlapping node 1 and node 2+ patient population. I mentioned the Category 1 NCCN guidelines, which is really positive for the brand. And importantly, as well, we announced this morning that we've settled the compound patent litigation with a generic manufacturer and that supports Kisqali® US patent protection until at least Q1 2031.

Outside of the United States, we grew 34% in constant currency with a leading share – NBRx share at 42%. The early breast cancer launch is ongoing now in Europe and other geographies, and that should provide a further driver of growth for Kisqali® over the course of this year. So we guided to USD 8 billion plus, and I think the early signals are clearly indicating that we're going to be able to get there and hopefully do better.



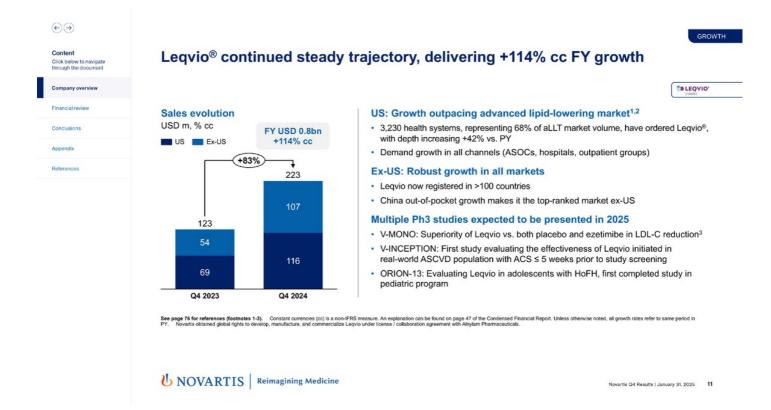
Now, moving to slide 10. Pluvicto® delivered full year sales of USD 1.4 billion, 42% in constant currencies in the post-taxane setting. And most importantly, we spent a lot of our energy in quarter four, laying the foundation for the pre-taxane PSMAfore launch, which we expect in the first half.

Now, when you look at the quarter, we grew, you can see 28%. Overall, our performance was absolutely in line with what we guided to in our quarter three conference call. US was up 12%. We achieved 40% NBRx share within the VISION population. Pluvicto® is now available in over 20 countries outside of the United States. And we're confident that we can now accelerate growth with the PSMAfore launch in 2025.

The final OS was read out over the course of January with HR – unadjusted hazard ratio of 0.91. And you can see the confidence intervals here. The file has been submitted to the FDA last year, and the review is ongoing. And as we – so far, there's no AdCom planned for this brand. So I think that's really a positive signal, and we'll see now how quickly we can get to launch. We have over 590 sites open for the brand; 350 sites are actively ordering. And every month, every week, we're adding more sites. We're getting more sites actively order. We're getting further into community oncology which will set us up not only for Pluvicto®, but our broader RLT pipeline over time.

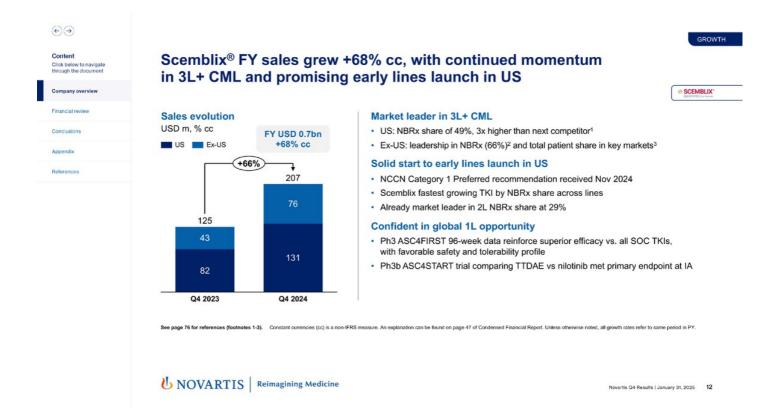
And we expect the initial uptake for PSMAfore to come primarily from the depth we'll get in these existing sites and then grow over time, certainly as we try to reach deeper into the oncology community practices. We're also progressing on our efforts to expand Pluvicto® further and as well as our broader RLT expansion. The PSMAddition readout is on track for the second half of this year. We have Pluvicto® filings ongoing in China and Japan. And in both of those geographies as well we've announced manufacturing facilities to support the launch of Pluvicto® and, of course, Lutathera®.

And we've also now initiated planning for our Ac-PSMA-617 Phase III study, the first of two actinium studies, we're now planning to move into Phase III on to have continued life cycle management in prostate cancer with radioligand therapies.



Now, moving to slide 11. Leqvio® showed a steady trajectory delivered 114% constant currency full year growth in the quarter, 83% growth versus prior year. We're really pleased that now in the US our growth is outpacing the overall advanced lipid lowering market. We have over 3,000 health systems ordering now Leqvio® that represents 68% of the overall market volume. We have depth that's increasing, and I think we're getting better and better traction with the overall buy-and-bill comfort levels within cardiology practices. We see demand growth in all relevant channels.

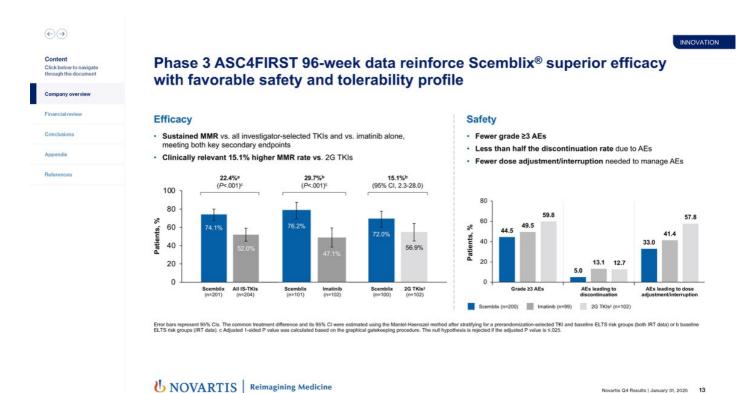
Outside of the United States, we've seen robust growth as well. Leqvio® is now registered in over 100 countries. We see solid uptake in markets such as Germany. And in China, our out-of-pocket growth really makes it one of the top-ranked markets we have outside of the United States. We have an ongoing launch as well now in Japan. So looking ahead, we have a number of clinical stage readouts coming over the course of 2025, which will help, I think, round out the profile of Leqvio® as we await the outcomes trials readouts in secondary prevention in 2026 and 2027.



Now, moving to slide 12. Scemblix® grew 68% for the full year with continued momentum in the third line setting and early progress that we're already seeing in the frontline setting. We're a market leader now in the third-line CML setting with NBRx share of 49%. We're three times higher than the nearest competitor, which I think shows how well established now Scemblix® is amongst hematologists. Outside of the United States, our leadership is at 66% for NBRx and total patient share in our key markets.

And when you look at the earlier line launch, what was critical is that we have already received NCCN Category 1 preferred recommendation in November. And then we also already see now Scemblix® is the fastest-growing TKI by NBRx share across all lines of therapy and we're the market leader now in second-line NBRx with a share already at 29%. And that's just in the first few months of launch. So assuming we can really drive that continued trajectory, we should see a very strong uptake overall for Scemblix® in the coming quarters.

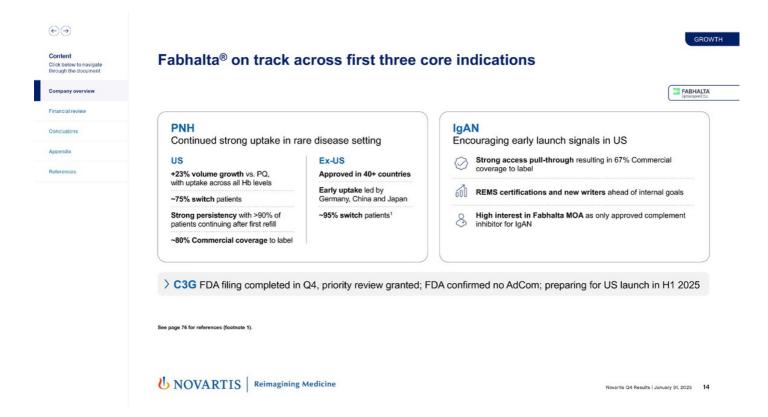
So we're confident in the global first-line opportunity. We read out the 96-week data recently as well, which reinforces superior efficacy, and I'll say more about that in a moment. And then we also showed some very good data that showed treatment discontinuation as well that Scemblix® provides a clear profile win over nilotinib.



Now, going to slide 13. That ASC4FIRST 96-week data reinforce superior efficacy and safety. When you look at the data set here at 96 weeks on the left-hand side of the chart, you can see against all TKIs, we continued to show a significant improvement, a statistically significant improvement in major molecular response similarly versus imatinib a significant improvement in major molecular response. And while we weren't powered our point estimate difference against second gen TKIs continues to improve as well over time.

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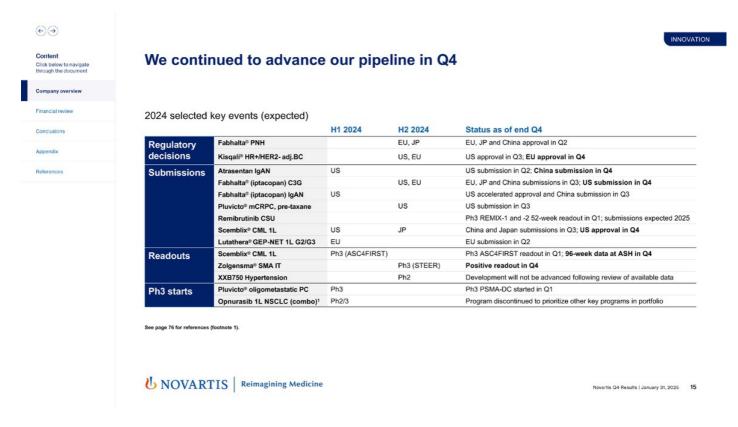
Now, when you look at the safety profile, we maintained a very excellent safety profile that we had at the earlier time point, whether it was grade 3 AEs, AEs leading to discontinuation or AEs leading to dose interruption, an excellent profile for the brand. So overall, we offer here a medicine that has high efficacy, compelling safety. And we believe over time, as there's more and more experience, we'll become the preferred agent in first, second, and third line for CML patients.



We move to slide 14. Now, turning to Fabhalta®. As you're aware, Fabhalta® has now launched in two indications in PNH and IgAN. And while it's early days, I think we see really solid, steady performance for this brand, a 23% volume growth in PNH. Most of the source of business at the moment is switch patients from the established therapies. We see over 90% of patients staying on therapy after the – continuing after their first refill, very good commercial coverage levels. We're approved now in 40 countries. And so, step by step as well, we're progressing the launch in other geographies.

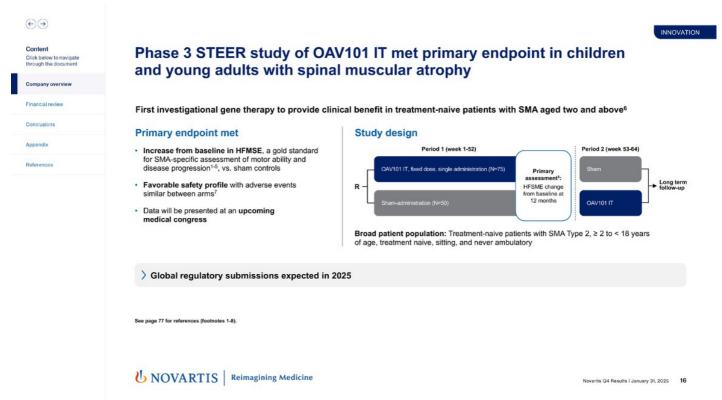
The early signs for the IgAN launch as well are very encouraging. We've seen strong access with 67% commercial coverage already to label. We're seeing a number of nephrologists, a sizable number of nephrologists, completing REMS certification. And we also see a high interest in our conversations with opinion leaders on the Fabhalta® MOA.

One other update we have as well for Fabhalta® is that the C3G filing was completed in quarter four. We received priority review. The FDA has confirmed no AdCom for C3G. So we're now preparing for a launch in the first half of 2025.



So moving to slide 15. So when you look across the full year, I think we delivered very good innovation momentum across regulatory decisions, submissions, readouts, and Phase III starts. Obviously, the critical approvals were delivered upon, particularly the Kisqali® early breast cancer, Fabhalta® approvals, the filings of Pluvicto® and the approval for Scemblix®, so I think we really are looking forward to maintaining and continuing that momentum in the year to come.

Slide 16



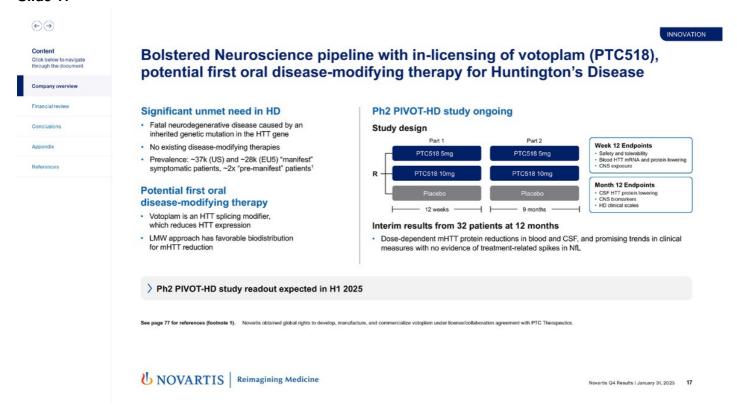
One important readout that we did have in quarter four, turning to slide 16, was for the STEER study for OAV101 IT. This is the intrathecal version of Zolgensma® that is administered intrathecally at roughly 1/10 the dose of what we see in the IV administration. This was tested in children and young adults over two years of

age.

We're really pleased to see that we've met the primary endpoint for an increase versus baseline for the Hammersmith score, HFMSE, which is the gold standard. Not all of the therapies in the space have been tested against the Hammersmith score. So we chose the gold standard, and we demonstrated that we met the primary endpoint of a statistically significant improvement versus a sham or placebo as requested by FDA. A very favorable safety profile consistent with what we've seen in other settings. We're looking forward to present the data at an upcoming medical congress.

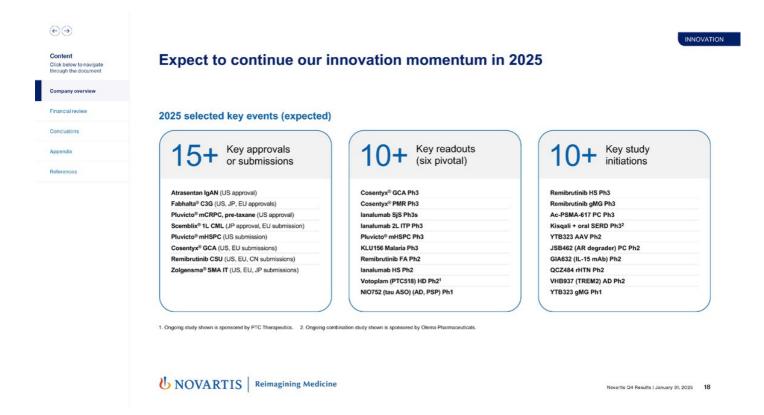
You can see the study design over on the right. And our goal here will be to try to secure a broad indication across the various age levels and looking forward then to advance these global regulatory submissions across the various geographies. A sizable number of patients have not had the opportunity to benefit from Zolgensma® in the first six months of life. And now we're really excited now to give those patients a very compelling onetime treatment option that can hopefully stabilize and potentially improve their disease.

Slide 17



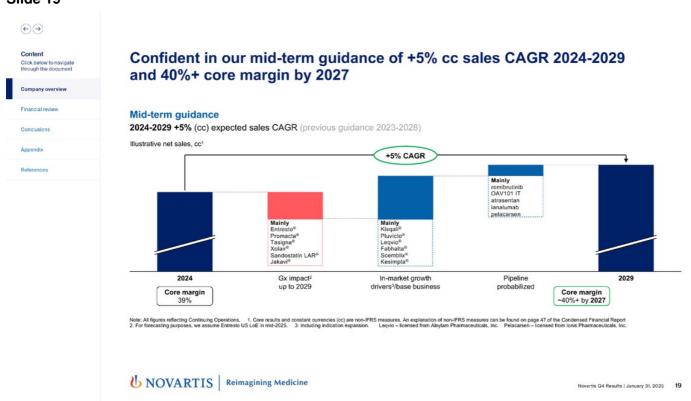
Now, moving to slide 17. We also completed an exciting deal in our neuroscience pipeline. This is for votoplam, PTC518. It's a potential first-in-class oral disease-modifying therapy for Huntington's disease. We have a lot of expertise in oral splicing agents. We had a molecule called LMI070, which ultimately did not progress because of peripheral neuropathy signals that we had during the development program. So this is a space we know well, and we really believe PTC518 has a very strong profile as evidenced in the interim readout of their Phase II study.

As you know, in Huntington's disease, a very fatal neurodegenerative disease with really no disease-modifying therapies at the moment. Prevalence is 37,000 in the US and 28,000 in EU. So we have an opportunity, hopefully, to make a big difference. We would expect the Phase II readout for the study in the first half of 2025 and then moving to pivotal Phase III studies thereafter.



Then moving to slide 18. So our goal will be to continue our innovation momentum in 2025. We outlined at "Meet the Management" we have a deep and broad pipeline across our four therapeutic areas across our key platforms and our goal now is to advance the next wave of therapies, both in terms of approvals and submissions. You can see the list here, but also read out some study initiations, which will really fill up that mid-stage pipeline and then allow us to maintain our growth momentum well into the 2030s and beyond.

Slide 19



So moving to slide 19 and to close, I just wanted to remind you of our confidence in our midterm guidance of 5% plus sales growth out to 2029 and a 40% core margin by 2027. We're very comfortable that we can – with our replacement power outpace the GX impacts that we have to 2029. We have an exciting set of in-market

growth drivers, many of which have protection well into the 2030s.

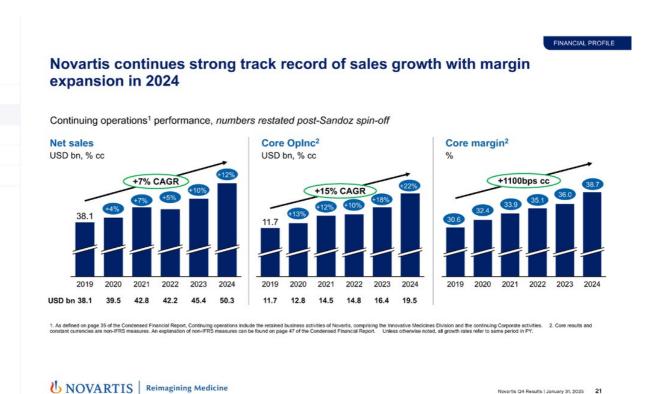
We have the pipeline probabilized and are hopefully – with positive clinical data and approvals, that pipeline will become further unprobablized in medicines like remibrutinib, OAV, ianalumab, pelacarsen, and atrasentan can further drive the growth profile of the company. So an exciting year. We're really excited about our performance in 2024 and excited about continuing delivering the strong results and strong innovation delivery into 2025.

So with that, I'll hand it over to Harry.

Slide 20 - Harry Kirsch - CFO of Novartis



Yeah. Thank you, Vas. Good morning, and good afternoon, everyone. I'll now talk you through our financials for the fourth quarter and full year '24, which as Vas mentioned, has shown some of the strongest performances in our history. As always, my comments refer to continuing operations and growth rates in constant currencies, unless otherwise noted.



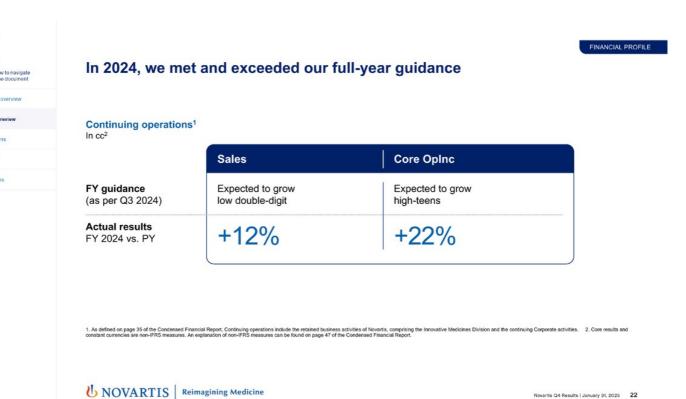
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So starting on slide 21, giving a bit of context – our results in 2024, which is here on the far right of each of the three charts. It was really our first full year as a pure-play innovative medicines company, and we continue to show a strong track record of sales growth with margin expansion.

If you look back over the last five years, we have grown sales at a 7% CAGR and core operating income at a 15% CAGR through consistent, strong commercial execution and overall significant progress on operational productivity. This has resulted in core margin expansion of 1,100 basis points in constant currencies, putting us on a clear path to achieve our midterm margin guidance of 40% plus by 2027. I think when you look at this track record, it becomes very clear that we have lifted the company to a whole new level of sales, margin, and as we will discuss later, free cash flow.

Slide 22

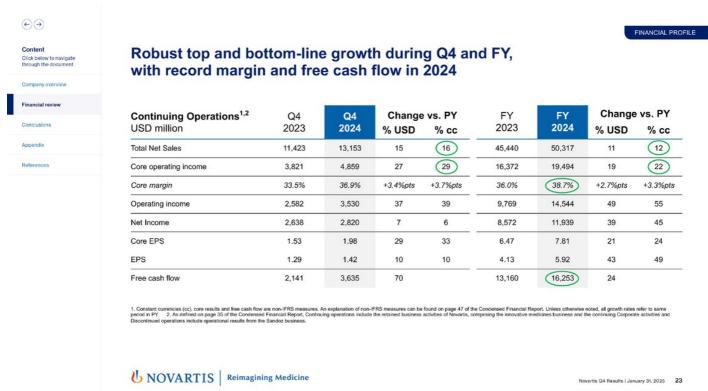
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Moving to slide 22. We guided to a low double-digit sales growth for full year 2024, and we achieved 12%, so meeting our guidance. And for core operating income, we delivered 22% growth exceeding by 1 notch our guidance, reflecting the strong momentum we have seen in our priority brands, good also and launches as well as cost discipline throughout the end of the year, including some productivity gains.

Slide 23

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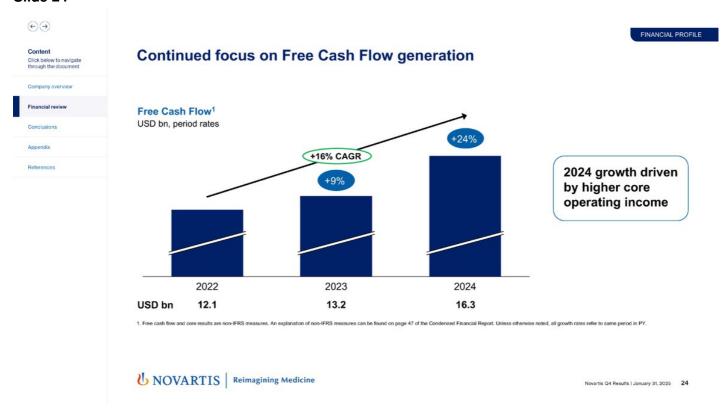


On slide 23, you see a summary of our financial performance. In the quarter, sales were up 16%, and core operating income increased 29%. Core EPS was USD 1.98, up 33%. To note, in quarter four, we benefited from some gross to net favorability, mainly in the US. This added about 3% points of growth in quarter four from gross to net true ups based on invoices for prior guarters in 2024. So the underlying growth in quarter

four has been a very strong 13%, slightly better than the 12% sales growth for the full year in 2024.

For the full year, core margin expanded 330 basis points versus prior year in constant currencies to reach 38.7%. Core EPS was USD 7.81, up 24%. And free cash flow grew 24% to USD 16.3 billion, a record high for Novartis.

Slide 24



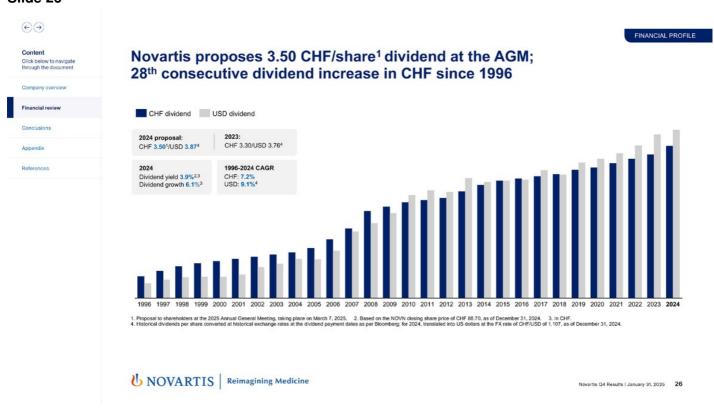
Now, speaking of free cash flow, let's turn to the next slide. You can see free cash flow generation has really accelerated since we completed our transformation into a pure-play pharma company end of 2023 and also finalized our transformation program, Transformation for Growth program, which we announced April '22. This has been a focus for us to, of course, ensure that not only core operating income increases, but appropriately also free cash flow, so high quality of core earnings and strong free cash flow generation.

And in fact, we have generated more cash than we did as combined businesses, be it with Sandoz or a few years back, even with Alcon. This gives us also ample capacity, of course, to reinvest in the business pursue bolt-on deals and return attractive – attractively to our shareholders via growing dividends and buybacks.



This brings me to my next slide. So we continue to execute in line with our shareholder-friendly capital allocation strategy, which balances the priorities I mentioned. We invest over USD 9 billion in R&D in 2024 and completed more than 30 bolt-on deals over the last two years to strengthen our pipeline, particularly in the area of Neuroscience, RLT and Renal. With respect to returning capital to shareholders, we remain committed to consistently growing our dividend in Swiss francs per share and completing our ongoing share buyback, which has about USD 5.4 billion still to be executed in 2025.

Slide 26



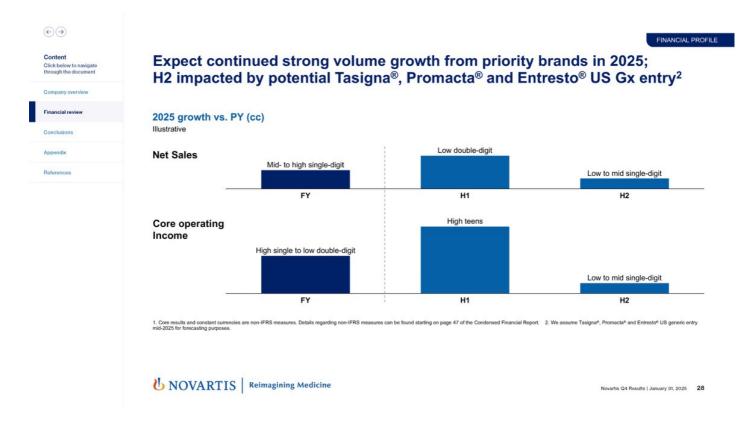
Now, on to the next slide, please, to the dividend. So we are really pleased to propose the 28th consecutive dividend increase to CHF3.50 per share. an increase of \$3% in Swiss francs and 20 Rappen after the prior few

years of 10 Rappen per year. As you know, we did not rebase our dividend for the spin-off of Sandoz, nor Alcon. So this represents really an attractive, consistent growth over time, in line with our commitment to our shareholders.

Slide 27

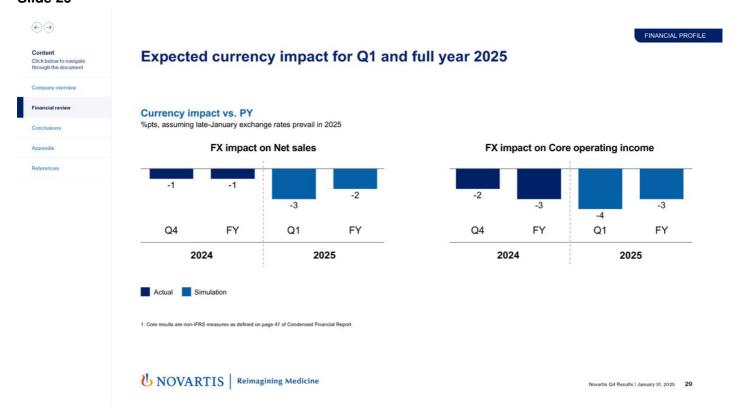


Moving to slide 27. For full year 2025, we expect continued strong sales growth with margin expansion, with sales growing mid- to high single digit and core operating income growing high single to low double digits. Embedded in our guidance is the financial planning assumption that Tasigna®, Promacta® and Entresto® US generics entry occurs in the middle of, and I'll give some more detail on expected half one versus half two dynamics on the next slide. To complete our full year guidance, please note that we expect core net financial expenses to be around USD 1 billion, and our core tax rate to be around 16% to 16.5%.



On slide 28, we have shown illustratively how we expect half one and half two dynamics should generics for Entresto®, Tasigna® and Promacta® enter in US in mid of 2025 as per our financial planning assumption. Overall, we expect continued strong volume growth from priority brands in 2025. In half one, we expect sales to grow low double digit while we expect, of course, a softer half due to the impact of the three potential generic entries with low to mid-single-digit sales growth. Likewise, we expect half one corp inc to grow the high teens versus low to mid-single-digit growth in half two.

Slide 29



And finally, let's have a quick look at the currencies as they always move around. And if late January rates were to prevail for the remainder of 2025, we would expect the full year currency impact to be a negative 2%

on sales and a negative 3 percentage points on core operating income. As a reminder, we always provide an estimated impact of exchange rates on our results on a monthly basis on our website.

And with that, I hand back to Vas.

Slide 30 - Vasant Narasimhan - CEO of Novartis



Conclusions

Vas Narasimhan, M.D. Chief Executive Officer





Terrific. Thank you, Harry.

Slide 31





Continued strong business momentum in Q4, delivering one of the best financial performances in our history



Met and exceeded our full-year guidance



Continued to advance our pipeline, including new approvals and readouts for assets that will fuel our midto long-term growth



Expect to continue strong sales growth with margin expansion in 2025, and remain on track to deliver our mid-term guidance



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So coming to the final slide, and really, just in summary, continued strong business momentum in quarter four, one of the best financial performances in the company's history, met and exceeded our full year guidance.

We're advancing our pipeline, including new approvals, but importantly, readouts for assets that will fuel our mid- to long-term growth and really ensuring we advance the mid-stage pipeline. And expect to continue strong sales growth with margin expansion in 2025, as Harry outlined. And we remain on track to deliver our midterm guidance of 5% plus sales growth through 2029.

So with that, Sharon, we can open the line for questions.

Q&A







Operator

(Operator Instructions) And your first question comes from the line of Florent Cespedes from Bernstein.

• Florent Cespedes - Bernstein

Q. Good afternoon. Thank you very much for taking my question. A quick one on the guidance as the guidance is a little bit better than expected on the top line, but also on the margin. And as Entresto® is a very profitable product and if you will lose [inaudible] generics from the mid of this year. I was just wondering if you could elaborate, Harry, what are – where we should see some pressure? And where you will have some growth that will offset the generic impact on the P&L and on the top line. Thank you.

Vasant Narasimhan – CEO of Novartis

A. Thanks, Florent. Harry?

• Harry Kirsch - CFO of Novartis

A. Yes. Thank you, Florent. I mean, in the end, it all starts with the top line, as we all know, in the pharma businesses. So having our mid- to high single-digit sales growth, given the strength of our growth brands and launches – that's a good starting base. And also, our other products are quite profitable. Now, of course,

24/33

profitability does vary by the different brands. But overall, with the mid- to high single-digit sales growth and our ongoing resource allocation and productivity programs, we are very confident that with that, we will have also some moderate margin increase, right? So from that standpoint, and I laid out half one, we will be more, obviously. And if these generics would enter half two would be basically pretty much low to mid-single digits, both on top and bottom line. That's fine.

But overall, very confident in that sales growth with these assumptions as well as this – the underlying volume growth when you look at it, right, 14% - 15% volume. And then it depends a bit pricing was quite neutral last year, and then it depends simply on generic assumptions there. But also with a 5%, very confident the 5% CAGR on the five years, and then, of course, from 38.7% to 40% plus, it's not that far, right, in 2027. But we have good ongoing productivity and therefore, especially on SG&A with good resource allocation and the launches are mostly in areas where we have already strong presence, we would expect SG&A to grow below sales growth as you have also seen in the prior two years.

• Simon Baker - Redburn Atlantic

Q. Thanks for taking my question. And it's kind of a continuation from Florent's question. Just mindful of the lots of exclusivity potentially for Entresto® later in the year. Historically, you have been very, very good at managing gross margin through patent expires. I just wonder, Harry, I know you don't guide on gross margin. If you could just give us any commentary around the resilience of the gross margin in 2025 in light of that event? Thanks so much.

• Harry Kirsch - CFO of Novartis

A. Thanks, Simon. So as I mentioned on prior calls and IR road shows – the further margin improvement, I expect to basically fully come from SG&A as we – with good resource allocation, basically slightly grow SG&A, but significantly below sales growth, right? The gross margin comes a little bit under pressure as we lose small molecules where we don't pay royalties with either small molecules where we pay some royalties or larger molecules. But all of that will be more than offset by the SG&A efficiencies.

And then, of course, also our colleagues in manufacturing and supply chain continue to work on very good productivity programs and have cost reduction programs on each of our products in a very impressive way. Of course, never compromising quality or supply, very high 99.5% plus supply customer service levels. And with that, a little bit pressure on the gross margin because of increasing royalties but by far, compensated from SG&A efficiencies.

• Richard Parkes - BNP Paribas Exane

Q. Hi. Thanks for taking my question. I think I'll take one on the Huntington's program. Obviously, a huge unmet medical need, terrible disease, but there have been some of the failures in that area in the past. So I'm just wondering what makes you more confident in the approach what you've learned from those past experiences. And to what degree do you think the PIVOT-HD trial will derisk the probability of success given it's a slowly progressive disease and the studies relatively short? Or will we still be seeing it as a high-risk program? That would be really helpful. Thank you.

Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Richard. And I think as you're aware, the goal here is to take down mutant huntingtin, but at a level where you're not taking it so low that you have some – you have adverse consequences from reducing Huntington's too much. I mean, generally speaking, the feeling in the field if you want to reduce mutant huntingtin protein by 30% to 50%. And then alongside that biomarker, you want to see clinical signs of

improvement. So I think that their interim results, PTC has shown the relevant mHTT lowering. They've seen some signals of clinical efficacy and a very good safety profile without some of the peripheral neuropathies that we saw in our own programs.

So I think all of that taken together makes the program looks like it's headed in the right direction. I think the big question, of course, is thus reducing a mutant huntingtin at that level lead to a large enough or important enough clinical benefit that would lead to most importantly helping patients, but also regulatory approval. I think we'll see how the Phase IIb study reads out. Obviously, if it's a very compelling result it might enable us to take it forward for a filing. And if not, we would then need to go to a full pivotal study and then really answer the question does reducing mutant huntingtin at that level lead to the clinical benefits that one would hope.

So it's been – I think PTC has developed a product in all the right ways. It's got good dialogue with the regulators. So we're hopeful that we see a good results on the Phase IIb study, and then we'll take over and run those Phase III studies. And hopefully, we can bring an important first disease-modifying therapy to these patients who badly need it.

• Emily Field - Barclays

Q. Hi. Thanks for taking my questions. The first one was just a clarification question from the first question that was asked by Florent. If you could just confirm the contribution of favorable gross to net adjustments to sales in Q4 '24.

And then I just wanted to ask a question about Pluvicto®. I mean I know the guidance has been not to expect significant sales growth until the additional indication of PSMAfore was added. But was there any particular driver between the sequential decline in the US quarter-over-quarter. And would you expect any of the DTC and promotional efforts that you've been putting in place to have an impact on sales ahead of the PSMAfore approval? Thank you.

Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Emily. So back on the guidance, Harry?

• Harry Kirsch - CFO of Novartis

A. Yes. So I think your question was about the gross to net and quarter four impacting the guidance. So let me try and then you can tell me if it was sufficient. So we had a growth of 16% in quarter four, as you have seen in constant currency. About 3 points of that was due to true ups of gross to net for prior quarters of 2024. So underlying 13%. The full year sales by brand in 2024 is basically undistorted. The underlying growth for '24 is 12%, right, as you see in the report. So if you want to have a basis, it's best to take the full year 2024 sales, and these are undistorted overall.

Now, of course, that has lifted the overall 2024 sales and we have, of course, computed that, if you will, into our 2025 gross to net calculation, right? And a key element of this as really Medicaid utilization is continuously reducing to pre-pandemic levels. Now, we do not assume that it gets lower and lower, we basically assume that in 2025, we see what we have seen at the latest for 2024, right, which is a reasonable assumption.

So we never take risky assumptions on gross to net. It's obviously a big pot of money, right, like USD 16 million to USD 20 billion of sales as we have like 50% of our US list prices be gross to net. But from that standpoint, it has lifted this more favorable gross to net situation for 2024, our sales level. And from that, we expect to grow mid- to high single digit. I hope that clarifies your question.

Vasant Narasimhan – CEO of Novartis

A. On Pluvicto®, when you look at it in Q4, it was really in line with what we had expected. In Q3, we had the benefit of some onetime adjustments in France and Germany. But then when you overall look at where we had guided for Q4, it's roughly – exactly with where we had expected.

Now, I think looking ahead, we are hopeful to see further progress in the VISION population, but I think that will be not a rapid increase. I think we've already gotten to 40% NBRx share and that we'll need to get to steady gains by expanding further and further the number of treating sites for the VISION population. But it is possible certainly that the DTC will start to have an impact that we kicked off in quarter three of last year. Usually, it takes six months for DTC to have an impact – so it would be around February, March of this year, we might see some impact on the VISION population. But really, our organizational focus is on the PSMAfore launch.

I think now that we have a really compelling rPFS data. We have very compelling data on distant mets. We have now the OS unadjusted for crossover at 0.91, I think everything now is a good setup to go into a population that's three times larger, really ensure the sites that are already using Pluvicto® now fully maximize their capacity to get as many patients to benefit from the therapy as possible and also accelerate our efforts to get even more sites ready in the community.

We've launched a number of initiatives. We're launching a few more over the course of the quarter to really simplify and hopefully get clinicians very comfortable even in the community oncology setting, providing radiopharmaceuticals or radioligand therapy. And that's where I think we're going to see the next uplift for the brand.

Matthew Weston - UBS Equities

Q. Thank you. I don't know what happened earlier. It's a question for Harry. And it's again about guidance, Harry, but particularly about the impact of Medicare Part D reform on what you've assumed within your growth. So one of the questions we've had a lot this morning from investors is how can you be so confident given that you have a very large oral oncology portfolio, which is assumed to be used largely in the Medicare Part D population. So what have you assumed in your outlook are the puts and takes around that portfolio from that new reform?

Vasant Narasimhan – CEO of Novartis

A. Yeah. Thanks, Matthew. I'll actually take that one. Overall, we expect a modest headwind from the Part D reforms, and we fully factored that into our guidance. The two brands where we see the biggest impact of the reforms, primarily paying into the – to cover in the catastrophic phase are for Cosentyx® and Kisqali®. But overall, when we look at it, we've factored in the expected modeled headwinds from that. We look at the potential volume uplift, which we don't really put a lot of stake in yet because we'd really like to see how that ultimately unfolds over the course of this year. And we see a modest headwind, which we think we can manage fully, and that's incorporated into our guidance. .

I think we'll see. I mean I think in the midterm, the policy should lead to volume uplifts, more patients staying on therapy, which is why the industry wanted a 2,000 out-of-pocket cap and that would ultimately, of course, improve patient compliance, staying on their medicines and ultimately impact – positively impact their sales in the coming years. In this first year, I think it's hard to put much credence on that. But beyond that, we feel very comfortable with the modeling that we did. We think we've taken appropriately conservative assumptions.

Richard Vosser - JPMorgan

Q. Hi. Thanks for taking my question. Question on Kisqali®. Looking at the NBRx share in metastatic, it stayed

at sort of 50% for a number of quarters and maybe a couple of years now. So I'm just wondering what it takes to change that. You have a superior product. Does the – the sort of halo effect from the adjuvant allow you to get more accounts on board – just can we see that displacement of Ibrance®, just your thoughts.

Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Richard. I think the Kisqali® shares really started to gain in the first part of last year. After we had the early breast cancer readout that led to a lot more confidence overall in the brand as well as the NCCN guidelines further supporting the use of Kisqali®. I think now we are hopeful that with the early breast cancer readout and the opportunity to have a single medicine for all patients within a clinic that we can drive the overall share – NBRx share higher than 52%. We do have a cap probably somewhere around 75%, 80% just because of some of the payer dynamics and some of the contraindications for Kisqali®. But of course, our goal is to get from that 52% as high as we can to that 75% over the coming years.

Of course, we have plenty of time now to do that. And I think we should see steady gains over time on that one. But the biggest focus for us right now is maximizing the opportunity in the node 0 and node 1 patients without risk factors where Kisqali® is uniquely labeled, and our competitors are not. And our ability to get those patients diagnosed and then ultimately on therapy, it's such a sizable population and the size of – obviously, the public health benefit we can deliver, that's the core focus for us overall. And then with that, of course, we should see metastatic gains as well.

• Graham Parry - BofA Global Research

Q. Great. Thanks for taking my question. It's just on Entresto®, just wanting to get perhaps a little bit more detail on the dynamics that are factored into the guidance for 2025. So what sales progression are you looking at worldwide and in the US. And in the US GCA benefit in the first half of the year from donut hole discount removal? And to what extent does that offset some of the generic decline you should get in the second half of the year?

And on generics, how confident how you can hold off Entresto® generics until 16th of July, and the court filings suggest MSN is trying every which way to launch at the moment and there's only one appeal court stay in place, blocking them from doing that? And are you confident they haven't shipped any product at all in that narrow window there wasn't actually a stay in place a couple of weeks ago. Thank you.

Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Graham. On the overall dynamics, Harry.

Harry Kirsch – CFO of Novartis

A. Yes, overall, we would expect continued good growth of Entresto® until from a forecast assumption standpoint, middle of the year. Of course, our colleagues in the Legal and IP department will do everything to appropriately defend further patents, but that's for now the financial forecast assumption. And so we would see growth on that. And yes, you are right, there is some favorability from the Medicare Part D design on Entresto® as it is not a very high-priced specialty product. So very positive dynamics expected until LOE would happen in the US.

And then, of course, what – actually, when we look at the multiyear outlook and forecast, Entresto® is one of the products that's really under-forecasted versus our model from the consensus due to the fact that Europe, at least end of '26, Japan 2030 – and then we have a large tail end product over a large – even small molecules in emerging markets. So also there quite a lot of, let's say, remainder of sales because of Japan should be a blockbuster and then emerging markets pages even end of '26 Europe would see generic entries.

Vasant Narasimhan – CEO of Novartis

A. Thanks, Harry. And of course, we're pursuing all options in Europe and Japan to ensure we maximize the exclusivity for Entresto® in those geographies, and there are certainly options that might materialize. Now, I think on the US dynamic to our knowledge and our best understanding, there were no products shipped into the channel in those few hours. The stay is in place. MSN has requested a reconsideration of the Circuit Court's stay. And of course, we'll monitor that situation, but we believe it's very clear that the spirit of the law very much is that we did our pediatric exclusivity studies and those pediatric – that pediatric 6-month extension on the combination patent, which has been upheld should be respected. And so that's our very clear position.

We, of course, continue to litigate out the amorphous complex patents as well as the lawsuit that we have that the FDA should not have approved products with a carve-out on the dosing regimen on the label. So those court cases also continue to go on over the course of these months. And we'll see how it unfolds. Our best estimate at the moment is to give you that forecasting guidance of middle of the year. And if anything changes, either we or I think IPD will let you know probably IPD sooner than us, but we do the best we can. So thank you very much.

• Etzer Darout - BMO Capital Markets

Q. Great. Thanks for taking the question. I had a couple of inbound this morning. Just wondering if you had any maybe additional commentary you could provide on the push out of the HORIZON Phase III and maybe what could be driving that the event sort of rate dynamic relative to your initial event rate assumptions? Thank you.

• Vasant Narasimhan - CEO of Novartis

A. Yes. Thanks, Etzer. So this is an event-driven study. We've been modeling the event rates. I think I've also heard a few questions. There's been no interim analysis of – no interim analysis drove this. This is just event rate modeling on the blinded event rates that we saw, and we expect now to reach the final number of events, which is, I think, always preferable for a cardiovascular study that we need to ensure is adequately powered in the first part of next year.

We don't have a good unnecessarily guess. I mean, in general, I would say cardiovascular outcome studies have been trending to lower event rates over time. It's important to note that in these studies, we very rigorously ensure that all patients are at their appropriate treatment levels for LDL lowering to ensure that we can isolate the impact [inaudible] of the Lp(a) lowering therapy. So quite – it could be the background rate. It could be – the drug is working. That's always our hope, but we can't be sure of that as well. So we'll see over the course of – we'll see next year at the end, how the study reads out. But we remain very confident that the drug is doing what it's supposed to do. Mechanism of action is clear.

When we look at the profile of the patients that we enrolled, this is the high-risk patient population we wanted to enroll high levels of Lp(a), but then with the lowering that we are seeing – that we expect to see that, that should lead to the cardiovascular risk reduction that we hoped for. So that's the best guidance I can give you at this point in time.

• James Quigley - Goldman Sachs

Q. Great. Thanks for taking my questions. Going on the guidance, unfortunately. Harry, would you be able to sort of split the guidance out between volumes, generic impact and pricing, presumably, pricing is close to 0 or slightly negative. But super helpful if you could give us an idea of how that breaks down.

And then secondly, on the slide, where you break out the salf one versus half two, obviously, the second half

takes a hit because of generics. Where would that land if you didn't have the generic impact and is low to midsingle digits, say, a sort of sensible exit rate for the second half of your guidance out to the end of 2029. I appreciate that you don't guide on the individual years, but just some color would be useful.

Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, James. Harry?

Harry Kirsch – CFO of Novartis

A. Yes. Okay. So let's give it a try. So overall, we expect continued, if not slightly increased volume growth due to our launches and continued very good execution from a volume standpoint. Pricing probably will be a little bit more pressure. Usually, we have on a year like 1% to 2% points negative. Last year, in '24, we had flat, but there's a little bit of gross to net pressure due to Medicare point redesign, but nothing dramatic there. And the key impact will be an increased generic according to these forecast assumptions.

Now, for the US, we have taken simply analogs for small molecules in the different categories, cardiovascular as well as onco. And that's what you can model yourself. Now, if these three would not happen, I would expect the first half to look like the second half. Unfortunately, there is not an unreasonable assumption, that will happen. So that's why we carefully have modeled this.

Seamus Fernandez - Guggenheim Securities LLC

Q. Great. Thanks for the question. So my question is on ianalumab. You guys have Sjögren's data coming this year in my understanding as well as some additional Phase II and III data sets. Where are you most excited about the opportunity for ianalumab? It would strike me that Sjögren's is the highest unmet medical need where even just a positive study would gain substantial utilization. Just trying to get a better understanding of how you're thinking about the market opportunity in Sjögren's and then more broadly for ianalumab. Thanks so much.

Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Seamus. We are very excited about ianalumab's potential, both in hematology and in immunology. So in immunology, clearly, the Sjögren's will be the first key foundational readout. We're studying it in the roughly 40% of patients who have systemic manifestations of Sjögren's disease. In the Phase IIb study, we demonstrated, for the first time, significant improvements in the ESSDAI, which is focused on the systemic manifestations, including improvements in areas such as fatigue and other physician assessed parameters.

And so if we can get a positive read, we'll try to get as broad a label as we can. And we're also assessing should we also study the medicine over time in those patients, the remaining 60% of patients, a subset of them who primarily have symptom manifestations without the systemic manifestations. So I think there's significant opportunity in HS.

Then, of course, following up on that, we have the systemic lupus and lupus nephritis studies as well running and as well as you note, the Phase IIb in hidradenitis. Alongside that, I think while there is reasonable standards of care in idiopathic thrombocytopenic purpura, ITP, this medicine also has the potential with its mechanism to be an improvement in second line and first-line ITP and that we also have a readout in 2025 as well. And so that would obviously enable us to start the process in hematology.

We have worked through ensuring we have different dose levels as well so we can manage the different indications in immunology and hematology from a price standpoint. So taken together, I mean, you have six 30/33

Phase III studies across the board already running for ianalumab, multiple Phase IIs. So assuming they go our way, this could be a very significant medicine, probably underappreciated overall.

Naresh Chouhan - Intron Health

Q. Hi, there. Thanks for taking my question. Just one on OAV, please. So the consensus currently modeling very little, if anything at all for OAV101. Can you help us think through the bolus opportunity and the speed of ramp up? We think it could be a blockbuster by 2027. Is that unreasonable? And how do you think about the speed of ramp-up? Thanks.

• Vasant Narasimhan - CEO of Novartis

A. Yes. I think it's obviously early days from our standpoint. But certainly, with - I can use the analog of what we saw with Zolgensma®. And certainly, in that case, we did see a very fast ramp. And then to the steady state and then we stayed at that steady state. I think it was two, three years until we got to the steady state. And that's generally what we would expect, I think, in the case of gene therapies. And so I think we'll see with OAV, the dynamic is obviously a little bit different because many of these patients will need to be switched patients.

But I think when you look at the competitive set that we're going up against. You have a competitor that requires quarterly intrathecal administrations into the spinal cord, which is quite challenging for patients over time. And also, patients often have malformations and the deformities that happened in the spine as a result of the repeated injections.

And then the other competitor medicine was not tested with the standard of care Hammersmith score, which is the gold standard, which is what we used. And I think our hope is by going to the physician and patient population saying, look, you have a onetime gene therapy using the gold standard Hammersmith score demonstrating statistically significant improvement using that score with a very expected safety profile that could be very compelling for a large number of patients. That's the approach we're going to take in rolling the medicine out and I'm hopeful that it will surprise people as well because I think there is the opportunity as we guided, this could be overall a USD 3 billion plus medicine over time. And that's very much the goal.

And I think also, of course, with gene therapies, we have the opportunity to have medicines that are – don't – at least to our current understanding, be difficult to face real generic erosion. So these become medicines that kind of stay in the long run in our portfolio.

• Eric Le Berrigaud - Stifel Nicolaus and Company, Incorporated

Q. Yes. Hi. Again, on guidance, but this time on the midterm guidance and trying to put the '25 guidance in the context of midterm guidance. Since you implemented this midterm guidance, you systematically beat and raise. '23 was much higher, '24 was much higher. And then we thought that maybe the transition with the significant LOEs in '25, '26 would be the reason for the midterm guidance to be lower than what you achieved. But now in '25, you're guiding for mid- to high single digit, which is again higher than the midterm guidance.

And so, if we think that '26 will very much look like '25 because it's a 50-50, mid '25, mid '26 impact. And then '27, '28 should see some rebound with no significant LOE. It becomes hard to understand why the midterm guidance is not more, let's say, higher or, let's say, to articulate things. So maybe something is missing, but could you put that in some context or just the global policy of underpromise and overdeliver. Thank you.

Vasant Narasimhan – CEO of Novartis

A. No, certainly not a global policy. We do our best to give you the midpoint estimate of where we think things 31/33

will go. And then, of course, if we do better, and over the last two years, I think our performance – operating performance has been outstanding. I see 2-plus years now. And I think that's part of the reason you've seen the consistent beats and raises. I think certainly, over the coming years, we'll see. I mean, we, of course, will update over time. I mean the 2026, we have the full year impact, of course, of these generic entries.

And then we'll clear them and then accelerate growth from there. So I don't think we're in a position at this moment to change our midterm guidance. But obviously, if we consistently perform at a higher level than the 5% midterm guidance, we'd have to reconsider it. But I think right now, our focus is delivering 2025 per plan, getting these launches up on the trajectory, closing the current gap that consensus has to our view, which I think is roughly 2 points '24 to '29.

So I think, Eric, you're there, but some of your colleagues are not. And so I think that getting that gap closed by showing confidence in Kisqali®, in Leqvio®, in Pluvicto®, in Scemblix®, in Fabhalta®, with the remibrutinib launch, with some of the pipeline delivery, continuing delivering on Cosentyx® – and then, of course, we'll reconsider the midterm outlook as appropriate.

• Richard Parkes - BNP Paribas Exane

Q. Hi. Thanks for taking my follow-up. It's just on Cosentyx®, the competitive environment. We've now had Bimzelx® on the market for a year or so. And I believe that has some recent formulary wins and obviously launching in the HS indication. So just wondering how that competitive environment is playing out and what you anticipate in your guidance? And maybe if you could quantify the opportunity for Cosentyx® and the new indications that you outlined, GCA and PMR.

And then finally, I'd like to thank you for the Lp(a) test at your Meet Management day because given that mine was minus borderline, I've now started on a statin. So I appreciate the opportunity.

Vasant Narasimhan – CEO of Novartis

A. That's great to hear, Richard. I'm glad we could help. On Cosentyx®, we had 25% growth this year. So I think that shows the robust growth profile of the brand. In terms of the competitor entries, when you look at our formulary position, it's as we expect, we've had to give the appropriate level of adjustments on our rebates, but we've maintained very good formulary position. We see very good performance in Asian markets such as China as well as continued good performance in Europe.

In Asia specifically, we think our profile of having very good flare resolution where we showed very compelling data on flare, on pain, I think on itch, on some of these, I think this really gives us a very compelling data set. And given the long history of safety with Cosentyx®, we think a very competitive profile to hopefully maintain that 60% plus NBRx share that we have. We believe in HS Cosentyx® to be over USD 1 billion medicine globally.

Now, for GCA and PMR, our current estimates are USD 500 million plus for each one of these. I think the question, of course, we'll have to see. I think originally for HS, we thought this would be USD 500 million to USD 750 million, and we delivered that almost in the first year. So I think we're learning as we go as we get into these new indications. And as we have a better sense from launching of, of course, positive data and then launching, we can, of course, update over time.

Florent Cespedes - Bernstein

Q. Good afternoon, again. Thank you for taking my follow-up question. This time, not on guidance, but on the pipeline for US, as pelacarsen is now expected in 2026, and it was supposed to be the big Phase III readout. Now, on the list of the products that will read out this years that would be the Phase III. Please, could you

share with us, which is, or which are the most meaningful one, please?

Vasant Narasimhan – CEO of Novartis

A. Yes, absolutely, Florent. So I think there's a couple of things I'd say. First, ianalumab is a key readout. And I think we've already highlighted that both Sjögren's and second line ITP, both of these will be, I think, really important for the profile and opportunity in ianalumab and also hopefully give a read-through of what we might be able to do in lupus, in lupus nephritis in a frontline ITP amongst others.

In addition, we're going to have the readout of Pluvicto® in hormone-sensitive prostate cancer, which will further create a patient population that's as large as the VISION – sorry, the PSMAfore population. And I think that would be another leg to build Pluvicto® out to that guidance that we've given of USD 6 billion plus over time. In addition, you're going to have, I think, importantly, the remibrutinib food allergy Phase IIb readout, which will then enable us to move rapidly for the next third indication. We hope remibrutinib on top of CSU and CINDU.

I would say for remibrutinib, we expect to file soon and then we do currently intend to use a priority review voucher. And we do believe that remibrutinib in CSU is going to be bigger than the markets expect. And I think the opportunity here in the US and around the world to have an oral medicine that can address such a symptomatic disease within two weeks of therapy is something we're quite excited about. So we're very much focused on that launch as well.

And then, of course, on slide 33, you see a long list of other things. But I think those would be the big ones that I would highlight that would really move the needle for this year.

Vasant Narasimhan – CEO of Novartis

A. I think that's it. So thank you all very much for joining. We look forward to seeing you in various settings over the course of the coming quarter and then again at the Q1 earnings call. Have a great day.

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