

 View Summary

Novartis AG

Novartis AG - Q3 2025 Earnings Call

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Operator Operator

Good morning and good afternoon, and welcome to the Novartis Q3 2025 Results Release Conference Call and Live Webcast. [Operator Instructions] The conference is being recorded. [Operator Instructions] A recording of the conference call, including the Q&A session, will be available on our website shortly after the call ends. With that, I would like to hand over to Ms. Sloan Simpson, Head of Investor Relations.

Please go ahead, madam.

Sloan Simpson Executive

Thank you, Sharon. Good morning and good afternoon, everyone, and welcome to our Q3 2025 earnings call. 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. Please refer to the company's Form 20-F on file with the U.S.

Securities and Exchange Commission for a description of some of these factors. The discussion today is not the solicitation of a proxy nor any -- nor an offer of any kind with respect to the securities of Avidity Biosciences or SpinCo. The parties intend to file relevant documents with the U.S. SEC, including a proxy statement for the transactions and a registration statement for the spin-off. We urge you to read these materials that contain important information when they become available.

Before we get started, I want to reiterate to our analysts, please limit yourselves to one question at a time, and we'll cycle through the queue as needed. And with that, I will hand over to Vas.

Vasant Narasimhan Executive

Great. Thank you, Sloan, and thanks, everybody, for joining today's conference call. If you turn to Slide 5, Novartis delivered solid sales and core operating income growth. And I think importantly for us, important pipeline milestones through quarter 3. Sales were up 7%.

Core operating income was up 7% with our core margin at 39.3%. And in the quarter, we were able to deliver some important approvals, including Rhapsido, our FDA approval in CSU for our BTK inhibitor. As well as important Phase III results, which we'll go through in a bit more detail, lanalumab, Pluvicto, Kisqali's 5-year data as well as positive opinions for Scemblix and then also positive data that came out relatively recently on Cosentyx in PMR and Fabhalta in IgAN. Now moving to Slide 6. Our priority brands drove robust growth in the quarter.

So I think really, while we, of course, are contending with our LOEs that particularly Entresto, but also Tasigna and Promacta, what I hope we can get the focus to be on is on our strong underlying growth of our key growth drivers. Here, you can see growing 35%, really excellent performance from Kisqali, Kesimpta, Pluvicto, Scemblix, solid performance from Leqvio and Fabhalta. So I think we're on a solid track to drive growth through the coming years. Now moving to Slide 7. Now taking each brand in turn, Kisqali grew 68% in quarter 3, outpacing the market and our CDK4/6 competition.

If I could draw your attention to the center panel, our total to brand NBRx now, as you can see, is in a market-leading position, particularly driven by the early breast cancer launch. Our U.S. growth was up 91% in quarter 3. We are the metastatic breast cancer leader in NBRx and TRx. And in early breast cancer, our share is 63%, and we're leading both in the overlapping populations with our competitor and the exclusive population.

In particular, I see -- I'd say we see significant growth potential in that exclusive population where we estimate more than 60% of patients are currently not on a CDK4/6 inhibitor. Outside of the U.S., we saw 37% growth in constant currency. We are the NBC leader in NBRx and TRx share across our key markets. Our early breast cancer indication now is approved in 56 countries. And so we'll start to see the effect of the early breast cancer launch in the next few quarters ex U.S.

Now I think it's a good indicator of what we see as possible outside the United States. Our Germany NBRx share is already at 77%. And I think that helps demonstrate the kind of power that we have to drive Kisqali's utilization and enable women to prevent breast cancer recurrence across the globe. I'll close by just reminding you, we have a Category 1 NCCN guideline support as the only preferred CDK4/6 inhibitor with the highest score in early breast cancer and metastatic breast cancer. Now moving to Slide 8.

Just wanted to say a word about Kisqali's 5-year data, which we showed at ESMO. There was a 28.4% reduction in the risk of recurrence in the broadest population of early breast cancer patients that have been studied. You can see here the data is very consistent across tumor Stage 2 or Stage 3 in node-negative patients and node-positive patients. I'd also note that our OS data, while still maturing, has reached a hazard ratio of 0.8, and we see a narrowing confidence interval, as you can see here in the third bullet, just a little bit above 1 on the upper bound of the confidence interval. So a clear trend favoring Kisqali.

The safety is consistent. We also had some notable important trends in the data continue to demonstrate a reduction in distant recurrence to distant metastases, which is excellent to see. So we'll continue to follow these patients and continue to provide updates on this data as it matures.

Now moving to Slide 9. Kesimpta grew 44% in quarter 3, and this was primarily demand-driven growth, particularly in the United States. U.S., we had 45% growth in Q3, robust TRx growth outpacing both the MS and B-cell markets. We have broad first-line access now almost 80% of the patients receiving Kesimpta are first line or first switch. Outside of the U.S., we had 43% growth, and we're the leader in NBRx share in 8 out of the 10 major markets that we participate in.

And we see a significant opportunity now looking ahead for Kesimpta outside of the U.S., where approximately 70% of disease-modifying treated patients are not currently being treated with a B-cell therapy. So as we continue to get that B-cell class up with Kesimpta having leading share in many markets, we see the opportunity to drive dynamic growth ex U.S. We did present some additional data at ECTRIMS that show the benefit of Kesimpta. I think I'd highlight that 90% of naive patients receiving Kesimpta showed no evidence of disease activity at 7 years, really demonstrating the durability of the response to this medicine. Now moving to Slide 10.

Pluvicto grew 45% in constant currencies in quarter 3. That's really momentum driven off of the pre-taxane castrate-resistant prostate cancer approval, which we recently achieved. The U.S. growth is driven -- so the Q3 sales in the U.S. were up 53%, driven by new patient starts increasing to 60% versus prior year.

60% of our new patients in the pre-taxane setting are -- with market share already surpassing chemotherapy. So really driven now by the pre-taxane launch. The key enablers to sustain our growth now in the U.S. is really to drive community adoption. We have 60% of our TRx in the community.

We have 9 out of 10 patients within 30 miles of a treating site, so over 730 sites. We believe that we need to get to around 900 sites to also support the HSPC indication. So we're well on our way. Our rollout of the pre-filled syringe is really positive, around 70% of sites using the pre-filled syringe already. And outside of the U.S., the rollout continues.

We see good growth in the post-taxane setting in Europe, Canada, and Brazil. And we also received a Japan approval and expect the China approval in quarter 4. So all on track for Pluvicto to reach its peak sales potential. Now moving to Slide 11. We presented last week the PSMAAddition data, where we demonstrated that Pluvicto plus standard of care reduced the risk of progression or death for standard of care alone by 28%.

The primary endpoint was met, clinically meaningful 28% reduction in these patients with a compelling p-value, a clear positive trend in OS with a hazard ratio of 0.84, and that's even with crossover. So I think that really demonstrates we're having the attended effect the time to progression to castrate-resistant prostate cancer was delayed, which demonstrates we are achieving disease control. And overall, the Pluvicto tolerability profile was consistent with the Phase III trials in PSMAfore and VISION. So we would see global regulatory submissions in quarter 4 of this year. So moving to Slide 12.

Leqvio was up 54% in the quarter, on track for over \$1 billion in sales in the year. In the U.S., we're up 45%, outpacing the advanced lipid-lowering market. We had solid TRx gains of 44% versus prior year. And our key focus is particularly in Part B accounts and accounts that have a high interest, of course, in using the buy-and-bill Leqvio model to drive more depth in those accounts, particularly as we've now evolved our field model to better support those accounts. Outside of the U.S., we see a continued strong performance, 63% growth.

driven by a number of markets, particularly China out of pocket, but we also see strong uptake in Japan, strong uptake in the Middle East and the Gulf countries. So all of that taken together, I think, really portends well for Leqvio in the medium to long term. We did achieve some important regulatory and clinical trial highlights. Our U.S. monotherapy label expansion, removing the statin prerequisite in the primary prevention population was added to the label.

The V-DIFFERENCE data was presented at ESC, which showed Leqvio helps patients get to goal faster. I'd also note that our pediatric submissions are on track, which, of course, supports our longer-term LOE profile. Now moving to Slide 13. Scemblix grew 95% in constant currencies in quarter 3. It's on track to be the most prescribed TKI by NBRx in the U.S.

Focusing on the middle panel, you can see that our all line of therapy, NBRx has now reached 39% and is steadily climbing built off of that first-line approval. In first line specifically, we've reached 22% share. So we're now approaching NBRx leadership in first line. We already are the NBRx leader in second line and third line plus with 52% and 53% share, respectively. Outside of the U.S., our focus currently is on the third line plus setting, where we have 68% share.

But we do have the early line now approved in 26 countries, including China and Japan and a positive CHMP recommendation from October. So we would expect now to start to see our ability to reach patients in the first-line setting picking up outside of the United States. As an indicator of that, you can see here our strong launch momentum in Japan, first-line share already up to 18%, second line at 25%. So we continue to be very optimistic about the outlook for Assembly.

Then moving to Slide 14. Now Cosentyx had a mixed quarter. Our growth was impacted by a onetime effect in quarter 3, which I'll go through in a moment. But most importantly, we remain on track for mid-single-digit growth in full year 2025 and are confident in the peak sales potential of the brand. So you can see that in constant currencies, our growth was down 1%.

In U.S. dollars, we're more or less flat. Now when you remove the onetime RD adjustment of \$74 million, our global sales growth was around 4% in constant currencies. In the U.S., when we adjust for that onetime RD, our growth goes from plus 1% to plus 9%. Cosentyx continues to be the #1 prescribed IL-17 across indications.

In HS, now we see a stabilization of the performance, 52% share in naive and 50% overall. So when the competitor came in, we did see a dip in that share, but that's now stabilized. And we are better able now to manage patients alongside physicians to achieve step-up dosing rather than switching off of Cosentyx. And I think that will be important. And so we can really turn our focus to market expansion in HS with the stable share that we've been able to achieve.

Outside of the U.S., we were down 3% in constant currencies, but this again was driven by a onetime price effect in the prior year. Importantly, we saw 4% volume growth, and we're the leading originator biologic in Europe and China. So overall, I think the key message is we're confident in the \$8 billion peak sales potential. We expect continued market growth in our core indications and rollout of the recent launches in HS and IV. But I think also importantly, we did achieve a positive Phase III readout in polymyalgia rheumatica.

It's the second most common inflammatory disease in adults over 50, an estimated 800,000 patients in the U.S. and 1 million patients in Europe to have the condition. So this is a market that's on par with the HS market when you think about the size of the segment. We have global regulatory submissions planned in the first half of 2026, and we'll be working to accelerate them as well and really hope to drive rapid uptake in PMR. We believe the data is compelling.

We demonstrated, as you saw in the press release, a positive clinically meaningful primary endpoint, and we also hit all of the secondary endpoints. So we're looking forward to presenting that data and taking this launch forward. Now moving to Slide 15. Our renal portfolio continues to gain traction in the U.S. We had a positive Fabhalta eGFR data, really the first oral therapy to generate such compelling eGFR data.

So looking forward to presenting that. We see steady growth in the U.S. Our IgAN portfolio grew 98% versus market growth of 23%. Our NBRx share is now 18% climbing steadily. We see strong uptake as the first approved therapy in C3G.

Outside of the U.S., we're beginning to get the key approvals, particularly in China, where there's a large market for IgAN therapies. And turning to the Phase III APPLAUSE-IgAN study, we saw a statistically significant clinically meaningful improvement in eGFR slope versus placebo. It's the longest renal function data for IgAN to date. So we're excited to present that data at a future meeting. And this data should support a full approval -- traditional approval with FDA.

Now moving to Slide 16. Rhapsido was approved by FDA as the only oral targeted BTK inhibitor for CSU. I think many of you know the medicine well. It's something we're quite excited about. It's indicated for the treatment in adult patients who remain symptomatic despite antihistamine treatment.

And we estimate that patient population to be around 400,000 patients uncontrolled out of 1.5 million treated patients. We achieved a clean safety profile with this medicine, no box warning, no contraindications, no requirements for routine lab or liver monitoring. oral administration, 25 milligrams twice daily with or without food. So a really good profile for these patients. I would want to highlight as well.

We're very excited to have a medicine with rapid onset in a highly symptomatic condition. These patients have to deal with itch, loss of sleep, discomfort. And so if you can have a medicine that has a really rapid efficacy benefit that's really, I think, something that could drive rapid uptake. Our initial patient -- physician feedback is excellent, and we're already seeing a steady increase in start forms. Our goal will be to improve the access environment for the drug as fast as possible, and then we would start -- expect to see rapid uptake over the course of next year.

And then lastly, in both EU and China, we've completed our submissions and our Japan submission is slated for also later this year. And moving to the next slide. Ianalumab, we announced our positive Phase III studies earlier in the quarter. Yesterday, we released our top line data. The full data set will be presented soon, I think, tomorrow.

And then our Analyst Day to discuss this data as well as the Rhapsido data as well as other immunology data, including our CAR therapy platform for immunology. Immune reset platform will be on Thursday. So I hope you'll be able to join that, and we'll give you a lot more detail on the secondary endpoints, on post half endpoints, on biopsy data, et cetera. But here, just on the top line, the Phase III endpoint was met in both studies, statistically significant improvement in ESSDAI. I do want to highlight here, there's a lot of focus, a lot of report on the aggregate ESSDAI from a patient standpoint and a physician standpoint, what matters is where the individual patients are and how much we're able to improve their relative disease.

And also what is the starting point for the ESSDAI score. So the fact that we've achieved two positive Phase III trials, I think, will really enable us to roll this out to patients. And then as patients see the symptom benefit given their profile, they'll hopefully be able to get the benefit and stay on the medicine. We have consistent numerical endpoints, improvements in the

secondary endpoint, a favorable safety profile. And as I mentioned, the data will be provided shortly.

So regulatory submissions are on track for the first half of '26.

And moving to Slide 18. Overall, I think a strong innovation year for the company. You can see all the various milestones that we've reached. Also, we've been, I think, the leading player in the sector in terms of deals bringing in medicines at all stages from preclinical to Phase I to late-stage assets, also continuing to bolster our technology platform. So we'll look forward to giving you a full innovation update and technology update at Meet the Management in November.

So with that, let me hand it over to Harry.

Harry Kirsch Executive

Thank you very much, Vas. Good morning, good afternoon, everybody. As usual, I will take you through the financial results now for the third quarter, the first 9 months and the full year guidance. And as always, unless otherwise noted, all growth rates are presented in constant currencies. So if we go to our Slide 20, you see a summary of the financial performance.

In the third quarter, net sales grew 7% versus prior year. Core operating income was also up 7%. In the U.S., we had some negative gross to net true-ups first time since the year. Prior, we had mostly positive. But they were mainly related to Medicare Part D redesign, which was new for the industry this year based on invoices for prior periods, mainly quarter 2.

And excluding these true-ups, the underlying growth would have been 9% on the top line and 11% on the bottom line as the priority brands and launches continue to offset the increasing generic erosions, mainly for Entresto, Tasigna, and Promacta in the U.S. Our core margin was 39.3% in Q3 and core EPS came in at \$2.25, reflecting a 10% increase and free cash flow totaled \$6.2 billion. For the first 9 months, obviously, as we had less generic erosion, net sales grew 11%, core operating income 18% and the core margin expanded 250 basis points to reach 41.2% and with core EPS at \$6.94, up 21%. Free cash flow reached after 9 months already \$16 billion, growing 26% in U.S. dollars versus prior year.

Moving to next slide. Speaking of free cash flow, up 26% billion, as I mentioned, already close to actually prior year full year \$16 billion after 9 months. So it really shows continued strong conversion from profits to cash flow. And of course, cash flow remains a strategic priority as it increased further our ability to convert strong core operating income growth and robust free cash flow and gives us the capacity to reinvest in our business organically, pursue value-creating bolt-ons like the proposed acquisition of Avidity and return attractive shareholder -- attractive capital levels to our shareholders through growing dividends and share repurchases. Speaking of capital allocation, let's go to the next page, right?

It's really unchanged. And again, based on very strong free cash flow, we really can optimize both a significant investment in the business to drive top and pipeline and returning capital to our shareholders at attractive levels. In the first 9 months, aside from Avidity, we have executed multiple bolt-on M&As, smaller in size, but still very important and -- which strengthened our key platforms and pipeline for our four therapeutic areas. And of course, we also continue to invest in our internal R&D engine. On the capital return side, we successfully completed our up to \$15 billion share buyback program early July and have launched a new up to \$10 billion buyback program targeted for completion by the end of 2027.

We also have distributed \$7.8 billion in dividends during the first half of this year as part of our annual dividend. Turning to the next slide. We reaffirm our full year guidance. We expect high single-digit growth in net sales and low teens growth in core operating income, even after accounting for negative gross to net true-ups in the third quarter. And to complete our outlook, we now anticipate the core net financial expenses is slightly higher at \$1.1 billion before we had \$1.0 billion, a bit higher hedging costs.

But overall, nothing dramatic. And the core tax rate continues to be in this range of 16% to 16.5% so far in the first 3 quarters at 16.2%. Now let's move to the next slide. So usually, we don't provide so much level of quarterly guidance, right? Quarters are a bit more volatile than the full year usually.

But given that we have U.S. generics entry in the middle of the year for three of our brands, of course, the biggest being Entresto, but also Promacta and Tasigna were, of course, blockbusters, it results in very different quarterly dynamic this and next year. And so as a reminder, in quarter 4 of last year, we benefited from significant positive gross to net adjustments, which added back then about 3 points of growth. So it makes for a very high prior year base. Adjusting for these one-timers, we expect quarter 4 underlying growth to be low single digit on the top line and mid-single digit on the bottom line, reflecting the increasing generic erosion from a full year impact of Entresto U.S.

generics but better, obviously, than what we expect to report, including the prior year gross to net adjustments.

We provide full year guidance for 2026, of course, next quarter with the full year results, but you can imagine it will be a year of two halves. The first half of 2026 will be depressed due to the impact of generics with still a high prior year base, but we expect to emerge much stronger in the second half, but much more on that as we go -- as we report our full year results early February. Now let's move to our currency estimate impact of currencies should -- currencies remain where they are basically late October. Then we expect a full year in '25 impact of 0% to 1% on net sales and minus 2% points on core operating. You see also the quarter.

And we roll this forward to '26. So in '26, we would expect with these exchange rates, a slight positive 1% point on net sales and basically no material impact on core operating income. And as you know, we publish this on a monthly basis as it is quite difficult to forecast this from the outside in, and we hope you find it helpful. And then lastly, I hope you were able to join our presentation on the proposed acquisition of Avidity yesterday. If not, I would encourage you to listen to the replay.

And -- adding Avidity, as we mentioned yesterday, raises our '24 to '29 sales average growth rate from 5% to 6%. But of course, even more importantly, further supports our mid-single-digit growth over the long term with main impacts, of course, in the 2030s and beyond. And it brings, of course, these near-term product launches two with multibillion blockbuster potential with LOEs in the 2040s and no IRA impact. Now we also mentioned yesterday that we do expect some short-term core margin dilution given Phase III trials are basically now starting to run or up and running shortly in the range of 1% to 2% points for the next 3 years. But we are confident that we return to the 40% margin, which we already achieved this year also will return them back to that in 2029.

And please make sure that you also model this 1 to 2 points core margin dilution as you finalize your 2026 models for us. This deal, of course, overall is expected to deliver very strong sales

and profit contributions post -- starting in '29 and then even more and therefore, driving significant shareholder value with a small price to pay over the next 3 years on the margin dilution as part of the investment. That's all I had for now and handing back to Vas.

Vasant Narasimhan Executive

Great. Thank you, Harry. So moving to Slide 28. In summary, solid sales and core operating income growth in the quarter despite generic headwinds. So I think we're navigating that well with strong underlying performance of our priority brands, which is reflecting the strong execution, a strong pipeline progress.

We delivered strong pipeline progress in the quarter. And we also reaffirm our 2025 guidance and remain highly confident in our mid- to long-term growth, which is further bolstered by our proposed acquisition of Avidity, not just through the end of the decade, but into the next decade and beyond. I want to just quickly remind you as well, we have our immunology pipeline update on October 30, and our Meet Novartis Management on November 19 and 20, in person in London. So thank you again, and we'll open the line for questions.

Operator Operator

[Operator Instructions] We will now take the first question. And the question comes from Matthew Weston, UBS.

Matthew Weston Analyst

I hope you can hear me. It's a question about policy, Vas. And we've seen now two companies do deals with the White House around Medicaid and tariffs. And I wondered from your perspective, how much you felt we could see the industry do a cookie cutter of those deals or whether there are meaningfully greater challenges for some companies and when we should expect something from Novartis? And if Harry, I can steal, I guess, an extension of the same question.

Can you walk us through CapEx over the next 5 years given the investments that you've announced in the U.S. and how we should think about modeling that as part of cash flow?

Vasant Narasimhan Executive

Thank you, Matthew. So I think from an industry-wide perspective, I think the pharma industry's view is that the proposed negotiations or proposed actions are not going to address the underlying issues here, which, of course, we believe are PBMs, 340B and importantly, perhaps most importantly, G7 countries and related countries outside the United States properly rewarding innovation and properly assessing the appropriate price for innovation. That said, I think, as you point out, there are I think now three companies that have reached agreements with the administration. I'd say Novartis has -- I can't speak to what other companies are doing. We've been in conversations with the administration since the beginning of the year as we've had the various turns in these discussions.

And I'd say we're meeting with the administration weekly to look at what are the best solutions we can come up with. It is important to note that the President was very clear on the four parameters, and I think those are the four parameters that are in discussion. And we'll have to see in the coming weeks and towards the end of the year if we can come to a proposed approach that makes sense for all involved. And in terms of CapEx, Harry?

Harry Kirsch Executive

Matthew, I think as we mentioned when we also introduced the \$23 billion over the 5 years commitment, we made it clear that the majority is actually not CapEx. Majority is R&D OpEx, where we have the choice to invest in the U.S. or anywhere else in the world. And we choose, of course, to have a strong commitment also for R&D in the U.S. And then there's a portion, yes, it's CapEx, but it's actually part of our overall worldwide financing plan also for -- and we choose basically incremental to invest in U.S.

to build up there our manufacturing base to supply the U.S. from the U.S. instead of further expanding, for example, European sites. So from that standpoint, overall, I don't expect a significant or meaningful CapEx increase. We are always in this range of 2.5% to 3% of sales, actually quite a low end of the industry given our very focused and efficient manufacturing setup.

And it's always -- there can be annual fluctuations, but nothing meaningful. Also, we have further opportunities in cash flow and inventory. They are usually on the high side. We keep that as a bit of a buffer in certain times. So overall, in short, I would not expect a significant CapEx increase.

And I would expect free cash flow to grow roughly in line with core operating income growth.

Operator Operator

Your next question comes from the line of Peter Verdult from BNP Paribas.

Peter Verdult Analyst

Pete Verdult, BNP. Only one, so I'll keep it topical for Vas. Just on the market reaction to that ACR abstract, I think you've alluded to it being disappointment and you perhaps sharing a different view. So just pushing you on -- do you think the market depreciation of the data set will improve once we see the full details tomorrow? And just could you remind us, I'm sorry to get technical, of the 12 domains that make up the ESSDAI index, which ones are seen as the most important to patients and physicians?

Vasant Narasimhan Executive

Yes. Thanks, Peter. I mean, I think for us, the most important thing is that we make a compelling proposition to patients and physicians. And then if we deliver a strong launch, then I think, obviously, the markets will do what the markets will do, but presumably will follow. I think -- we will present detailed data on Thursday, and I think that will help at least understand where our conviction comes from.

I think very important for us is the individual patient benefit. I think practicing physicians and patients don't measure an ESSDAI. They're actually looking for symptomatic benefits in things like fatigue, in salivary flow, in activities of daily living. And I think looking at that -- the global assessment of physicians and how they see patients benefiting is going to be really important for this launch. It's a highly variable disease.

So a lot of this will depend on finding those groups of patients that have a significant benefit. And I think important for these patients as well is to feel like they don't need the same level of steroids that they typically are using, which can be hugely disruptive for their lives. Sleep is another topic as well. So we'll present that information. But I think we feel confident that there is a high willingness even from the physicians that we're talking to now in Chicago, a high interest and a high willingness to make this option available for patients.

And assuming we can make patients materially feel better versus the current standard of care, which is frankly just high-dose steroids, we expect to be able to drive significant growth from this medicine.

Operator Operator

Your next question comes from the line of Stephen Scala from TD Cowen.

Steve Scala Analyst

It seems like there may be a subtle change in the messaging on Cosentyx in HS. While Novartis grew overall market share quarter-over-quarter on Slide 12 of the Q2 deck, Novartis noted continued HS market growth. And in the Q3 slide deck, that was not stated explicitly. It's clear Novartis has been playing defense on share. But with that now stabilized, is the point that you need to grow the market and it's not growing at the pace that you expected?

So is that the contour of the market? This would seem to be a factor in whether Novartis grows earnings in 2026. And when Harry was talking about 2026, he didn't say that specifically.

Vasant Narasimhan Executive

Yes. Thanks, Steve. So what I can say is that we feel confident that our share has stabilized after the competitor entry. I think we have not seen the market growth that we had originally hoped for that we -- there's clearly a lot of patients who can benefit from biologic therapy with HS. We continue to see this as a \$3 billion to \$5 billion-plus market, but it's clearly going to take longer for that market to develop.

And so I think we probably did not do the careful analysis that you did on our slides, and I'll look to our IR team to do that more carefully in the future. But I think your point is absolutely on that we need to see -- we need to grow this market, and that's what really both companies should really be focused on and get more patients on these therapies. Now with respect to earnings, we don't comment on 2026. We're focused on clearing out 2025. And so once we get there in January, we can provide you our outlook.

I would say that I think I would focus much more on the dynamic growth you saw in the quarter on Kisqali, Pluvicto, Scemblix, Kesimpta, all of which, to my eyes, were ahead of consensus. And I think that's where I think the focus should be now looking ahead for the company. Next question, operator?

Operator Operator

Your next question comes from the line of Shirley Chen from Barclays.

Xue Chen Analyst

Can I ask about Pluvicto. So congrats on a great quarter. Could you please help frame where you are in the launch curve for pre-taxane new label? And how do you expect the inflection in 4Q and also next year? Can you remind us your peak sales ambition of this drug?

And when do you expect Pluvicto to reach at the full potential within the PSMAfore population and also potentially PSMAAddition population? And also in addition, you -- I think you previously mentioned a few challenges for commercialization, such as reimbursement, education of staffing and referral networks. And how do you find where you are tackling these challenges?

Yes. Thanks, Shirley. So for Pluvicto overall, I think we're on the steep part of the curve right now. We see -- as you saw, very strong growth in quarter 3. We would expect very solid growth in quarter 4.

It's important to note in quarter 4, we always have a slowdown in the Thanksgiving and Christmas holidays. So in effect, lose 2 to 3 weeks because of those holidays, simply because patients don't want to "have a nuclear medicine, radioactive medicine that prevents them from being around children or family members, so for a period of time." So important to note that. But that said, we do expect continued strong performance in quarter 4. And then going into next year, we would expect solid growth, but I think as always with these launches, good growth, but maybe not the same levels of growth you're seeing in quarter 3 and quarter 4, kind of an S-shaped curve. And then our plan would be to bring on the HSPC indication, which will then propel us, we believe, to the \$5 billion peak sales that we've guided to.

So we fully are confident on that. We see high levels of now receptivity. And that, I think, brings me to your point on the structural challenges, which I think we've successfully tackled now with the PSMA and VISION launch, we struggled to get into the community in a way that was scaled. Now through years of effort by our U.S. commercial team, we've successfully, as I noted, have over 700 prescribing clinics across the country.

9 out of 10 patients are very close to a center that can provide Pluvicto. We're adding centers just to be on the safe side. We've done careful mapping to know the referral pathways. Physicians are much more comfortable now using the PFS, a pre-filled syringe and dealing with some of the other logistics associated with radioligand therapy. So we're in a very good spot in that sense.

And that's what gives us confidence that the pre-taxane launch can propel us into the \$3 billion-plus range and then the HSPC launch will propel us into the \$5 billion-plus range and will be where we expect. We continue in the as well in the oligometastatic setting as well to go earlier. We also have a number of Phase IV studies, including in the mCRPC setting in combination with ARPIs to give physicians even more options. So we're doing all of the work as well to fully build out the data package to maximize this medicine. I think while I'm on Pluvicto, I think all of that builds the base for our radioligand therapy platform more broadly.

We have that full range of 10 -- around 10 different indication medicines that are advancing in the clinic. And now as we bring those forward, we have that infrastructure built in the U.S. and now increasingly Japan, China, and other markets to make those other launches successful. So I think all on the right track. It was a very important element for us to strategically solve.

And in my view, we have solved the challenge of rolling out radioligand therapy in the United States. Next question, operator?

Operator Operator

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

Florent Cespedes Analyst

A question on Rhapsido. Could you maybe share with us how you see the ramp-up of the product as you have a clean safety profile, convenient administration? And do you have any

feedback from the Street even though it's still early days? And any thoughts for the situation in Europe, the adoption knowing that the product will be compared with much cheaper drugs?

Vasant Narasimhan Executive

Yes. Thank you, Florent. So we're in the early stages of the launch. Right now, our focus is on sampling through patient start form, getting through patient start forms and negotiating with payers to ensure broad access in the early part of next year. I think once we get to the early part of next year, we get that base up through sampling in this initial phase, we would then start to expect a more rapid uptake through Q2 forward next year, where I think there will be the opportunity then to really drive uptake.

We would expect initial uptake to be in patients who are not responding to biologic. But then our goal very much is to be positioned pre-biologic. That's really where the opportunity is for this medicine, and that's what we're going to be our long-term focus in the U.S. and really around the world. I think in Europe, you raised an important point.

I mean, a lot of this will come down to our payer negotiation. And I think in light of the current situation in the U.S., it will be absolutely our goal to hold the line and ensure that Rhapsodo is appropriately reimbursed for the innovation it's bringing and not have it be compared to old generic drugs, but really compared to what it is a pureless oral twice-a-day option for patients that really need a rapid onset of action. And we're hopeful that European payers will realize that and then appropriately reward it, and then we'll be willing to be patient to achieve that. But then I think once we get access, all of our indications, there's a lot of enthusiasm in both the allergists and the derm community for a safe oral option, and we should see rapid uptake there as well. So I think overall, very excited about the medicine.

As you know, we're progressing as well in CINDU. We would expect that readout next year. We're progressing in food allergy. We're progressing in HS. So we have a number of opportunities now ahead of us as well for this medicine.

Next question.

Operator Operator

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

James Quigley Analyst

I've got a follow-up on lanalumab, please. So one question we've had is that, obviously, the slide suggests in NEPTUNUS-1 that statistical significance was only achieved in the last two blocks of data. Was that just because of when the tests were run? Or is that sort of what you're expecting as well in terms of when you're planning the study? And a second quick one on lanalumab as well, hopefully not to preempt tomorrow or Thursday.

But you talk about the sort of secondary endpoints and fatigue and salivary flow being more important, but the secondary endpoints were not statistically significant. So again, was this a case of hierarchical testing or anything else? How can you show that when you -- when the drug hopefully gets approved and you talk to physicians about the data?

Vasant Narasimhan Executive

Yes, absolutely. I mean, I think the endpoint here is at 52 weeks. And so I think we were trying to indicate all of the time points to reach nominal significance. But given that endpoint, the goal

here is 52 weeks, and both studies achieved the prespecified primary endpoint at 52 weeks in the independent analysis and in the pooled analysis. So no issues there.

And so we feel from a regulatory standpoint, we've -- 48 weeks, excuse me, 48 weeks the standard. So I think you can see here on Slide 17, 48 weeks was hit in both trials. And then -- separate from that, there is hierarchical testing here as often is the case. And so if one of the secondaries are hit, even if they hit from a nominal standpoint and lower the hierarchy, it's no longer valid from a pure statistical hierarchy standpoint. It could be nominally statistically significant, but wouldn't reach the threshold from a regulatory standpoint.

That said, I mean, I think as I've tried to articulate, there's the regulatory standpoint here. And in a disease that's never had an approved drug, there's really what our patients and physicians looking for. And we've really tried to understand once we hopefully can get the regulatory approval, then what do we need to educate physicians and patients on. So you'll hear more about that on Thursday, but our team has done a range of analyses to look at secondary outcomes, look at post-hoc outcomes, look at also biopsies and really try to demonstrate that you're seeing the benefits that patients want. I myself have spent time talking to patients with Sjögren's.

And I think what really matters to them is quality of life metrics and very specific quality of life metrics that varies patient to patient. So I don't think that for them that the ESSDAI score is going to make the difference. It's going to be whether or not their symptoms are getting better and they can live their daily life day in and day out better. Next question.

Operator Operator

[Operator Instructions] Your next question comes from the line of Richard Vosser from JPMorgan.

Richard Vosser Analyst

One on Kesimpta, please. Just whether you're seeing any impact in the U.S. from the OCREVUS subcutaneous launch. It doesn't seem like it, but just wondering what you're seeing here. And linked to that, there's some discussion from you about your new formulation.

Just wondering on details of treatment interval, whether this could be a new BLA and how this could protect from potential biosimilars down the line.

Vasant Narasimhan Executive

Yes. Thanks, Richard. So on OCREVUS subcu, we don't see an impact to date, as you can see on our overall performance. We're holding share in a growing market. I think -- the overall market growth for multiple sclerosis drugs has been solid.

Within that, the B-cell class continues to steadily increase with a bigger opportunity outside of the U.S., but still we see the opportunity. I think 25% of patients in the U.S., give or take, are still not on B-cell therapies that could be. And so we're really benefiting from the market growth. We are doing a lot of work now to get better at targeting physicians that we think would be more amenable to a patient self-administered administration rather than the various other options available. But I think overall, this is a growing market where the medicine is holding its share, performing really well.

It's all volume-driven growth. From a life cycle management standpoint, we are advancing our Q2-month formulation. And so we'll keep you updated as we progress, but that's something that's a trial that's currently on rolling. And then we're exploring other options, no details I can get into at this point to get into longer intervals as well potentially with novel technologies. And I think as those progress and if there is the opportunity to get those launched before biosimilar entry, that's something that we're highly, highly focused on, absolutely.

But I think it's premature to comment on that at this point. Next question, operator?

Operator Operator

Your next question comes from the line of Thibault Bouterin from Morgan Stanley.

Thibault Bouterin Analyst

Just a question on abelacimab, the injectable Factor XI acquired with Anthos. I think we're getting the first Phase III data in AFib next year. This is for patients at high risk of bleeding and for whom oral anticoagulants is not adequate. Can you just sort of frame the opportunity in terms of size? And are you looking to potentially go into a broader patient population with this asset?

Vasant Narasimhan Executive

Yes. Thanks, Thibault. So this is the -- as you know, the antibody that we acquired back from Anthos is originally a Novartis-originated antibody. So we know it quite well. As you know, the study next year will be in patients who are ineligible for DOACs, NOACs.

And so the opportunity here is for these patients, which is a reasonable sizable patient population to provide them a significant option with monthly dosing. I think the opportunity here will really -- the size of the opportunity, we believe is multibillion, but the scale of that multibillion-dollar opportunity will really depend on how the oral Phase III program from one of our competitors performs. I mean, clearly, if that oral medicine, which is an all comers in a very large study, if that is unsuccessful, then we would have a very significant potential with our medicine. I think with an oral and an antibody, we'll be much more than focused on these more refractory patients and the opportunity won't be quite as large. But I think in either case, it will be a multibillion-dollar asset we can bring into our cardiovascular portfolio.

And we're -- yes, we're quite excited about it. Next question, operator?

Operator Operator

Your next question comes from the line of Michael Leuchten from Jefferies.

Michael Leuchten Analyst

If I could please go back to Cosentyx. Could you tell us, please, what your pricing assumptions, the net pricing assumptions are for the U.S. into the fourth quarter? Do you expect any drag? And just trying to understand the increase in step-up dosing comment on your slides around HS, the 25% utilization.

Could you put that into context? What was that maybe at the half of the year? And how has that developed?

Vasant Narasimhan Executive

Yes. Thanks, Michael. So on Cosentyx pricing, we don't expect any shifts going into quarter 4. And I'd say, overall, we expect stable gross to nets as well going into next year. I mean it's relatively mature brand, but also with multiple new indications and a solid payer position.

So I think we should be stable on that front. We are also monitoring the impact of the Part D redesign, but most of the impacts we've seen on Part D redesign have actually been on Entresto earlier in the year, and then I think that will fade away now as generics enter. On HS, this really referred to the fact that early on with the competitor launch, what we were seeing is with patients who were on the monthly dosing, if they weren't seeing the effect that they are, physicians weren't seeing the effect that they hoped for, the effect was wearing off, they were switching rather than up dosing Cosentyx every 2 weeks. And so now we see about 25% of patients on Cosentyx moving up to that every other week dosing. And that's something we'd like to get even higher over time because I think that really demonstrates patients are persisting on Cosentyx, and that's going to be important for us to retain our greater than 50% NBRx share and then the correlating TRx share as well.

So that's very much in focus for us. And then I'd come back again that we also just need to work on growing the market. I think if this ends up being two competitors just trading the same group of patients, that would be disservice to this patient community. I think we have to get better now at reaching patients who have either fallen out of the system or for whatever reason are being identified as biologic appropriate patients and get them on therapy. Next question, operator?

Operator Operator

Your next question comes from the line of Simon Baker, Rothschild & Co Redburn.

Qize Ding Analyst

I hope you can hear me okay. So this is Qize Ding speaking on behalf of Simon Baker. So I have one quick question. So one quick question on the rebate adjustment. Is there anything you can call out other than the Cosentyx?

And also, did any drug benefit from the rebate adjustment in the Q3?

Vasant Narasimhan Executive

Yes. Thank you for the question. I'll hand that to Harry.

Harry Kirsch Executive

Yes. Thank you for the question. So overall, of course, when you see the amount that is prior period is roughly \$180 million. You see that this has about this 1.5 almost rounding the 7% to 9%, if you will, effect on the quarter. And Cosentyx is a big piece of it.

Another big piece of it is Entresto actually where patients got quicker into the catastrophic as part of the Medicare Part D redesign. And of course, that part really should go away as Entresto kind of goes away. And there has been some smaller elements, including like really going back into '24 with some inflation penalty part. But the two biggest ones are Cosentyx and Entresto.

Vasant Narasimhan Executive

Thank you, Harry. So Sharon, next question.

Operator Operator

[Operator Instructions] And your next question comes from the line of Rajesh Kumar from HSBC.

Rajesh Kumar Analyst

Just trying to understand the margin cadence over 2026. I know you're not giving a '26 guidance at the moment. But very helpfully, you said it will be a year of 2 halves. So given what you know about Part D now and how generics are coming and what sort of operational gearing you're getting on your Kesimpta, Pluvicto, and other, drugs which are growing. If you were not cutting the costs, would the cadence be a lot more steeper?

And what have your actions done to offset that impact? So what is the mix impact versus self-help? If you could help us quantify as well as the seasonality of Part D cadence? Because this year, you have done a prior period adjustment that might not be the next year because you have some accrual history now. So you will base your quarterly accruals on the evidence you have.

So it would really help us model out first half, second half for '26.

Harry Kirsch Executive

Yes. Thank you, Rajesh. A very thoughtful question, of course. And so in our business with our mix, we usually do not have Medicare kind of related different gross to net levels quarter-by-quarter other than when we have a gross to net true-up, right? So when channel mix changes, when a product goes quickly into the catastrophic and those -- if there are -- I mean, there are always some deviations, right?

We have over 20 billion RDs in U.S. But when these are significant or meaningful, then we let you know, right, how much it is, like in quarter 4 of last year, it was 3 points of growth, which is now impacting as a high base. Quarter 1 was 2 points to the positive and quarter 3 is now 2 points to the negative. So we show you that stuff. But that's basically true-ups.

The underlying is not changing quarterly dynamics for us. So for next year, you will have a very high base Q1 right, with the 2 points of growth that we got from the -- and you will have a relatively low base in Q3 from the 2 negative points this year. And other than that, it's all about launch uptake and generic erosion of the three main products. Maybe long-winded, but I hope it was addressing your question.

Vasant Narasimhan Executive

And we'll do our best, I think, at the full year earnings as well to provide more guidance on how best to think about the full year 2026. Next question, Sharon.

Operator Operator

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

Matthew Weston Analyst

It's just a quick follow-up actually to one of the prior questions. Harry, Kesimpta looks like a very strong quarter in Q3 that looks somewhat off trend. And I'm just making sure that as we go into Q4, we aren't going to learn that it was lumpy one way versus the other. Can you just confirm that was underlying operational growth?

Vasant Narasimhan Executive

Absolutely. Harry?

Harry Kirsch Executive

Yes, it was mainly underlying operational growth, a little bit of inventory, but not much.

Vasant Narasimhan Executive

Just a strong global volume, I think, in both U.S. and ex U.S. for this matter. Next question.

Operator Operator

Your next question comes from Simon Baker, Rothschild & Co. Redburn.

Qize Ding Analyst

Just one quick question on the lanalumab in Sjögren's disease. So we observed the placebo response in the Sjögren's trial tend to be plateau at week 48. So why did it reverse in the first trial of those two Phase III trials, please? The Phase III trial is called NEPTUNUS 1.

Vasant Narasimhan Executive

Yes. I think the question is regarding the placebo response. I mean I think -- look, I think these were both adequately controlled, well-designed studies, global studies. This is just a highly variable disease. And so you're going to see some variability in how the placebo responds.

When we look at background therapy as well, it's very comparable across the studies and so also versus normal standard of care. You do see as well that the month data looks much better than the Q3-month data, but you do see as well the dose response that we would expect. So I think that's all positive. And so we'll have our experts on the line on Thursday. So if you want to get into more detail, and they'll also be able to go through some of the background on the study design and baseline characteristics.

But I think, obviously, I can't comment more until the full data is presented. Next question, Sharon?

Operator Operator

Your next question comes from Stephen Scala from TD Cowen.

Steve Scala Analyst

Novartis raised the long-term revenue guidance yesterday, half of which was attributed to the existing business. Of the half attributed to the existing business, how much is due to currently marketed products? And how much is due to higher sites for the pipeline agents?

Vasant Narasimhan Executive

Yes, Steve, I think we can provide better midterm guidance on that and meet the management. But most of that is in-line brands. Obviously, you see the strong performance of Kisqali, Kesimpta, Pluvicto, Scemblix, I think solid performance on Leqvio. And there is probably some in there of what we expect will be a strong launch for remibrutinib, so Rhapsido and the label expansion for Pluvicto. Yes, I think that's roughly the breakdown more or less.

I think any other pipeline assets we would expect to have limited ramp in this period, just given how long it takes to ramp up these launches when you think out to '29. And we will provide guidance as well out to 2030, as I said yesterday, and meet the management as well as update our peak sales guidance on our various brands where appropriate. Next question, Sharon?

Operator Operator

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

James Quigley Analyst

Just a quick one for me. I mean you may have already answered it, Harry, but again, it's coming back to the Cosentyx, the rebate adjustment. Which prior periods does that relate to? Is that a Q1, Q2 this year? Or is that a 2024 thing?

I'm just trying to think in terms of modeling for next year as we look at Cosentyx. Is there a slight headwind from where there was a higher price that you realized in Q1 and Q2 that then reversed out in Q3? And also what does that mean sort of going forward into 2026? Again, I appreciate there is going to be other dynamics with PMR and HS, but just wanted to clarify that from a modeling perspective.

Harry Kirsch Executive

Thank you, James. It's mainly quarter 2 this year, most of it. And -- but the quarter 3 underlying, that's why we gave you the quarter 3 underlying is what the underlying is already taking into account if such channel mix would continue to prevail. So from that standpoint, it gives you a good basis for future modeling.

Vasant Narasimhan Executive

I think, Harry, if I'm correct, if you net out the prior period upside versus this that really the year-to-date is relatively clean.

Harry Kirsch Executive

Across the whole portfolio.

Vasant Narasimhan Executive

Across the whole company, the year-to-date is close to red.

Harry Kirsch Executive

Quarter 1, we had 2% upside. Now we have almost 2% downside, right? It's a bit different brand by brand. But that's why we've given you on the brand that has most of it and is -- Entresto is deteriorating, of course, but this one, of course, is a brand that will stay long with us. That's why we gave you the underlying, which gives you the real underlying at the moment for quarter 3.

Vasant Narasimhan Executive

Sharon, next question.

Operator Operator

Your next question comes from the line of Sachin Jain from Bank of America.

Sachin Jain Analyst

So firstly, just a clarification on margins for Harry. So 3Q margins were a little bit below Street. I guess, partly on gross margin, which is sort of first impact from generics. I wonder if you could just talk about gross margin, EBIT margin as we think about a full year of Entresto impact in '26.

My simple question is, can you maintain margins stable next year through the full year of generics before we model the underlying Avidity dilution?

And then given, I might just take an additional one on pipeline for Vas. You flagged good uptake in IgAN. You have the Phase III for the APRIL, BAFF next year. So I wonder if you could just talk to your excitement on that and differentiation and what's the competitive landscape?

Vasant Narasimhan Executive

Great. Harry?

Harry Kirsch Executive

So on the margins, of course, when you have a product like a small molecule, high-priced products like the 3 going off patent, especially Entresto being so big, there's a slight negative mix effect. Now Kisqali is also a super high-margin product, right, and growing significantly. So that's partly offsetting. But we have also a significant productivity efforts, especially in our manufacturing and supply chain. So as I mentioned before, there will be, as we go forward, some pressures on the gross margin.

On the other hand, we do also expect that our SG&A becomes even more efficient as we go forward, offsetting that. Now for the next couple of years, this year, we will be around 40%. And quarter 4 is usually a bit lower. Historically, we have been in the first 9 months at 41%. So Q4 bring that in the range of around 40%.

And then for the next 2, 3 years, we said because of the Avidity proposed acquisition, 1 to 2 margin points down from the 40% and returning to 40% in 2029. So with that, basically -- but it's driven by development investments. And overall, to close that long answer on a short question, basically, the gross margin headwinds, I do expect to be offset by SG&A productivity.

Vasant Narasimhan Executive

And then Sachin, was your second question around the anti-APRIL antibody, I didn't catch it.

Sachin Jain Analyst

Yes. Sorry, in the introduction, you talked about the strength of the existing IgAN launches, but I wonder if you could touch on the APRIL BAFF with data next year and how that wraps out your portfolio.

Vasant Narasimhan Executive

Yes, absolutely. So first to note, ours is an anti-APRIL antibody. Our competitors are anti-APRIL, BAFF. And so I think one question, of course, will be to see the profile of those two drugs and does BAFF add anything and also differences in safety profile. But I would say, overall, we expect to see proteinuria in the range, we hope of what the others have seen.

And certainly, our Phase II data -- final Phase II data indicated we have very strong proteinuria reductions. We will be third to market in all likelihood. And so for us, it's really going to come down to a portfolio opportunity that we bring to patients, physicians, payers, firstly physicians' offices and payers because we'll have the opportunity to have an endothelin antagonist with Vanrafia. We have the Factor B inhibitor with iptacopan and then with Fabhalta, and then we have the anti-APRIL antibody and bringing that entire solution set to the clinic and then also the opportunity for us to run combination studies. So we're already now evaluating what would be

the right combination studies to run, generate that combination data so that nephrologists know what would be the right combination agents to optimize care for these patients.

So these are all the opportunities I think we're looking at. But it's going to be important for us to think through those given that at least in the anti-APRIL space, we'll likely be third to market. Next question, Sharon. I think it's the last question, if I'm not mistaken.

Operator Operator

It is. Your final question for today comes from the line of Stephen Scala from TD Cowen.

Steve Scala Analyst

Given the proof of concept established by the CANTOS trial 8 years ago, what new evidence compelled Novartis to go down the same pathway and acquire Tourmaline at this time?

Vasant Narasimhan Executive

Good question, Steve. So I think we clearly understand that IL-1 beta and hitting the inflammasome has a powerful effect on cardiovascular risk reduction. But in that trial, where we did an all-comers study of patients who had a prior event without, I think, focusing down, you saw the challenge of having a significant CVRR. Now IL-6 has the opportunity to be a little bit further downstream of IL-1 beta. And the idea here is to get within the first few months to max 6 months to a year after an event when -- if patients are at that point in time with an elevated hsCRP, the knocking down that CRP can lead to a significant -- we believe the opportunity exists to lead to a significant impact on cardiovascular risk.

So I think it's really -- we've learned from the CANTOS study. We understand a lot more about the biology based on that. And we think by targeting now prospectively patients right after an event who are at elevated CRP levels as a marker of elevated inflammation, we can then have a much more compelling cardiovascular risk reduction than the kind of 14%, 15% that we saw in the CANTOS study. Now we do have a competitor ahead of us, but a lot of our focus is designing, we think with our expertise, a study that can really maximize the opportunity for the IL -- the Tourmaline asset, the anti-IL-6. All right.